The Official Journal of Indian College of Cardiology, Kerala Chapter

Vol. 7, Issue - 1 August 2024

KJC 7

Kerala Journal of Cardiology

The Fellow's Edition

Cover image: Achilles learns archery.

Chiron and Achilles (1873), oil painting on canvas
by Doukas Ioannis (1841- 1916), the renowned Greek painter of 19th century.

KJC

Kerala Journal of Cardiology

The Official Journal of Indian College of Cardiology, Kerala Chapter

KJC

Journal lay-out and printing: Vision Grafix, Thiruvananthapuram-695 012. Phone: 9072340914, E-mail: visiongrafix@gmail.com

CONTENTS

Editorial

The Training of Achilles — Abhilash S P — 01

KJC Diamonds

Achilles Learns Archery

Large bore vascular access and closure - How do I do it? — Anoop A — 04

Step by Step Approach to Trans-Femoral TAVR with Balloon Expandable Valve — Asish Kumar M — 12

TAVR with Self-expandable Valve — Amit Kumar Chaurasia, Anoop Agrawal — 18

Implanting a Permanent Pacemaker: Technique and Challenges — Jyothi Vijay M S — 27

Left Bundle Branch Pacing - How do I do it? — Shunmuga Sundaram Ponnusamy — 43

My Angioplastic Techniques in Chronic Total Occlusions — S M Ashraf — 54

Left Main Coronary Artery Interventions - Challenges and Recommendations — Vishnu Kesavan — 60

Bifurcation Angioplasty - The Editors' Cut — Abhilash S P — 75

KJC Pearls

Chiron Teaches Art and Medicine Too...!

Unlocking the Secrets of Cardiovascular Implantable Electronic Devices: A Must-Know Guide for Cardiology Fellows! — Saikiran Kakarla — 78

Syncope in A Young Male - A Case Report — Teena Mary Varghese, Divya Saikumar, Ramesh Natarajan — 100

The Training of Achilles

Abhilash S P
Professor, Cardiology
Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala.

"*He who sweats more in training bleeds less in war*".

- The Spartans

Centaurs were mythical creatures with the upper body of a human and the lower body of a horse. **Chiron** was the most prominent centaur in Greek mythology, who became a teacher and mentor to many of ancient Greece's heroes including the great **Achilles**. Wise, gentle and kind, Chiron had an extensive knowledge of medicine, arts, music, archery, and sword fighting. In fact, in the Iliad, Homer called him the "wisest and justest of all the centaurs." Chiron's soft temperament made him suited to teaching, as did his excellent understanding on a range of subjects.

The seventh edition of Kerala Journal of Cardiology (KJC 7) is planned as a fellow's edition, targeting the young cardiologist in training, the Achilles of modern era. Chiron was the mentor of Achilles in many topics but obviously Achilles was best trained and known for archery. The first section of KJC7 – 'KJC Diamonds' - focuses on archery (interventional cardiology) viz. transcatheter aortic valve replacement (TAVR), pace maker implantation (PPI) and percutaneous coronary intervention (PCI). In the section 2, 'KJC Pearls' -Chiron teaches some art as well as medicine to Achilles!

Large bore vascular access and closure remain the 'Achilles' heel' in transcatheter aortic valve replacement. **Dr Anoop A**, additional professor, department of cardiovascular imaging and interventional radiology at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala discusses this critical topic in the very first chapter of KJC 7. **Dr Asish Kumar**, senior consultant at Myhart@Starcare, Kozhikode, Kerala is one of the most experienced TAVR operators in our country and gives us a stepwise approach to TAVR with a balloon expandable valve. Tips and techniques of TAVR with a self-expandable valve are revealed by another master operator in India, **Dr Amit Kumar Chaurasia** who is the chief of TAVR and structural heart disease program at Artemis hospital, Gurugram, New Delhi.

Dr Jyothi Vijay, assistant professor in cardiology at Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala handles the next chapter on permanent pacemaker implantation. Left bundle area pacing has revolutionised cardiac pacing in the last few years and KJC 7 is proud to have one of the pioneers of left bundle area pacing in the world to share his teachings with us. **Dr Shunmuga Sundaram Ponnusamy** is currently an associate professor in cardiology at Velammal Medical College, Madurai, Tamil Nadu.

Another master teacher, **Dr S M Ashraf**, professor and head of the department of cardiology at Government Medical college, Kannur, Kerala describes his elegant techniques in chronic total occlusions in the next chapter. **Dr Vishnu Kesavan**, consultant cardiologist at Rajagiri Hospital, Aluva, Kochi, Kerala covers intricacies of left main interventions with extra emphasis on common bifurcation techniques that fellows can come across. 'The Editor's cut' is a quick summary of important bifurcation learning points in a capsule form. Yes, Editor loves capsules and spoon feeding...!

In the 'Pearls' section, **Dr Saikiran Karkarla**, BCHIC

Address for correspondence: Dr. Abhilash S P, Bhavani, TC 7/491 (6), NLRA 333, Neerazhi Lane, Ulloor, Thiruvananthapuram - 695 011.
E-mail: abhispin@gmail.com

Fellow, BRICS Cardiovascular health innovation centre, Xiamen University, China gives a tinge of international flavour to KJC. He presents a pictorial art of more than 150 X-rays on cardiovascular implantable electronic devices which are relevant to young interventionalists. And finally, **Dr Teena Mary Varghese**, DrNB resident, KIMS health, Thiruvananthapuram, Kerala reports a case of sarcoidosis and adds that evergreen charm of Medicine to KJC7.

KJC would like to thank the officials of Indian College of Cardiology, Kerala Chapter Dr Vinod Thomas, President; Dr Anil Roby, Secretary; Dr Arshad M, Treasurer; Dr Suresh K, Vice President; Dr C D Ramakrishna, Joint Secretary; without their constant support KJC-7 would not have materialised. KJC-7 is going to be released at Indian College of Cardiology, Kerala Chapter annual conference at Kochi, 2024. We would like to thank Dr Rajesh T, Organising Chairman and Dr Renjukumar B C, Organising Secretary for providing us this platform.

Chiron taught Achilles a range of skills he would take with him to the battlefield and the journey of life. Legend has it the two formed a particularly close, familial bond, with Chiron becoming a parent-like figure to Achilles. Years later, in adulthood, Achilles would recall fondly his childhood years with Chiron - “So much do I remember, friends, of the training of my earliest years, and sweet is their remembrance.” **Dedicating KJC 7 to all the Chirons and Achilles over here.!**

Abhilash S P
Editor in Chief
KJC

KJC Diamonds

Achilles Learns Archery

Large bore vascular access and closure - How do I do it? Page: 04

Step by Step Approach to Trans-Femoral TAVR with Balloon Expandable Valve Page: 12

TAVR with Self-expandable Valve Page: 18

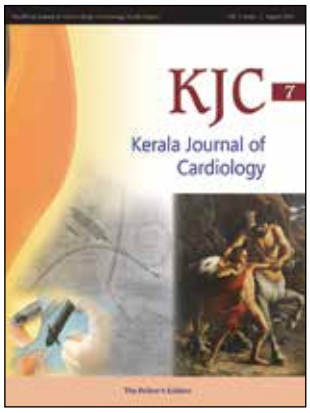
Implanting a Permanent Pacemaker: Technique and Challenges Page: 27

Left Bundle Branch Pacing - How do I do it? Page: 43

My Angioplastic Techniques in Chronic Total Occlusions Page: 54

Left Main Coronary Artery Interventions - Challenges and Recommendations Page: 60

Bifurcation Angioplasty - The Editors' Cut Page: 75



Large bore vascular access and closure - How do I do it?

Anoop A.
Additional Professor, Department of IS & IR
Sree Chitra Tirunal Institute of Medical Sciences & Technology,
Thiruvananthapuram, Kerala.

INTRODUCTION

Aortic valve stenosis and thoracic or abdominal aortic aneurysms are treated with transcatheter aortic valve replacement (TAVR) and endovascular aortic repair (TEVAR-thoracic endovascular aortic repair and EVAR-endovascular aortic repair), respectively, which are minimally invasive techniques. Large-bore vascular access is necessary for these procedures, which poses special difficulties for access closure and management. This article aims to give an overview of the methods, pointers, and strategies for large-bore vascular access and closure.

Understanding Large Bore Vascular Access

Large bore vascular access entails inserting sheaths into the vasculature with a large diameter (usually greater than 14 French). During TAVR and TEVAR procedures, this access is essential for delivering the required devices to the heart or aorta. Because of its size and accessibility, the common femoral artery (CFA) is the most often used site for large bore access. In the event of complications, the ability to perform manual compression or surgical or endovascular management is another factor favouring femoral access. Patients undergoing TAVR/EVAR have a different patient profile than those undergoing conventional surgical repair because the former group tends to be older, have more comorbidities, and have more fragile cardiac hemodynamic.

Nonetheless, the case selection guidelines apply to all endovascular repairs, and age is not a strict bar to treatment. The need for alternative access, surgical cutdown, or conduit placement to the non-diseased vascular territory will be determined by a detailed evaluation of the vascular anatomy and the devices selected for the procedure. The same closure technique may be applied if the operator also has experience in other unconventional locations.

The advantages of having percutaneous access over surgical cutdown include

I. Reduction in procedure time.[1]

II. fewer chances of wound-related seroma and wound dehiscence.[2]

Address for correspondence: Dr. Anoop A., Additional Professor, Department of IS & IR, Sree Chitra Tirunal Institute of Medical Sciences & Technology, Thiruvananthapuram, Kerala, India - 695011., Email: anoop123a@gmail.com

III. Early ambulation after the procedure, thus, reduces the duration of hospital stay as well as the risk of DVT and related complications.[1,2]

IV. Lesser size incision and less chance of wound infection.[2]

Critical Considerations for Large Bore Vascular Access

Pre-Procedural Planning: Proper planning includes imaging studies like computed tomography angiography (CTA) to assess the vascular anatomy and identify potential challenges such as calcifications, tortuosity, or small vessel diameter.

A CT scan with sufficient contrast opacification, resolution, and coverage is necessary to report the parameters above. This process cannot be skipped in favor of a doppler study or USG of the iliac and femoral vessels. When choosing the side of percutaneous access or, in certain situations, deciding on a surgical cutdown, a classification of the degree of calcification in femoral access based on the degree of circumference involvement is helpful (Figure 1).[3] Operators can identify areas of focal narrowing along the course of iliac arteries from a central lumen tracing software like 3-mensio, Terarecon, etc., which may need prior angioplasties to avoid challenges.

A good ultrasound assessment, as well as knowing the depth of the vessel from the skin, presence of abdominal pannus, level of calcification of vessel, and bifurcation of vessels are other factors deciding the choice of side of percutaneous access in cases as suited for percutaneous large bore access.

Patient Selection: Evaluating patient comorbidities, peripheral artery disease, and previous inguinal surgeries with scars, etc., helps to tailor the access strategy. Previous collagen-based/staple-based closure devices, prior groin hematomas, access site pseudoaneurysms, and AV fistula, are factors deciding against percutaneous closure techniques. Patients with vasculopathy like Ehlers-Danlos syndrome and Marfan syndrome have larger caliber access vessels but a chance of vascular complications during the endovascular device entry or due to closure devices. However, studies haven't validated vasculopathy as a contraindication for percutaneous closure devices.[4]

Alternative Access Sites in case of non-suitable femoral access for large bore access

In cases where femoral access is not feasible, alternative sites include:[5]

1. Axillary Artery/ subclavian access: Provides a direct and often less calcified route, but requires careful technique due to the proximity of nerves and other structures.
2. Transcaval Access: Involves creating a temporary connection between the abdominal aorta and the inferior vena cava (IVC), used in patients with severely diseased iliac or femoral arteries.[6]
3. Trans-carotid or right brachiocephalic trunk access
4. Transapical route

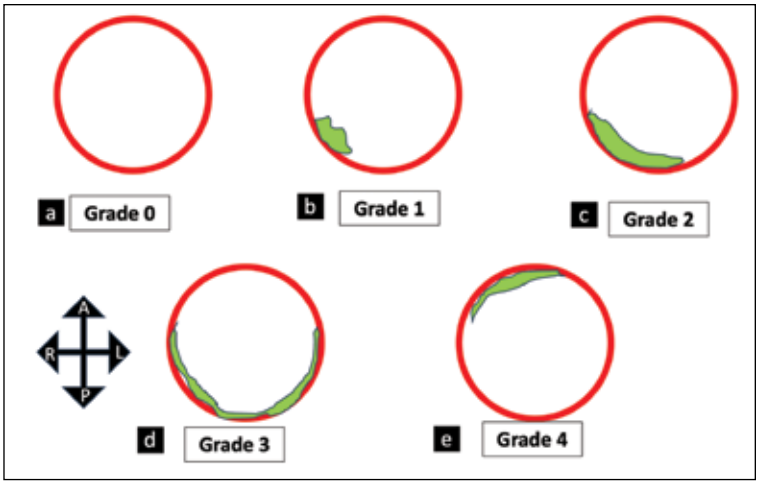


Figure 1: A pictorial classification based on CT images or USG images. Grades 3 & 4 are considered difficult for percutaneous access.

a. Grade 0= No calcifications
b. Grade 1 = Mild calcifications with< 90 degree circumference
c. Grade 2 = Moderate calcifications with< 180 degree circumference
d. Grade 3 = Severe calcifications with > 180 degree circumference
e. Grade 4: Any severity calcification involving the anterior wall of the femoral artery

5. Surgical Cutdown: Provides direct access and allows for meticulous closure, but is more invasive and associated with longer recovery times.

Percutaneous Closure Devices for large bore access

I. Suture-Based Devices: Perclose ProGlide and Prostar XL are commonly used suture-mediated closure systems. The pre-close technique involves placing these devices before the large sheath insertion and deploying them at the end of the procedure.

II. Staple-Based Devices: The MANTA Vascular Closure Device uses a resorbable polymer anchor and a collagen plug to seal the arteriotomy site.

III. Hybrid Techniques (Suture and Plug-based devices)

Combining various techniques, such as using a suture-based device followed by adjunctive collagen plug-based closure devices, can enhance hemostasis and reduce complications.

MECHANISM OF KNOT FORMATION AND PRE-CLOSE TECHNIQUE

Understanding the steps involved in knot formation is essential to avoid device malfunction-related complications.

- Two cuffs are held by a footplate, which will be inside the vessel at a 5 mm distance and in a position to align with the needle tips from the outside vessel (Figure 2a).
- Two ends of the same suture thread are aligned parallelly within the device with a preformed knot and a needle going through that knot to pull the other end of the wire using a special cuff (Figure 2a & b).
- The posterior needle tip will be holding suture threads (Railed suture) and will link with cuffs in intravascular position, and the anterior needle pulls out the same thread through the loop of the non-rail suture thread during deployment to form a complete knot (Figure 2c & d).

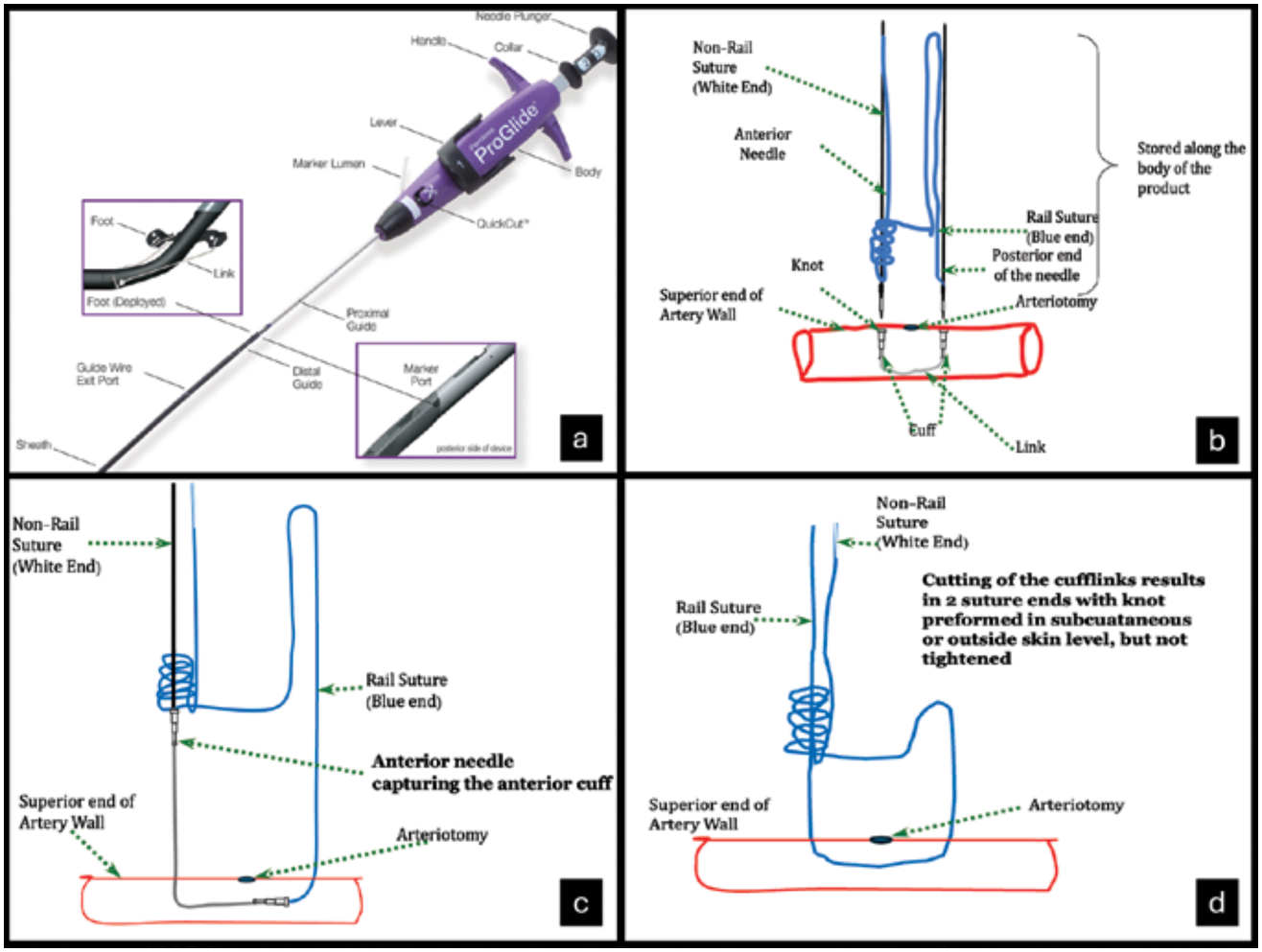


Figure 2: Mechanism of Knot formation using a suture-based closure device.

- Throughout the process, we will loosely hold the knot in Figure 2d away from the arteriotomy site. By using serial traction and pushing the knot over the rail suture, the arteriotomy hole can be tightened when the large bore access sheath is removed towards the end of the procedure. These sutures work similarly to stay sutures that were used before a surgical arteriotomy, only they are tightened to close the arteriotomy gap. Since the arteriotomy is closed with just two widely spaced sutures, platelet plugs play a part in this procedure as well.
- If the areas of mal-appositions are large enough, there will be blood leakage as spurts or ooze, which may be addressed by additional collagen-based plugging of the tract and outer surface of the arteriotomy, leading to complete hemostasis.

Step-by-step approach to pre-deployment of the sutures of ProGlide

1. Displacing the abdominal pannus laterally and superiorly using a plaster will reduce the depth of puncture in some instances, which may be a source of failure of approximation of sutures during closure.
2. The operator should prefer to go through the CFA with a lower-level bifurcation to avoid the suture going through the inguinal ligament.
3. Ultrasound-guided visualization of the femoral artery and puncturing 1-2 cm below the intended entry site, maintaining a 45 degree angle to the skin surface. Arterial punctures should preferably happen in the 12 o'clock position of the artery, as we see from

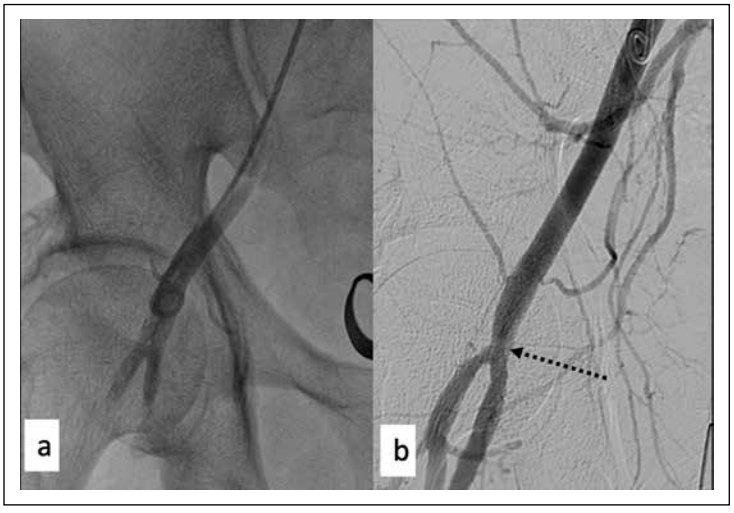


Figure 3: (a) An example of pigtail guided puncture of right CFA with pigtail catheter inside and slightly higher femoral bifurcation. (b) Post-procedure angio showing mild narrowing (dotted arrows) at the puncture site close to femoral bifurcation with no extravasation.

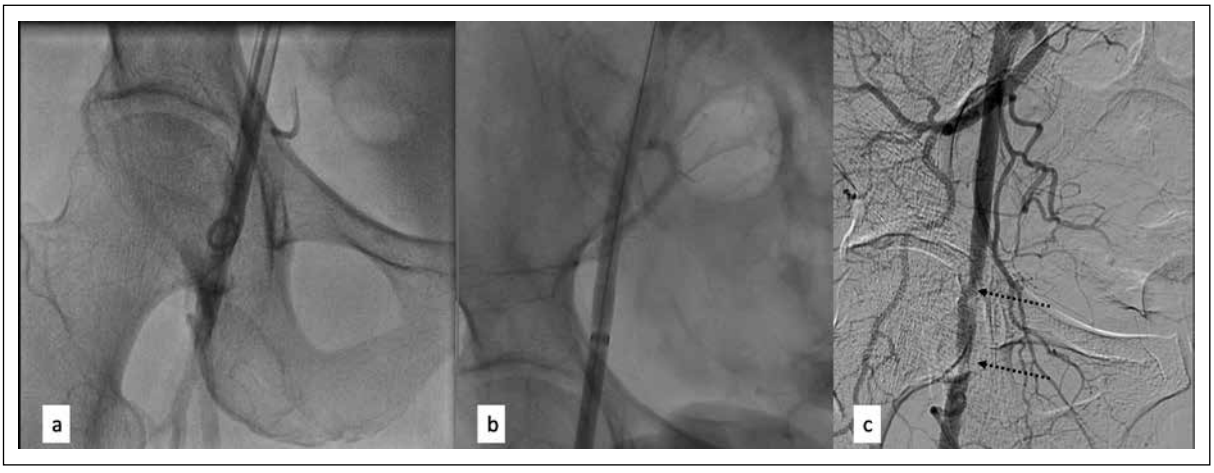


Figure 4: Right CFA angiogram through pigtail catheter from the opposite side. The loop of the pigtail is elongated because of the smaller caliber of the common femoral artery. Significant difficulty was experienced in advancing the large sheath, as evidenced by stagnation of contrast (b) in the right iliac artery. Following the procedure, there was narrowing (dotted arrows) at puncture and CFA but not flow limiting, which was managed conservatively.

the patient's feet. Fluoroscopy-guided punctures may cause problems while tightening sutures if entered through the side of the femoral artery. However, ultrasound vs. fluroscopy guidance is the discretion of the operator.

4. A small stab incision at the intended needle insertion site will give CFA a smooth, jerk-free entry of the micro-puncture needle. 22G micro-puncture needle with an echo tip will help visualize the needle along its course to the femoral artery and inside.
5. Through the arteriotomy, the dilator of the micro-puncture set is inserted and then secured with a 7 Fr short sheath.
6. The subcutaneous tissue around the sheath should be dissected circumferentially using non-traumatic artery forceps before the "close" technique all the way down to the femoral vessels. This will prevent tissue-generating friction to serial dilations and large bore sheaths.
7. If two perclose sutures are planned, sutures are to be placed over the femoral artery at 10 o'clock and 2 o'clock positions, and guide wires are inserted before taking out the second Proglide to maintain arterial access. It is useful to place two perclose sutures instead of one to have persistent hemostatic control in case of accidental breakage of the other.
8. Both limbs of the sutures are uniformly pulled and kept stretched in respective clock positions of the vessel to avoid entangling or additional knot formation during the remaining procedure. Wet gauzes kept over the sutures avoid unnecessary handling. The 7 Fr sheath is then re-inserted, and the wire is exchanged for a stiff wire for further serial dilations and large bore sheath insertion,
9. Serial dilations with intermediary size dilators like 10Fr or 14 Fr may be performed prior to directly passing the large bore sheath for the procedure.
10. The large bore sheath is then slid over a stiff guide wire. It will give stable advancement of the sheath in tortuous iliac anatomy.
11. Fluoroscopic guidance or contralateral femoral injections may be taken in case of any difficulty in advancing the large bore sheath (Figure 3). Pre-dilation of iliac narrowing is often performed, and stent placement is best avoided prior to TAVR as there is a chance of the stent displacement while advancing a large bore sheath or difficulty in advancing the device subsequently through the stented segment despite over-sizing.

Step-by-step techniques of closure of large bore access:

1. Closing the arteriotomy with the larger sheath first will give the option of using contralateral access for further endovascular interventions for control of bleeding or treating a stenosis
2. Preferably, a hydrophilic standard stiffness wire is kept across the sheath
3. The Proglide sutures kept on either side of access are irrigated for easy knot advancement, and any thrombus around the sheath is flushed and displaced.
4. The large bore sheath is removed by manually compressing the access site with a slow, constant

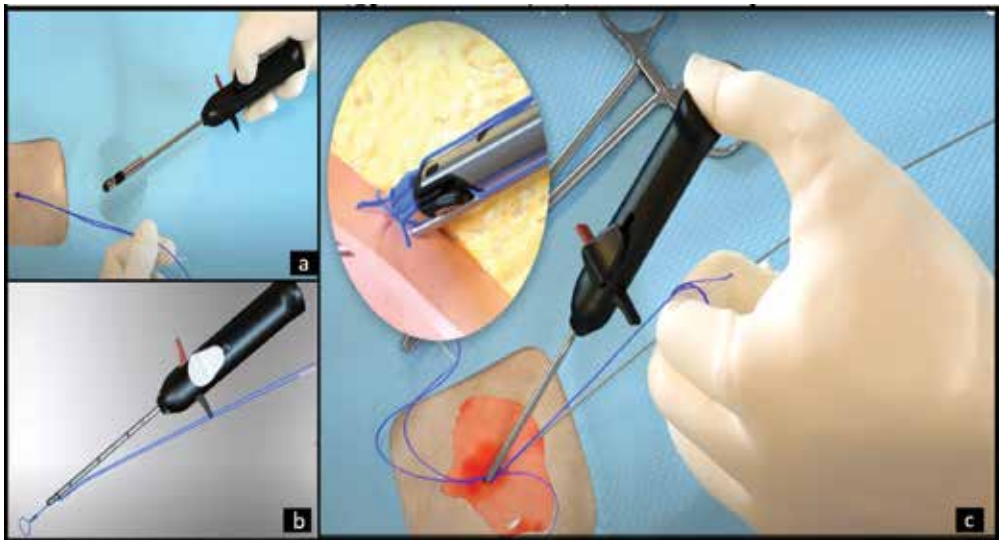


Figure 5: The process of suture tightening using knot pusher. (a) The knot pusher; (b) Sliding of knot pusher over the suture (c) The process of tightening the knots using the thumb and index finger of a non-dominant hand (Pic courtesy: https://www.youtube.com/@AbbottCardiovascular)

force. To advance the proglide knot to the arteriotomy site, the non-white suture end of the proglide is tightly held and is wrapped around the index finger, and a knot pusher device is used with moderate force over the stretched-out suture thread. When advancing the knot to an arteriotomy, sufficient pre-dilation (Step 6 before the procedure) will prevent any tissue entanglement along the knot.

5. The knot pusher is used to advance the knots further to the level of arteriotomy in the order of their original deployment. The position of the knot pusher in relation to arteriotomy may be verified using fluoroscopy or USG. All these steps require gentle but rigid traction of the index finger and push force using the thumb of the non-dominant hand of the operator to avoid perforation of arteriotomy or buckling of sutured layers of the artery at the closure site (Figure 5).
6. Once both suture knots are advanced adequately, the manual compression is totally released to see if any bleeding is happening.
7. If very minimal bleeding is there and a non-intense jet of blood leakage, we can plan the removal of wire across the access site and tighten the sutures further. At this stage, after wire removal, the white thread is also tightened, and a knot pusher is advanced over them.
8. Once complete hemostasis is achieved, suture trimming is usually done after verifying the flow across the vessel by USG or angiogram from the contralateral side.
9. If a suture breaks during closure and the arteriotomy is only held in place by one suture, it is preferable to advance a collagen plug-based closure device over the wire and use it to ensure sufficient hemostasis. The tightened proglide's suture is trimmed before a plug-based closure device is inserted because it may be challenging afterward.

TROUBLESHOOTING STEPS

1. Unsuccessful knot formation using proglide

After following the necessary steps of pre-deployment of the suture, if the knot is not formed and only a straight thread is received, then it is termed as unsuccessful knot formation. Difficulty in penetration of the needles of the Proglide through the anterior wall of the vessel to link with cuffs in intravascular location is considered as a reason for this. Probable reasons for these are:

a. The anterior wall is very thick, preventing needle penetration. Thickening may be because of previous scar tissue, calcification in the wall, or inappropriate tissue track dilation leading to entanglement of subcutaneous tissue along the needle track. Dilation of the track before trying once again may be attempted.

b. The inaccurate angle of holding the device- The suture knot formation requires a preferred 45-degree angulation for accurate positioning of the needle into cufflinks of the intravascular footplate (Figure 2a). A more horizontal or vertical location will likely result in unsuccessful knot formation because of cuff miss. Another attempt to correct angulation may solve the issue.

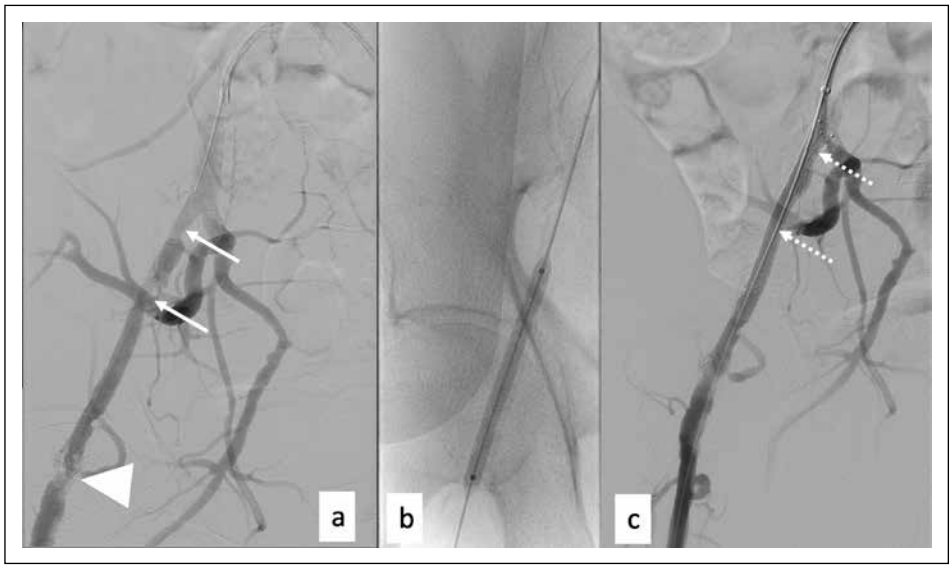


Figure 6: Right CFA angiogram (a) 1 month after TAVI with arteriotomy closure done using proglide and angioseal. The patient had significant peripheral arterial symptoms on the right side, with an angiogram showing right external iliac narrowing (arrows) and right CFA narrowing (arrowhead). The right CFA was angioplastied (b) using a noncompliant balloon. Final angiogram(c) revealed good restoration of flow across stenosis with external iliac artery showing implanted stent (Dotted arrows).

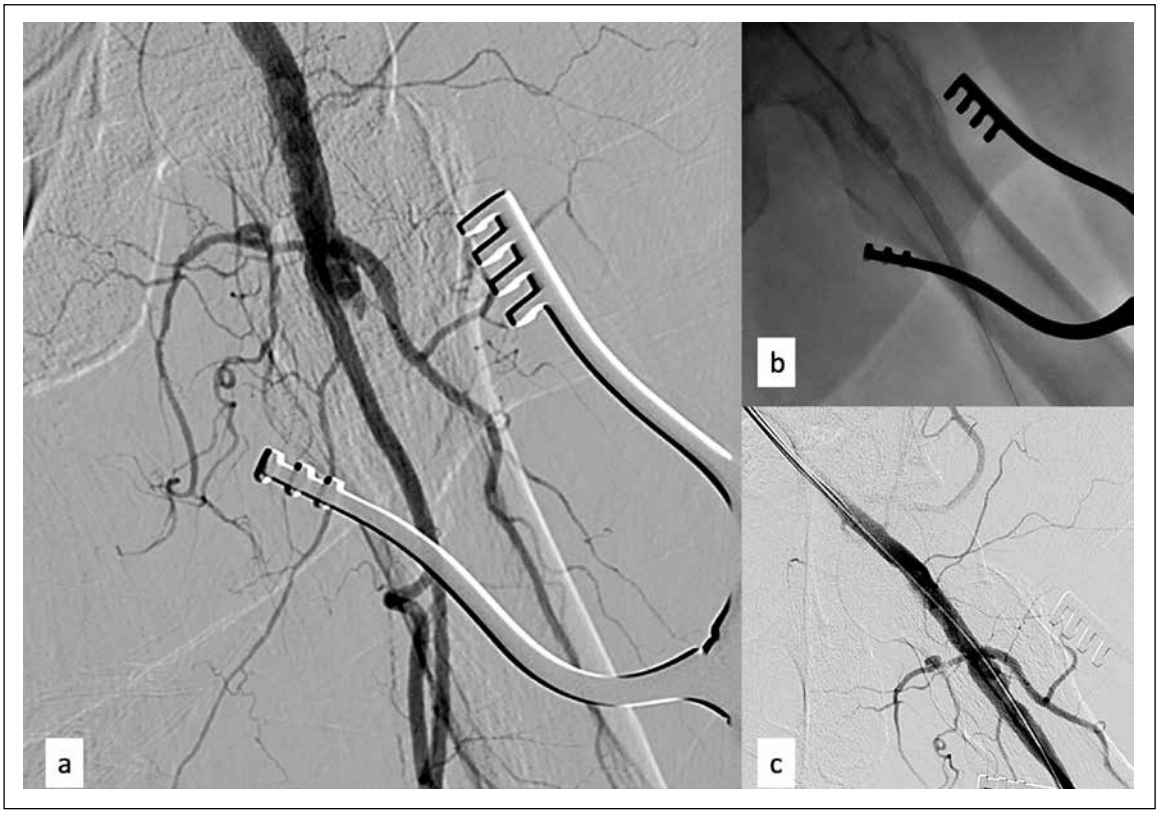


Figure 7: (a &b) shows total occlusion of SFA following the closure of the arteriotomy site as it was an inadvertent left SFA access. The site was surgically opened, and the occlusion was corrected by surgical repair (c).

c. Knot tightened before the arteriotomy closure: Asymmetric pulling of the non-rail thread of the knot before inserting a large sheath will result in tightening of the knot outside the arteriotomy, and this knot cannot provide arteriotomy approximation after the procedure. Putting another proglide prior to the large sheath insertion may be attempted. If knot tightening happens after large sheath removal, attempt of a new proglide insertion over the wire access can be attempted, after removing the tightened knot.

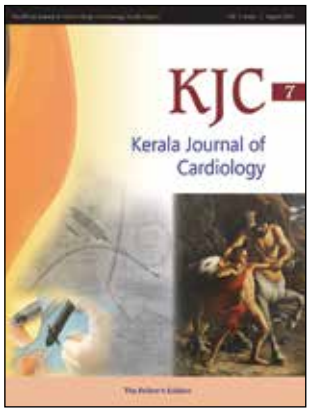
2. **Suture breakage during the procedure or after the sheath removal:** The remaining suture can be tightened carefully, and an additional proglide can be deployed across the wire access. Keeping the sutures wet will prevent their breakage during traction and knot pushing.
3. **Persistent bleeding:** attempt to put a collagen plug-based suture after tightening the suture by inserting a suitable sheath through the gap of the arteriotomy.
4. **Post Suture deployment arterial stenosis:** Balloon angioplasty through the contralateral side will usually open mild-moderate stenosis.(Fig. 6)
5. **Post Suture deployment complete occlusion:** If complete occlusion of the vessel happens subsequent to suture tightening, it may be attempted to be loosened or removed through the subcutaneous plane or via surgical exposure, and then open closure of arteriotomy can be attempted.(Fig. 7)
6. **Pseudoaneurysm Management:** Small pseudo-aneurysms can often be managed conservatively or with ultrasound-guided thrombin injection. Larger or symptomatic ones may require surgical intervention.

CONCLUSION

In TEVAR and TAVR, large-bore vascular access and closure necessitate careful planning, a solid grasp of vascular anatomy, and competence with various access and closure techniques. Practitioners can reduce complications and improve patient outcomes by using a combination of closure devices, ultrasound-guided puncture techniques, and advanced imaging for pre-procedural planning. The safety and effectiveness of these life-saving procedures will be further enhanced by ongoing learning and adaptation of new methods and technologies.

REFERENCES

1. Murthy K, Kumar J R, Kaur N, Chadha A, Chauhan R, Chadha D. Suture-Based Vascular Closure Versus Surgical Closure of Large Bore Arteriotomies: A Real-World Experience. Cureus. 2024 Feb;16(2):e54856.
2. Vierhout BP, Pol RA, El Moumni M, Zeebregts CJ. Editor's Choice – Arteriotomy Closure Devices in EVAR, TEVAR, and TAVR: A Systematic Review and Meta-analysis of Randomised Clinical Trials and Cohort Studies. European Journal of Vascular and Endovascular Surgery. 2017 Jul;54(1):104–15.
3. Philippe Généreux, Philippe Généreux, Généreux P, John G. Webb, Webb JG, Lars G. Svensson, et al. Vascular Complications After Transcatheter Aortic Valve Replacement: Insights From the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial. Journal of the American College of Cardiology. 2012 Sep 18;60(12):1043–52.
4. Peter R. Nelson, Nelson PR, Zvonimir Kracjer, Kracjer Z, Nikhil Kansal, Kansal N, et al. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). Journal of Vascular Surgery. 2014 May 1;59(5):1181–93.
5. Katsaros O, Apostolos A, Ktenopoulos N, Koliastasis L, Kachrimanidis I, Drakopoulou M, et al. Transcatheter Aortic Valve Implantation Access Sites: Same Goals, Distinct Aspects, Various Merits and Demerits. J Cardiovasc Dev Dis. 2023 Dec 22;11(1):4.
6. Lederman RJ, Greenbaum AB, Khan JM, Bruce CG, Babaliaros VC, Rogers T. Transcaval Access and Closure Best Practices. JACC: Cardiovascular Interventions. 2023 Feb;16(4):371–95.



Step by Step Approach to Trans-Femoral TAVR with Balloon Expandable Valve

Asish Kumar M.
Senior Consultant, Myhart@Starcare
Kozhikode, Kerala.

STEP I

PROPER PATIENT SELECTION

- Symptomatic severe AS with age above 75 years
- Asymptomatic very severe AS with age above 75 years
- STS risk score above 8%
- Symptomatic severe AS with age above 70 years with heart team decision
- Asymptomatic very severe AS with age above 70 years with heart team decision
- STS risk score 4-8% with heart team decision
- Feasibility of transfemoral route
- Complexity of associated coronary lesions if any
- Aortic complexity/calcification
- Affordability

STEP II

VALVE SIZING

Confirm the valve size by MDCT

This is based on the area-derived diameter for balloon expandable valve (BEV) and perimeter-derived diameter in case of self-expanding valve (SEV).

The two Transcatheter aortic valve replacement (TAVR) platforms under BEV available to us are:

SAPIEN (Edwards Life Sciences) (Figure 1)

MyVal and Octacor (Meril Life Sciences) (Figure 2)

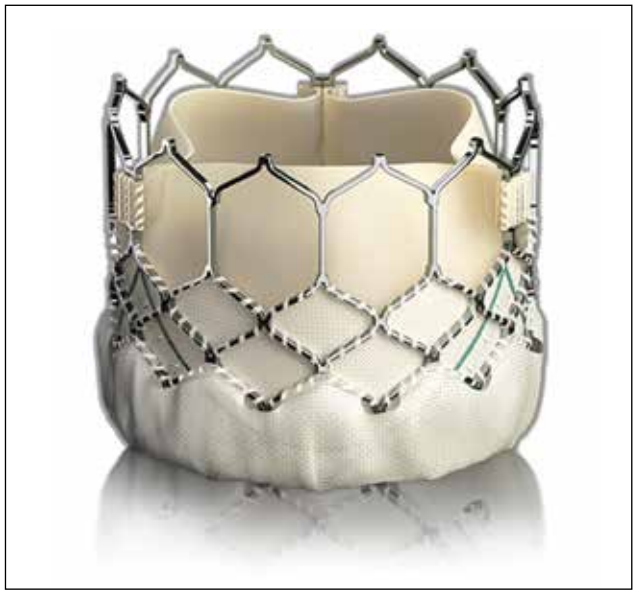


Figure 1. SAPIEN 3 Valve

Disclaimer: *Meril and Edwards valves are used as the prototypes of balloon expandable valves. KJC does not endorse any particular valve and the Journal, Editor or Author has not received any funding from the respective companies for this article.*

Address for correspondence: Asish Kumar M., Senior Consultant, Myhart@Starcare, Kozhikode, Kerala.
Email: asishmandalay@gmail.com

Figure 2. MyVal (A) and Octacor (B) Valves.

Sizing chart

The degree of oversizing with respect to the diameter depends on:

- The anatomy - bicuspid or tricuspid
- Severity and extent of calcification

Generally, 10-15% oversizing for tricuspid and 5-6% oversizing for bicuspid anatomy is considered appropriate. Bear in mind that significant annular calcification precludes the choice of a balloon-expandable valve.

STEP III

Once the appropriate patient and valve -size are selected, the procedure can be further divided into five sequential steps:

A. VASCULAR ACCESS

B. VALVE CROSSING

C. BALLOON AORTIC VALVULOPLASTY (BAV)

D. VALVE IMPLANTATION

E. VASCULAR ACCESS -CLOSURE

A. VASCULAR ACCESS

The common femoral artery (CFA) is the most widely employed vascular access for TAVR. The superiority of TAVR over SAVR is restricted to the transfemoral TAVR and not for alternate vascular access, though these accesses may have to be resorted to on specific situations.

Potential vascular access is thoroughly characterized by CT aortogram prior to TAVR. Cannulation of the CFA is best performed under ultrasound guidance. One could use a micro-puncture needle (Cook). It is desirable to place 1 (12' 0 clock) or 2 proglides (10 o'clock and 2 o'clock position) immediately after obtaining the vascular access. The author's preference is a single proglide unless other factors like morbid obesity would tilt towards securing the vascular access well with 2 proglides.

B. VALVE CROSSING

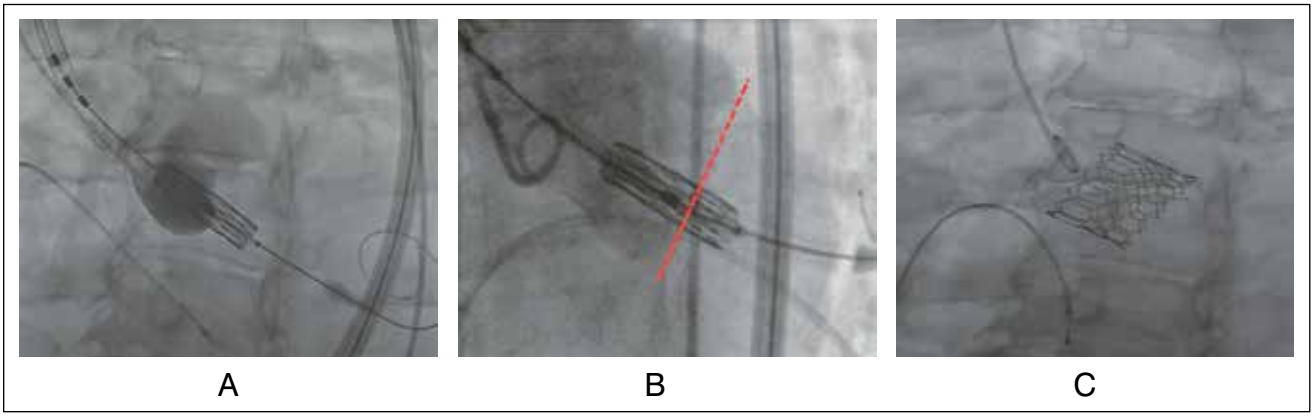
5F or 6F AL1 or AR2 diagnostic catheter is advanced over a 150 cm 0.35" J-tipped Teflon guidewire and exchanged to a straight-tipped 0.35" Teflon guidewire. The valve can be crossed either in the implanter's view or LAO projection (the advantage of the LAO projection is that it helps early recognition of inadvertent wire-entry into the left main coronary artery while attempting to cross the stenotic aortic valve). Once across, the wire is exchanged to a 300 cm J-tipped 0.35" Teflon guidewire in the RAO projection, and over the guidewire, 6F pigtail catheter is taken into the LV. Another pigtail catheter is positioned in the non-coronary sinus and both the catheters are connected to pressure transducers and the gradient recorded. A pre-shaped stiff guidewire (SAFARI - Boston Scientific, CONFIDA - Medtronic or in extreme cases Lunderquist - Cook Medical) is advanced through the pigtail catheter and positioned in the LV. Strict fluoroscopic surveillance of the guidewire portion in the LV is to be maintained.

C. BALLOON AORTIC VALVULOPLASTY (BAV)

Balloon aortic valvuloplasty (BAV) is performed in most situations except when there is very little calcification of the leaflets and/or in the presence of severe left ventricular systolic dysfunction (for fear of producing significant aortic regurgitation thereby leading to diastolic overloading of a poorly functioning left ventricle). The sizing of the balloon is based on the shorter diameter of the annulus (measured in two axes - the horizontal and vertical axes)

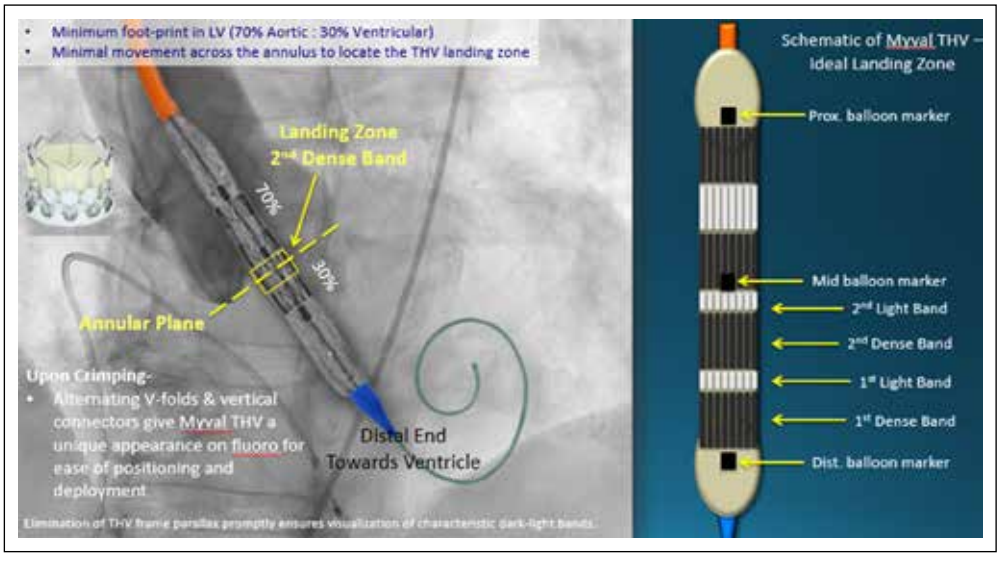
D. VALVE IMPLANTATION

The valve should be crimped on the delivery system and ready before BAV to circumvent any sudden hemodynamic instability after BAV, requiring rapid valve deployment. Once the valvuloplasty balloon is withdrawn, the crimped valve is taken into the body through the delivery sheath. For the SAPIEN valve, the valve cannot be taken back into the sheath once it exists the sheath into the aorta. The MyVal and Octacor on the other hand can be retrieved, reloaded and reintroduced. The delivery systems of both the available BEVs have flexing mechanisms which allow the catheter to traverse the aortic arch with minimal trauma. The native valve is crossed with gentle sustained forward thrust. Once across, the valve is positioned based on the calcium landmark and aortic root angiography from the pigtail in the non-coronary sinus. For the SAPIEN valve, the valve is positioned midway on the annular plane. (Figure 3 A, B, C). For the MyVal, (Figure 4 A, B, C) it is positioned on the second dark band from below and on the landing zone marker for the Octacor (Figure 5 A, B). This results in a final deployment position of 80:20 with respect to the aorta and ventricle. Once across, the balloon is inflated to the pre-filled volume under rapid pacing to lower the systolic blood pressure to around 60 mmHg.



A B C

Figure 3. Sapien 3 positioning (A, B) and final Angiogram (C)



A

Figure 4. MyVal (A)

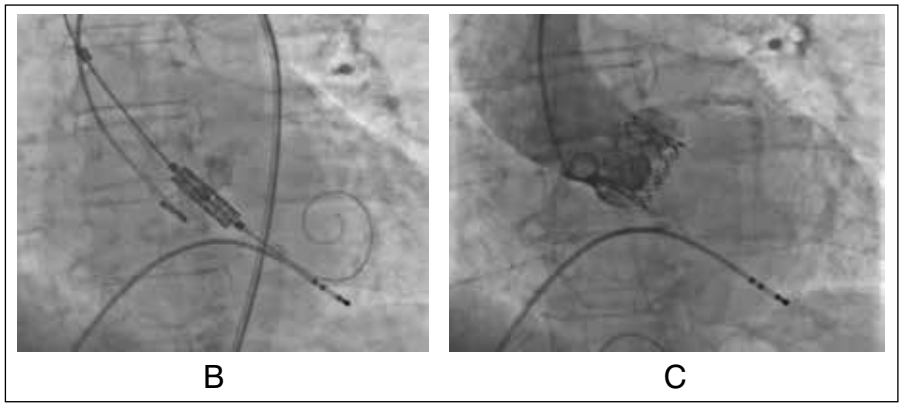


Figure 4. MyVal's positioning (B) and final angiogram (C)

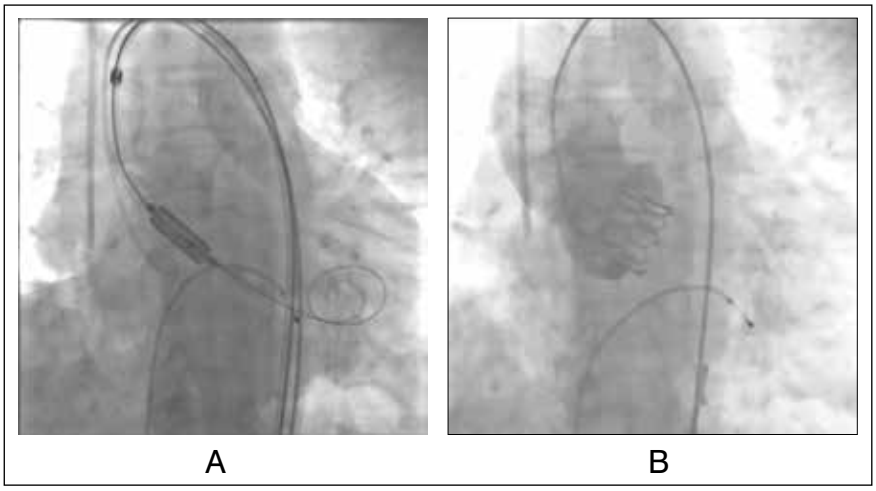


Figure 5. Octacor valve positioning (A) and final angiogram (B)

We prefer a 2-stage deployment with first 1/3-rd slow inflation which allows finer adjustments on the delivery system to achieve the best position of the valve and the rest 2/3rd rapid deployment. Once fully deployed, the balloon is deflated, pacing switched off and the delivery system removed. The transthoracic echo is checked to assess proper positioning and paravalvular leak (PVL). An aortic root angiography confirms the absence of significant PVL. Central AR could be wire-induced. The wire is removed, on a pigtail catheter; gradient measured and final aortic angiography performed after removing the pigtail catheter from the left ventricle.

Difficult subsets

1. Bicuspid aortic valve

Transcatheter aortic valve replacement (TAVR) was initially considered only for tricuspid anatomy, bicuspid anatomy was considered an off-the-shelf indication. Contrary to the Western data, Indian data suggests that bicuspid anatomy is relatively common in our country, amounting to 35 -40% of our implants.

The aortic annulus in bicuspid anatomy is often oval and the proponents of self-expanding valve (SEV) suggest the ability of the SEV to take the shape of the annulus, as an advantage. However, maintenance of circular shape of the annulus is the key to better durability and as such balloon-expandable valve (BEV) has a significant advantage in that it makes the annulus more circular after implantation.

There are a few factors which need to be addressed in a bicuspid anatomy -

A. Depth of the implant: The true annular plane is considered to be higher than the apparent annular plane and hence shallow implant is preferred, i.e. 90% aortic and 10% ventricular or even entirely (100%) aortic wherein the annular BEV is implanted in such a way that the leaflets are truly supra-annular. In bicuspid anatomy, the valve-frame is held in place by the usually calcific leaflets.

B. Degree of oversizing: As mentioned previously, 5-6% oversizing is sufficient in this subset. In heavily calcific anatomy, especially calcification

involving the annulus, the authors' preference is 0-5% oversizing or occasionally even under sizing the valve but overfilling it (more volume)

C. Horizontal aorta: Bicuspid anatomy is often associated with horizontal aorta (however, one might encounter horizontal aorta in non-bicuspid anatomy as well). Horizontal aorta is defined as an aortic angulation (angle between the annular plane and the horizontal) greater than 48°. The aortic arch in this subset is often horizontal and longer. Navigating the longer valve-frame and aligning the SEV in a horizontal anatomy is often challenging. With the balloon expandable Meril valve, we can rotate the rotator handle on the delivery system to the desired limit to achieve a truly horizontal position of the valve. (Figure 6)

2. Low coronary heights

Defined as a coronary artery takeoff < 10 mm from the annular plane. However, even in low coronary heights, BEV can be deployed safely, because of the lower frame-height and open cells on the upper part; the Meril valve-frame has a height of 18-21 mm, nearly half of this is open cells. (See figure 2) This means, in a given case, an 18-mm frame has roughly 10 mm of covered cells; when the valve is implanted with 2-3 mm below the annular plane, only 7 mm of covered portion is aortic and a coronary height of even 8 mm may not be a contraindication.

When to decide on coronary protection upfront? The factors which determine coronary obstruction are :

I. Low coronary height
II. Small sinuses (< 1.2 times the annulus)
III. Short sinotubular junction (STJ) height (< 10mm)

If 2 of the above 3 factors are present, upfront coronary protection with a guiding catheter, guide-extension catheter, guidewire and stent in the coronary artery is to be performed. The golden rule is – whenever in doubt, choose coronary protection.

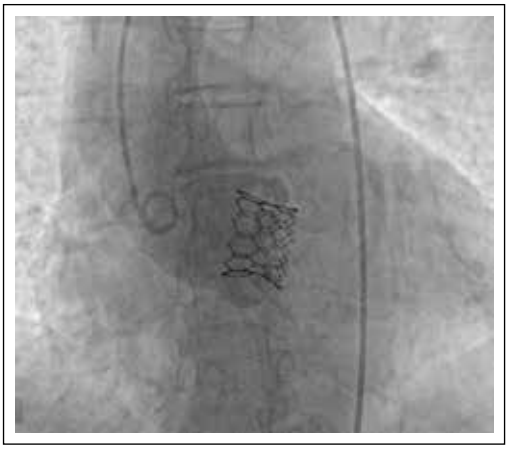


Figure 6. MyVal in horizontal aorta

In bicuspid anatomy, an additional feature is the unequal size of the leaflets – the fused leaflet is much larger. Herein, we measure the leaflet length to predict the possibility of coronary obstruction. Even with a coronary take off above 10 mm, if the sinuses are not roomy, because of the unequal and larger fused leaflet, coronary obstruction can occur. In bicuspid anatomy, it is a common practice to perform a balloon-occlusion angiogram to predict the behavior of the leaflets (contrast injection during BAV). If the leaflet is moving very close to the coronary artery takeoff, better to undertake coronary artery protection because the valve is always larger than the balloon used for pre-dilatation.

3. Predicting the need for permanent pacemaker

Pre-existing right bundle branch block (RBBB) is the single most important factor predicting the need for permanent pacemaker post-TAVR; especially if this is associated with first-degree atrioventricular block. Generally, the pacemaker rates are lower with BEV, because there is no outward thrust from the valve-frame in BEV as in SEV. Also, shallow implants (< 3 mm ventricular portion of the valve-frame) is the norm these days. Higher the implant, lesser is the chance of pacemaker implantation (PMI). The size of the left ventricular outflow tract (LVOT) also is important in predicting the need for PMI. LVOT smaller than the annulus is a risk factor predicting PMI. The value of other conduction abnormalities including left bundle branch block (LBBB) is still a matter of debate.

E. VASCULAR ACCESS - SHEATH REMOVAL AND HAEMOSTASIS

It is important to be meticulous during sheath removal. If the sheath- size was similar to that of the artery, blood would have been excluded from the space between the sheath and the artery effectively drying out the sheath with concomitant loss of its lubricant effect. Nitroglycerin may be administered through the side arm of the sheath prior to removal. It is always better to advance the dilator and then pull out the sheath gently and gradually. It is good practice to take a contrast injection from the contralateral side to be certain that there is no injury to the external iliac artery. Be sure to keep the 035' teflon wire in the vessel during sheath removal. Simultaneously tighten the proglide-knot by pushing the knot down and pulling on the thread. A final confirmatory angiography is advisable to be certain of the adequacy of closure. Another option is to keep a balloon sized to the exertional iliac artery inflated int the external iliac artery from the contralateral access at 4-6 atmospheres to achieve a dry closure.

TAVR - SEQUENCE OF EVENTS

Vascular access

↓

Temporary pacing lead

↓

Pigtail in non-coronary sinus

↓

Valve- crossing

↓

Exchange to 260 cm J-tipped Teflon guidewire

↓

Pigtail catheter in left ventricle

↓

Measure gradient

↓

Exchange to stiffer wire

↓

Delivery sheath in

↓

Pre-dilatation if required
(rapid pacing, inflate, deflate, pacing off)

↓

ACT 250 seconds

↓

Valve taken in

↓

Valve positioning - check angiogram

↓

Deployment under rapid pacing

↓

Echo (TTE) assessment for PVL & gradient

↓

Remove delivery system

↓

Pigtail catheter back in left ventricle

↓

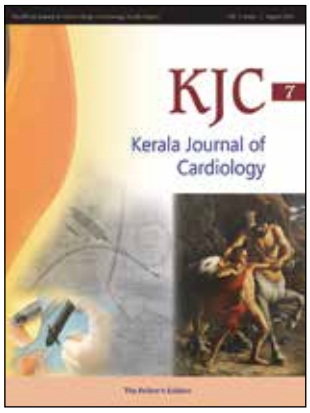
Hemodynamic gradient assessment

↓

Final angiogram

↓

Vascular access closure



TAVR with Self-expandable Valve

Amit Kumar Chaurasia
Chief, TAVR and Structural Heart Disease Program,
Artemis Hospital, Gurugram, New Delhi.

Anoop Agrawal
Director, Structural Heart Interventions,
CARE Group of Hospitals, Hyderabad.

Today, TAVR (Transcatheter aortic valve replacement) is the standard of care for patients with high-risk symptomatic aortic stenosis. Recently, the indication has been extended to intermediate-risk patients, and trials have shown TAVR to be non-inferior to surgical aortic valve replacement in selected low-risk patients. TAVR is better for patients with a porcelain aorta than surgical AVR.

Presently, TAVR's most extensive experience has been with Edward's balloon-expandable system and Medtronic's CoreValve—Evolut self-expandable system. Abbott Navitor and Portico, Boston Acurate Neo, Meril MyValve, and SMT Hydra are the other valves currently available in India. This review focuses on planning and performing a case with Medtronic CoreValve/ Evolut R/ Evolut Pro/ Evolut Pro plus/ Evolut Fx balloon-expandable valve.

MEDTRONIC COREVALVE/EVOLUT VALVE

Medtronic CoveValve was the first generation of self-expandable supra-annular valves. Its efficacy has been well demonstrated in several trials. However, it requires a longer learning curve to control while deploying and is not retrievable or repositionable. To overcome these problems, Medtronic introduced the Evolut series, which had better predictability during deployment and was retrievable and repositionable. Also, the size of the delivery catheter decreased to 14F from 18F, making it one of the lowest-profile delivery catheters available.

The first in the Evolut series is Evolut R, a fully retrievable and repositionable valve. The valve self-centres in about 80 per cent of the cases, thus giving equal depth and precise deployment in the LVOT. There are two spines on either side of the catheter to provide adequate strength while negotiating the catheter through the vessel. This catheter is flexible in one direction, while it is not in the other direction. The valve design also changed to increase the radial force of the valve. However, this still did not alter the incidence of para-valvular leak, so to negate this, the Evolut Pro series was introduced, which had an outer skirt on the valve that decreased the incidence of para-valvular leak post-deployment. The profile of the delivery catheter was 14F for 23, 26 and 29mm valves. With the introduction of Evolut Pro Plus, even a 34mm valve with an outer sealing skirt was available.

The two spines on either side of the catheter made trackability problematic in some patients. With the introduction of Evolut Fx, which has only one spine, this problem has been solved. Also, in the Evolut Fx series, the valve has three gold markers placed at 3mm so that the operator knows exactly how deep the valve is deployed. These markers also help identify whether commissural alignment has been achieved. As I write this review, Evolut Fx is available in India, and Evolut Fx Plus has been introduced in the USA. Evolute FX has the advantage of larger cells for better coronary access.

Disclaimer: *Medronic valve is used as a prototype of balloon expandable valves. KJC does not endorse any particular valve and the Journal, Editor or Author has not received any funding from the company for this article.*

Address for correspondence: Amit Kumar Chaurasia, Chief, TAVR and Structural Heart Disease Program,
Artemis Hospital, Gurugram, New Delhi. Email: amitkumarchaurasia@gmail.com

The fundamental property of Medtronic self-expanding valve

There are three fundamental properties of the Medtronic valve: (1) self-expanding frame, (2) supra-annular valve design, and (3) Porcine pericardial tissue. The frame of the valve is made up of nitinol. The nitinol frame can be compressed to the desired shape using ice-cold water while the valve is loaded into the delivery catheter. When opened at body temperature, it expands to take the original shape. Nitinol is a well-tested biomaterial and has stood the test of time. Supra-annular design helps the valve maintain a perfect round shape despite the annular segment being compressed in different shapes (Figure 1). This also improves the valve's effective orifice area (EOA) and thus enhances the hemodynamic performance of the valve. Porcine tissue is thinner than the bovine tissue, which decreased the delivery catheter profile to 14F. The valve is designed like a suspension bridge, which helps reduce the shear stress on the tissue and thus improves the durability of the valve.

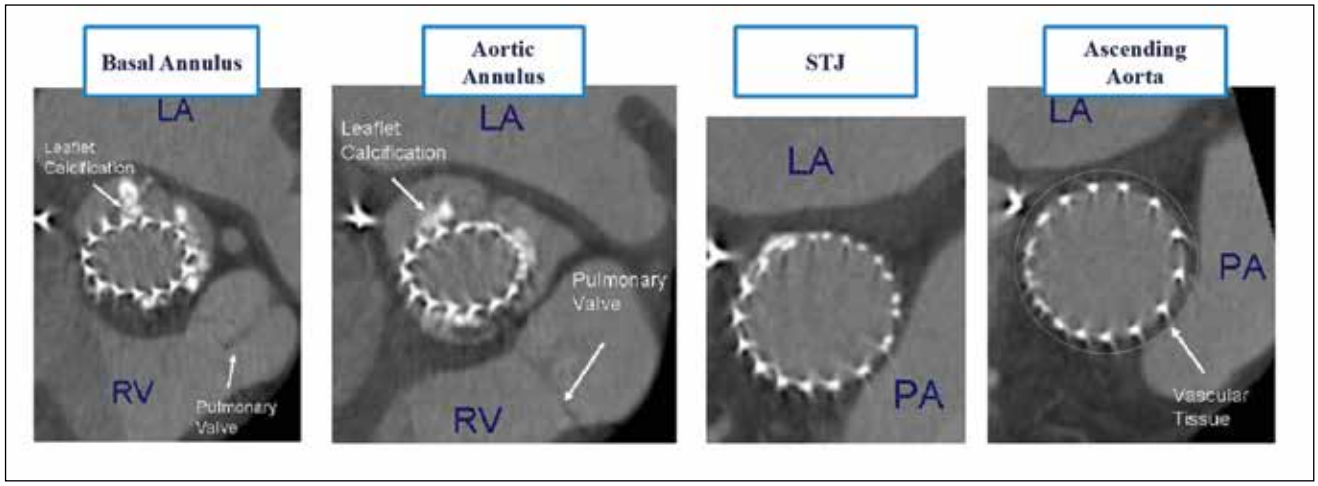


Figure 1: To demonstrate the advantage of supra-annular design. Note the ellipticity of the frame at the annulus level, whereas the frame is almost circular at the STJ.

Setting up a TAVR program

There might be a lot of apprehension initially, but this resistance can be easily overcome. First, the center needs to decide on a core team, and this core team needs to undergo training. Performing TAVR involves teamwork, and all the team members must take responsibility for it. The heart team concept is the key to success. A heart team comprises a clinical cardiologist, interventional cardiologist, echocardiographer, cardiothoracic surgeon, anesthetist, and radiologist. Apart from them, the nursing staff and the Cath lab technicians are also necessary. Everyone needs to know their role. It is always better to walk through the case with everyone present in the first few cases. Though I mentioned the first few cases, we have a practice of always walking through the case, even today

Materials required

The materials required can be classified into three groups: (1) required for loading of the valve, (2) required for performing the procedure, and (3) required for managing complications. The materials required are shown in Table 1. It is a good idea to fully equip the catheterization laboratory, as no one knows when the hell will break open and what material will be required.

Table1: List of common materials required for self-expandable TAVI

• One separate valve loading table
• One ice cold saline bottle
• Two normal saline bottle
• No. 11 blade
• Sterile sheets
• Contrast pressure injector
• High pressure injector tubing
• Straight tip Termo/Teflon wire
• Exchange length wire/ Amplatzer stiff wire/ Confida wire/ Safari wire/ Lunderquest wire
• 25/35mm Gooseneck snare
• Peripheral covered stent
• 14-18F sheaths
• Proglides and Angioseals
• Two Pigtails, AL-1, AL-2, JR, MP, IMA catheters

Position set up in the Cath lab

This is important in the planning stage to smoothly complete the procedure. At the same time, alternate route access requires special arrangements. The table arrangement for the transfemoral procedure is straightforward, like any coronary procedure. However, special care should be taken when arranging the echocardiography machine and the anaesthesia equipment. Preferably, the echocardiography machine should be kept towards the left hand side of the patient. The monitor should face the operator. This gives convenience to the operator as well as the person performing echocardiography. Today, in some Cath labs, the Echocardiography machine can be connected to a port, which allows the visualization of the image on the monitor. The anesthesia machine should preferably be on the right side of the patient's head. This makes it easy for the anesthetist to monitor the patient and administer the drugs through a triple-lumen catheter on the right internal jugular vein. Also, if the temporary pacemaker is inserted through the right internal jugular vein, it is easier to control. Depending upon available space, a sterile table arrangement should be made for valve loading.

Sometimes, bilateral femoral arteries may not be adequate for the procedure. In these settings, alternate route access is required. The alternate route includes (1) left subclavian artery, (2) right subclavian artery, (3) Direct aortic, (4) use of infrarenal aorta with conduit graft, (5) carotid artery, (6) cavo-aortic access. Transfemoral access provides the best outcome. With the introduction of Intravascular Lithotripsy (IVL), most cases can be easily treated with the femoral route.

The right subclavian is the least favoured route (1) because of its tortuosity, and (2) it requires the aorta-ventricular angle to be less than 30 degrees. If the left subclavian artery is chosen as the access site, the size of the left subclavian should be more than 6mm; however, in post-CABG patients with a left internal mammary artery, the size should be more than 7mm (this avoids decreased flow to the coronaries during the procedure). The change in lab setting for the subclavian route is given in Figure 2. Though percutaneous access through the axillary artery is also used these days, I do not favour this approach and surgical cut down is better to control if bleeding occurs. Nowadays, carotid access has gained popularity because of the straightforward course of the carotid. The size of the carotid should be at least 6mm if this is the chosen route.

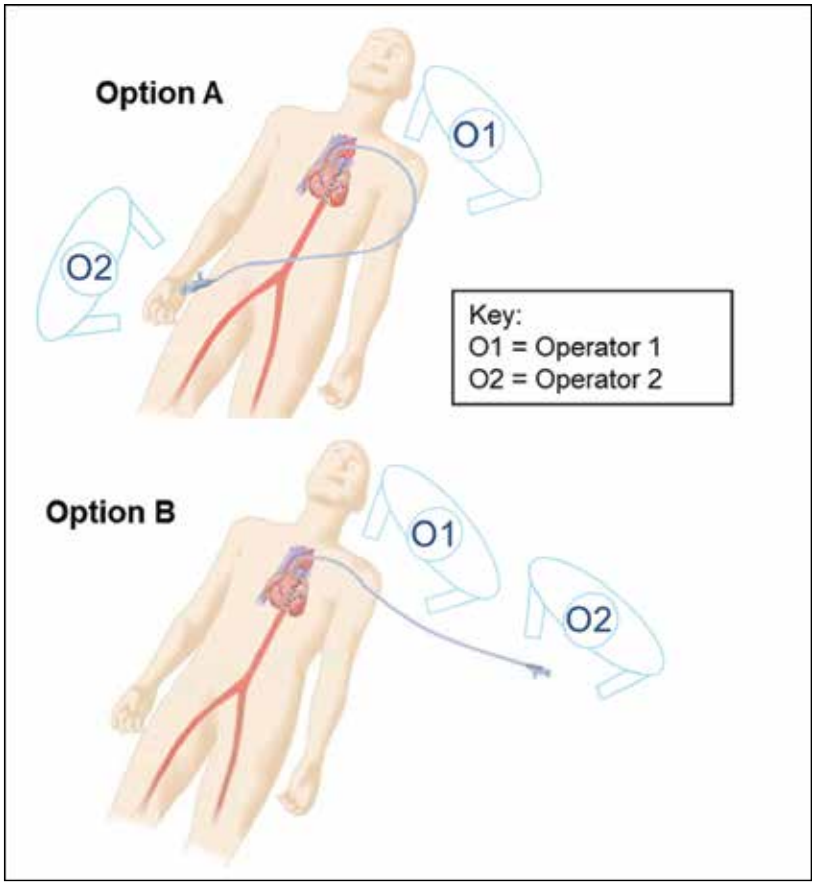


Figure 2: Position during subclavian TAVI

Case planning

The selection of the patient should be as per the appropriate guidelines. Echocardiography is the first line of investigation, followed by coronary angiography to rule out coronary artery disease. The patient then goes for MSCT analysis. If coronary angiography is yet to be performed, it can be done on MSCT itself. If the patient has tachycardia, then sometimes coronary analysis may be complex, and in that case, coronary assessment can be done just prior to TAVR. The MSCT protocol used is given in Table 2. To simplify, CT coronary protocol can be done with a stretch that includes the carotid artery up to mid-thigh. Then, reconstruct the CT at 25 percent systole with 08-1.0mm slice thickness. The following are noted on MSCT: (1) aortic annulus size, (2) sinus of Valsalva diameter, (3) sino-tubular junction diameter, (4) ascending aorta diameter, (5) the height of coronary ostia and the height of the sino-tubular junction, (6) amount of calcification on the aortic valve, (7) tortuosity and calcification on the whole length of aorta, (8) the diameter and tortuosity of bilateral femoral arteries and (9) lastly if any calcium is present at the puncture site. A special note should be made about the porcelain aorta. After this, the case should be presented to the heart team, and the final decision should be made regarding TAVR vs. surgical AVR.

For the self-expandable valve, the sizing of the valve is done as per perimeter-derived diameter. The choice of valve in the tricuspid aortic valve and most bicuspid aortic valve is as per Table 3. Sometimes, we also see the supra-annular perimeter in the bicuspid aortic valve. Suppose the supra-annular perimeter is the same as the annular perimeter. In that case, the sizing can be as per the table. Still, if the supra-annular perimeter is less than the annular perimeter, then at times, the valve size can even be downsized if the perimeter is in the borderline zone. However, if there is any confusion, always take the help of more experienced operators. Coronary artery occlusion is one of the most feared complications during TAVR. The chance of coronary artery occlusion during TAVR is a complex interplay between the height of the coronary, the sinus Valsalva's diameter, the sino-tubular junction's height and the aortic valve leaflet length. 10mm is the minimum required height of the coronary. However, as said earlier, other parameters should also be considered.

Table 2: MSCT Protocol

Complete CT Transversal Imaging (2D-reconstructions (AP)/multi-slices (64)):
Ascending, arch and descending aorta
Thoracic + abdominal aorta
Peripheral arteries
Left (right) SubclavianClavian Artery
Slice thickness: 0.8 – 1.0 mm
Full contrast filling
ECG gated chest CT scan:
Systolic phase: Cardiac phase 25-35% Annulus/ LVOT measurements
Diastolic phase: Cardiac phase 75-85% AO-root measurements (small anatomy)
NONE gated CT scan (full body scan) of the peripheral arteries.

Table 3: Criteria to select a valve

Valve Size Selection		Evolut™ PRO Bioprosthesis			Evolut™ R Bioprosthesis
					
Size		23 mm	26 mm	29 mm	34 mm
Annulus Diameter	23,3 mm	18-20 mm	20-23 mm	23-26 mm	26-30 mm
Annulus Perimeter†	73,3 mm	56.5-62.8 mm	62.8-72.3 mm	72.3-81.7 mm	81.7-94.2 mm
Sinus of Valsalva Diameter (Mean)	32,5 mm	≥ 25 mm	≥ 27 mm	≥ 29 mm	≥ 31 mm
Sinus of Valsalva Height (Mean)	23,1 mm	≥ 15 mm	≥ 15 mm	≥ 15 mm	≥ 16 mm
Oversizing Percentage		-1%	12%	24%	46%

THE PROCEDURE

A triple-lumen catheter for drug administration is inserted through the right internal jugular vein. A temporary pacemaker can either be inserted through the internal jugular vein or the femoral vein. A temporary pacemaker through the internal jugular vein provides the advantage of early mobility. The femoral artery is decided for therapeutic and diagnostic purposes based on MSCT. The therapeutic femoral artery is the one through which the valve is delivered, and the diagnostic is the one through which the pigtail is put in the NCC to guide the deployment of the valve. The therapeutic femoral artery should be less tortuous, with a size of more than 5mm, without calcium at the femoral head or any branch artery crossing it over the femoral head. Avoiding the femoral artery with calcium at the femoral head is better as the Perclose ProGlide/Prostar XL sutures may not stay in place. The other femoral artery can be used for diagnostic purposes. Instead of the femoral artery, either of the radial arteries can be used as a diagnostics side for placing the pigtail in NCC.

A cross-over is done to the therapeutic femoral artery using an IMA catheter and Termo wire through the diagnostic femoral artery. The right femoral artery angiography is performed to visualise the femoral artery on the femoral head. After right femoral artery angiography, the Terumo wire is re-introduced into the femoral artery and placed below the femoral head. With wire as a marker, local anaesthesia is infiltrated either side directly at the puncture site. This helps in the femoral nerve block that runs in close proximity. Now, either a direct femoral artery puncture can be done, or a USG-guided femoral artery puncture can be done. Having the wire in the femoral artery also helps to visualise the femoral artery while a USG-guided puncture is done. After this, the cross-over IMA catheter and Termo wire are removed. This is done before the introduction of Proglide, or else there is a chance that the Proglide may catch the wire when it is introduced. Nowadays, I use only a single Proglide, and at the end of the procedure, if the hemostasis is not achieved, I put an 8F Angioseal or a second proglide.

After Proglide is introduced, an 8F sheath is inserted. The 8F sheath needs to be upgraded to a 14F sheath. The 8F sheath Amplatzer stiff wire is placed in the descending aorta. On this wire, the femoral artery is gradually dilated using 10, 12, and 14F dilators, and then a 14F sheath is inserted. Before the 14F sheath is inserted, giving heparin at 100 U/kg body weight is mandatory. ACT should be maintained for more than 250 seconds during the entire procedure. A pigtail is introduced, placed in the NCC, and connected to the power injector with contrast for aortic root angiography through the other femoral artery.

The aortic valve is crossed using an AL1 catheter and a straight tip wire through the 14F sheath. The straight tip wire could either be a Teflon or a Termo wire. Be careful not to damage the coronaries or perforate the LV using Terumo wire to cross the valve. Also, the amount of backup support required to cross the valve should be considered while selecting the wire. Once the aortic valve is crossed, the AL1 catheter is inserted into the LV, then using an exchange length wire, the AL1 catheter is exchanged to a pigtail catheter, and hemodynamic measurement is performed.

The following are noted during hemodynamic measurement: (1) Aortic valve gradient, (2) aortic systolic and diastolic pressure, and (3) the left ventricle end-diastolic pressure. A stiff pre-shaped wire is introduced in the left ventricle (Confida/Safari wire) through the pigtail. In a horizontal aorta, a very calcified valve, and other difficult anatomy, a Lunderquest wire can also be considered. In a severely calcified valve, bicuspid aortic valve, valve area of less than 0.5cm2, fibrotic valve, predilation may be required. Since this is a self-expandable valve, care should be taken while choosing the size of the balloon, as the motive here is to predilate just enough to facilitate the crossing of the valve. Hence, it makes sense to remain below the minimum diameter of the valve as per MSCT. Also, it is important to have the valve loaded and fluoroscopy inspection done before predilation, as occasionally, predilation may cause severe AR, which may not be tolerated by the patient and may require immediate implantation of the valve. Points to be noted are given in Figure 3. Predilation should be done under controlled pacing at 160 beats/minute to 180 beats/minute.

After predilation, the 14F sheath is carefully removed, keeping the wire in LV and introducing the valve with the inline sheath. In a very hostile anatomy, if the femoral artery size permits, an 18F sheath can be introduced prior, and the procedure can be done without an exchange. All the forward movement and progress of the valve is monitored under fluoroscopy. The flush port of the valve should be kept at three O clock position. When the valve reaches the descending thoracic aorta, the C arm is turned in LAO 45 degrees so that the arch of the aorta is opened in perfect C shape, and the smooth movement of the valve through the arch of the aorta can be seen. Now, make sure to note that the hat marker on the catheter faces the outer side. When this is done, a commissural alignment is achieved in most cases, and access to the coronaries will be easier post-procedure if required.

Under fluoroscopy, slowly cross the arch of the aorta and reach the ascending aorta. Note that the hat marker on the catheter now faces the outer curve of the arch so that commissural alignment is achieved. Then, the

FLUORO LOAD INSPECTION GUIDANCE

A

Use the following recommendations to ensure an accurate load assessment:

Imaging Projection:

- AP projection
- High magnification
- Low resolution to locate paddles
- High resolution (30 FPS) for load check

Delivery System:

- Flush ports at 3:00/9:00
- Capsule flat on table or patient
- Rotate delivery system a few degrees in either direction until both paddles are visible simultaneously

FLUORO LOAD INSPECTION GUIDANCE
CHARACTERISTICS OF A GOOD LOAD

B

Focus inspection on the following areas to confirm characteristics of a good load:

1. **Paddles:** same height within the pockets and equidistant from paddle attachment
2. **Outflow crowns:** aligned straight and parallel to the distal end of the paddle attachment
3. **Capsule:** straight and free of any bends or curves with node bands appearing straight and uniform

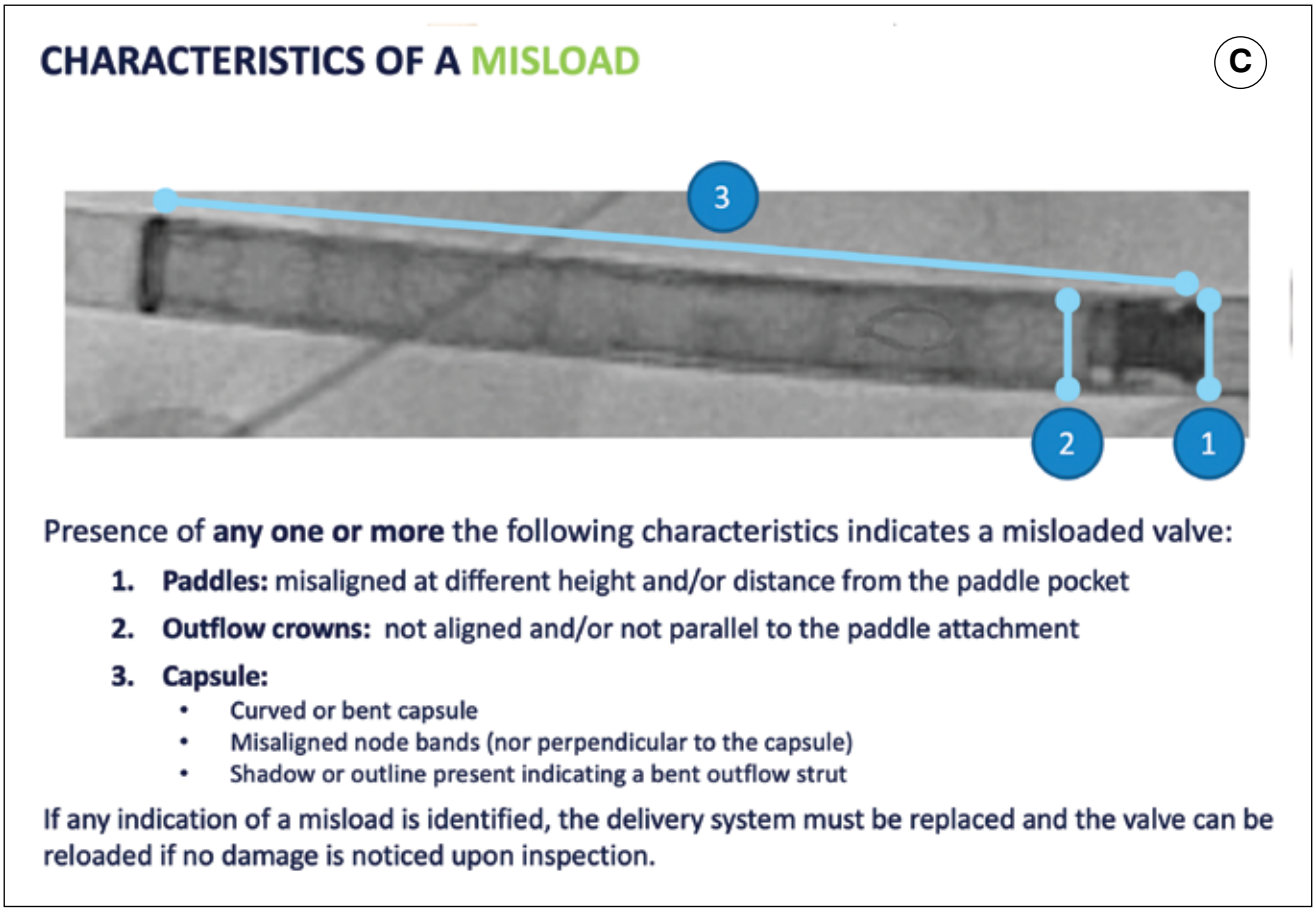


Figure 3: **A, B, C** - Points to note during fluoro-inspection of the valve

valve is slowly and gradually inserted into the left ventricle. The C arm is now positioned in cuspal overlap view. Please note the lower metallic ring on the delivery catheter is in a straight line at this position; if not, make a slight adjustment to the C arm position to achieve this. Note that the metallic ring is on the catheter and will move while deploying. The position of the pigtail is checked to ensure that it is at the lowest position in the NCC by doing an aortogram. The starting deploying position of the ring on the catheter in the case of Evolut Pro Plus is the midpoint of the pigtail circle and in the case of Evolute FX, the base of the pigtail circle. The ideal deployment depth is 3-5mm. The details about the catheter are given in Figure 4. The depth is determined by the nodes on the valve, as shown in Figure 5. The first node is at 6mm, and the subsequent nodes are at 4mm distance. In Evolut Fx, there is a gold marker at a 3mm distance, which acts as a guide while deploying. The valve is deployed in an anti-clockwise direction and recaptured in a clockwise direction. The valve is slowly

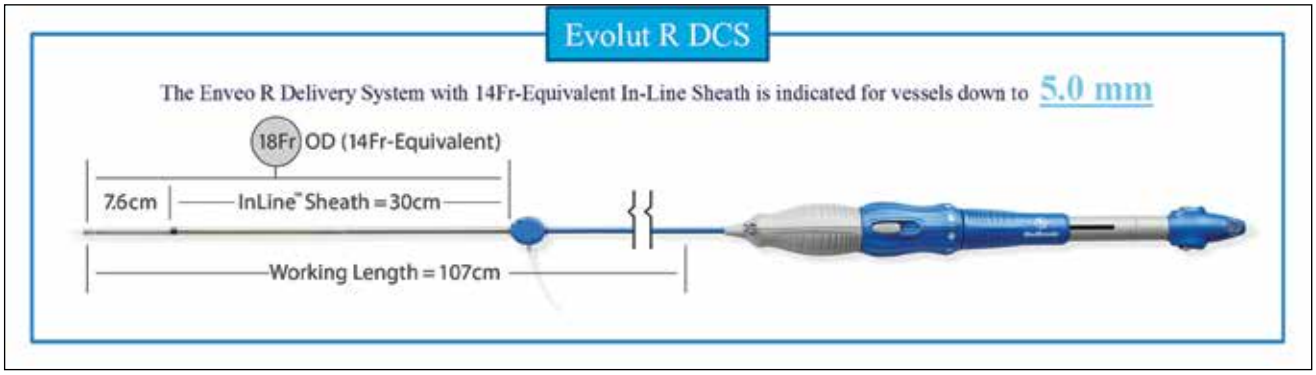


Figure 4: Catheter delivery system

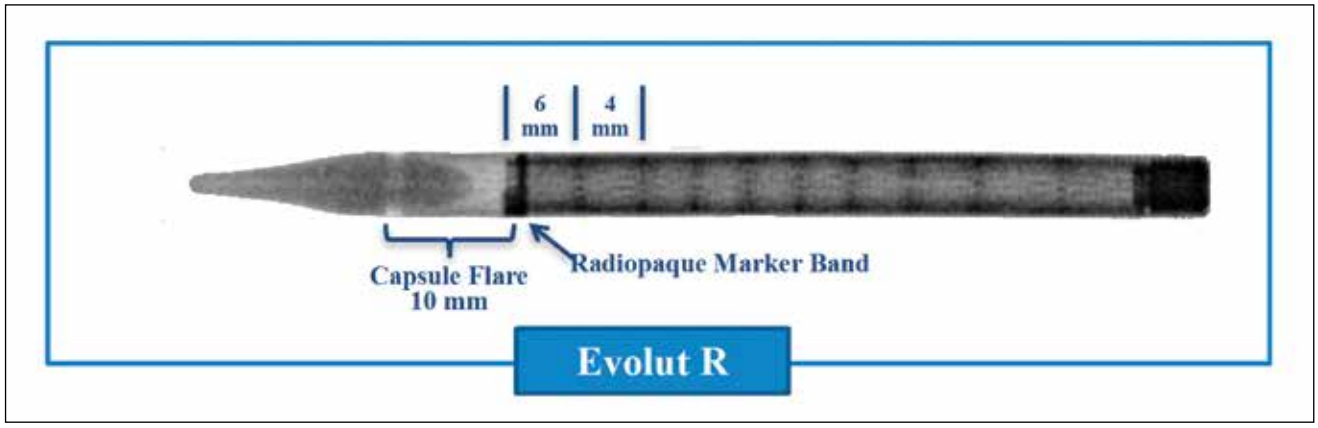


Figure 5: Loaded capsule under fluoroscopy (each dark band denotes conglomerate of nodes)

opened to the third node, and then an aortogram is performed to ensure the right depth. Small adjustments can be made at this point if required. After this, the heart is paced at 120-140 beats per minute, and the valve is further deployed. Up to the third node, the deployment is a slow process, and after that, it is a fast process under controlled pacing until 80% deployment, i.e. up to the last node. After 80% deployment, the valve is fully functional, and an aortogram is done to see the depth of the valve and if any paravalvular leak is present.

There are three markers at 3mm on the Elolut FX; if the marker is at the lowest position of NCC, then the valve's depth is 3mm. In Evolut Pro Plus, the first node is at 6mm, and if the position of the valve is half of the first node below the lowest position of NCC, then the depth of the valve is 3mm. If the position of the valve is not good, the valve can be recaptured and redeployed. The maximum number of recaptures allowed is three times. Even after that, if the position is not achieved, the valve is recaptured, retrieved from the body, reloaded, and redeployed. Both the delivery catheter and valve are changed before redeployment. The system needs to be pushed slightly forward to release the tension on the system during the final deployment of the valve. The position of the valve at various stages of deployment is shown in Figure 6.

The slow final deployment is performed under controlled pacing at 120-140 beats per minute. Before the final deployment, the stiff wire can be pulled back slightly into the nose cone so that the nose cone centralizes and the tension on the system decreases. After the valve is fully deployed, we need to check if the paddles are released completely. Do not pull the system, if the paddles are still attached, the valve may get embolized. Instead, push the system and if paddles are still attached the struts may appear distorted. Sometimes, the paddles are not released on their own, and if this happens, the paddles can be released by rotating the system in a clockwise or an anti-clockwise direction.

After the paddles are released and the valve fully deployed, the nose cone must be retrieved from the LV. To retrieve the nose cone, pull the stiff wire into the catheter until the floppy portion is in the nose cone,

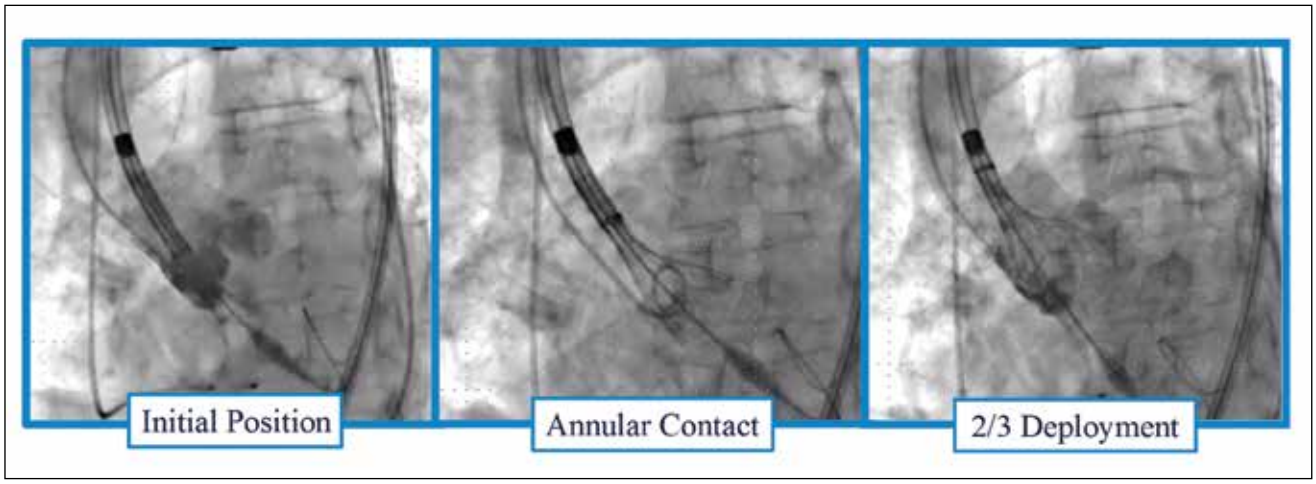


Figure 6: Various stages of valve deployment

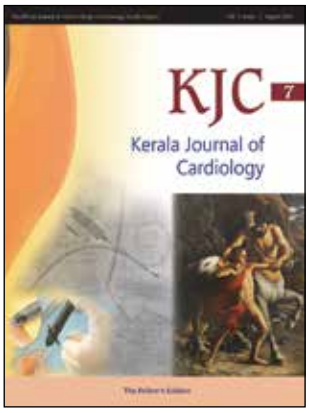
and in doing so, the nose cone centralises and can be carefully pulled out of LV. The nose cone is pulled back to the descending aorta. The nose cone is re-sheathed after the system is brought down to the descending aorta. After re-sheathing the nose cone, the system is removed, and the 14F sheath is re-inserted. A pigtail is introduced into the LV, and hemodynamics are noted. A high or normal aortic diastolic pressure with low LV end-diastolic pressure denotes a good result and probably little or no aortic regurgitation (AR). AI index can be calculated by dividing the difference between the diastolic pressure of the aorta and left end-diastolic LV pressure and then dividing the result with aortic systolic blood pressure and multiplying it by 100. If this index is more than 25%, the prognosis is good. An echocardiogram is done to see the aortic valve gradient, para-valvular leak, mitral regurgitation, pericardial effusion, and new RWMA. A final aortogram is performed to see for the degree of para-valvular leak. Post-dilation is required if the para-valvular leak is moderate or more and the AI index is low. However, care should be taken not to exceed the mean MSCT diameter of the aortic valve while choosing the balloon size.

A para-valvular leak can also occur if the valve is too deep into the ventricle. In this case, post-dilation is the first choice; snaring the valve up is the second choice. If the problem is not solved, a valve in the valve is done with the second valve deployed higher than the first. If the paravalvular leak is due to the supra-annular position of the valve, then the valve is stabilised with a snare, and another valve is deployed below the first. If the paravalvular leak is due to a chunk of calcium on a particular site in the aortic annulus and post-dilation with the recommended maximum-size balloon is already done; then it is better to stop as this may cause annular rupture if further aggressive post-dilation is done. With time, nitinol will take the shape of the calcium where it is deployed, and the AR may get reduced. After confirming everything is fine, the percutaneous suture that was placed is closed.

The pigtail is removed from the diagnostic femoral artery, and the patient is shifted out. If there is any change in rhythm during the procedure, then it is advisable to keep the temporary pacemaker for 24 hours. Remember that there is no definite duration for the patient to develop CHB; however, the highest incidence is seen during the first three days. Patients with RBBB on ECG, heavy calcium on the valve, and calcium running into LVOT have the highest risk of developing CHB. Also, controlling the depth of deployment helps to reduce the incidence of pacemakers, but at the same time, we should keep in mind that the best deployment depth is 3-5mm.

POST-OPERATIVE CARE

The care of a temporary pacemaker, triple lumen and access site is most important. The patient must continue on dual antiplatelets for six months and then single antiplatelets. A single antiplatelet and oral anticoagulant should be continued if the patient requires oral anticoagulation. Drugs for other symptoms should be continued as recommended. The patient can develop thrombocytopenia during the post-operative period, which usually settles in five days.



Implanting a Permanent Pacemaker: Technique and Challenges

Jyothi Vijay M.S.
Asst. Professor, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala.

INTRODUCTION

The decision to implant a permanent pacemaker is perhaps the most crucial step in planning a permanent pacemaker procedure.

Common indications to put a permanent pacemaker include irreversible symptomatic sinus nodal dysfunction, high-grade atrioventricular blocks and symptomatic bradycardia. Given below is the summary of available guidelines on the indications for implanting a permanent pacemaker (see Table 1)

There are three distinct types of pacemakers depending on the paced chamber.

- Single chamber pacemaker
- Dual chamber pacemaker
- Biventricular pacemaker or CRT

In this article, the implantation techniques of a conventional dual-chamber pacemaker are discussed.[3] A dual-chamber pacemaker is the most common type of pacemaker implanted.

Senning was the first to implant a permanent pacemaker in a patient with Stoke-Adams syndrome. Forty years (and 26 pacemakers) later, the patient outlived the surgeon.[4] In the last seven decades, significant and rapid technological development and refinement of the technique have occurred. The use of the Seldinger technique for venous access and the development of a peel-away sheath by Littleford has simplified the implantation technique and shifted the procedure from the operation theatre to the cardiac catheterisation lab.[5]

The technique of permanent pacemaker implantation can be divided into steps:

- Preprocedural planning
- The implantation technique and
- Post-procedural care.

Address for correspondence: Jyothi Vijay M.S., Asst. Professor, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala, PIN-695011. Email: jyothims09@gmail.com

Table :1 Indications for permanent pacing, adapted from guidelines[1, 2]

Indications for pacing	Remarks
Pacing for sinus node dysfunction (SND)	
• Evidence of sinus node dysfunction with symptoms clearly attributable (class I) or probable (class IIb) due to bradyarrhythmia • Syncope with asymptomatic pauses of more than 6 seconds due to sinus arrest • Bradycardia-tachycardia syndrome requires pacing and drug treatment for rate or rhythm control unless an ablation first strategy is preferred.	• DDD(R) is the pacing mode of the first choice in SND • Programming exceptionally long AV intervals to minimise RV pacing can lead to diastolic mitral regurgitation
Pacing for atrioventricular block	
• Pacing is indicated in Mobitz type 2 or high-degree or third-degree AV block, irrespective of symptoms. • In cases of prolonged PR of more than 300 milliseconds and symptoms entirely attributable to first-degree AV block.	
Unexplained syncope and bundle branch blocks	
• Especially elderly and frail at risk of traumatic recurrences. (class IIb) • HV interval of more than 70 ms on EP study (class I) • In patients with neuromuscular disorders and bundle branch blocks	• An EP study may be used for decision-making as appropriate in some instances. An HV interval of more than 70 ms may predict a progressive AV block. • Infra-Hisian block during incremental atrial pacing or an abnormal response to pharmacological challenge. • In those with severe LV dysfunction, an ICD/CRT-D may be preferable if the expected pacing percentage is higher.
Pacing for reflex syncope	
• Cardioinhibitory response on a positive tilt table testing • Documentation of asystole in loop recorder • Adenosine-induced AV block of more than 10 seconds • Cardioinhibitory carotid sinus syndrome	• Asystolic positive tilt test is defined when the spontaneous syncope is reproduced in the presence of an asystolic pause >3 seconds
Recurrent syncope in those over 40 years with documented symptomatic asystolic pauses of more than 3 seconds or asymptomatic pauses of more than 6 seconds. (class I)	
Alternating bundle branch block (class I) with or without symptoms	

PREPROCEDURAL PLANNING

Procedures should be done in the cardiac catheterisation suite, which should be maintained with the operation theatre quality standards. Like any other surgical procedure, pre-procedural investigations, including a complete hemogram, prothrombin time, renal function tests, and viral serology tests, are required.

All patients should have a 12-lead ECG before the procedure. A good transthoracic echocardiography should be done to identify the chamber enlargement, septal defects, endomyocardial fibrosis (EMF) and valvular regurgitation, especially the tricuspid valve, which may need a modified technique. A dilated coronary sinus may be the only clue for the presence of a left-sided SVC.

Studies like the BRUISE CONTROL trial have shown that when compared with bridging therapy with heparin, a strategy of continued warfarin treatment at the time of pacemaker or ICD surgery markedly reduced the incidence of clinically significant device-pocket hematoma.[6] However, this needs to be individualised according to the risk versus benefit and thrombosis versus bleeding risk, especially in the case of a patient with mechanical heart valves. Nevertheless, a large pocket hematoma carries an eightfold additional risk of device infections.[1]

Antiplatelet drugs may be stopped 5 to 7 days before the procedure if it can be safely done. In cases where discontinuation of antiplatelet drugs and anti-coagulation is not possible, the risk of bleeding should be explained. Informed consent, preparedness for a higher infection rate, re-exploration, or pronged hospitalisation, and availability of intraprocedural cautery should be ensured.

PATIENT PREPARATION

Informed consent: This is an integral step before the procedure. Though most permanent pacemaker implantations are done safely by experts, definite procedural risks include device infections, hematomas, pneumothorax, lead displacements, cardiac perforation, tamponade or, rarely, death. Patients and relatives should be made aware of the procedural risks associated with it, as some of the complications carry significant morbidity or mortality.

Analgesia: A typical pacemaker surgery requires local anaesthesia only. A combination of lidocaine and bupivacaine helps to have quick and longer local anaesthetic action. Sometimes, the pocket or the muscle needs infiltration of an additional anaesthetic agent. A combination of physician or nurse-administered anaesthesia is practised in many centres. If additional drugs are required, which include titrated doses of a benzodiazepine and small doses of fentanyl may be administered. An upfront sedation may be necessary for very young, anxious and agitated patients. If anaesthesia personnel (physician or trained anaesthesia nurse) are available to monitor the level of sedation, more sedative doses allow a calm and cooperative patient, which makes the procedure comfortable for the implanting physician.

Antibiotics: Antibiotic prophylaxis beginning before the procedure has been shown to reduce device infections. We follow a single dose of antibiotic with staphylococcal cover (cephalosporin) with aminoglycoside, which is continued for 24 hours post-procedure. Usually, the patient can be discharged home with a short course of oral antibiotics after completion of 24-hour postprocedural care. It will be imperative to avoid the routine use of antibiotics dedicated to CIED prophylaxis for other procedures to prevent the development of resistance.

A wide-bore IV cannula is placed on both sides unless contraindicated (like ipsilateral venous occlusion, post radiotherapy, post-mastectomy surgery lymphedema). A left-sided cannula is often put afresh on the day of the procedure. Medications are given through a right-sided cannula; the left-sided cannula is reserved for contrast injection. This prevents any inadvertent bacteraemia on the side of the device due to phlebitis.

IMPLANTATION TECHNIQUE

Equipment required

A sterile table with the instruments required for a conventional dual-chamber permanent pacemaker implant is shown in the picture. Every operator implanting a cardiac implantable electronic device (CIED) should be well-versed in the instruments required (Fig. 1).

Preparing the site

Traditionally, a Pacemaker is implanted in the left pectoral region of the patient. This is often suited for a patient with right dominance and devices with defibrillator capability, like ICD and CRT D, are better implanted on the left side due to wider myocardial coverage for the shock energy.

A right-sided implant may be preferred in cases where there is obstruction of the left-side venous system or thrombosis. A group with particular concern is those participating in sports or working in the armed forces, where recoil from rifles to shoulder may be a concern when selecting the appropriate side. In patients with a left superior vena cava joining the coronary sinus, a right-side implant may be superior to an implant through the coronary sinus.

Preparation of site: The patient should be instructed to bathe using soap at least before and on the morning of the day of the implantation of the pacemaker. The surgical field is initially prepared by a trained nurse who scrubs an antiseptic solution based on chlorhexidine or iodine. Care should be taken to strap the loose soft tissue or breast falling into the pectoral region or wrinkling the subclavian area. Adequate contact time should be given for the action of iodine-containing antiseptics. A custom-made square-shaped metal frame for support is kept on the head end to ensure patient comfort and ventilation during the procedure when the patient's face is covered.

Temporary pacing backup: Temporary pacing leads are usually kept for patients who are dependent on

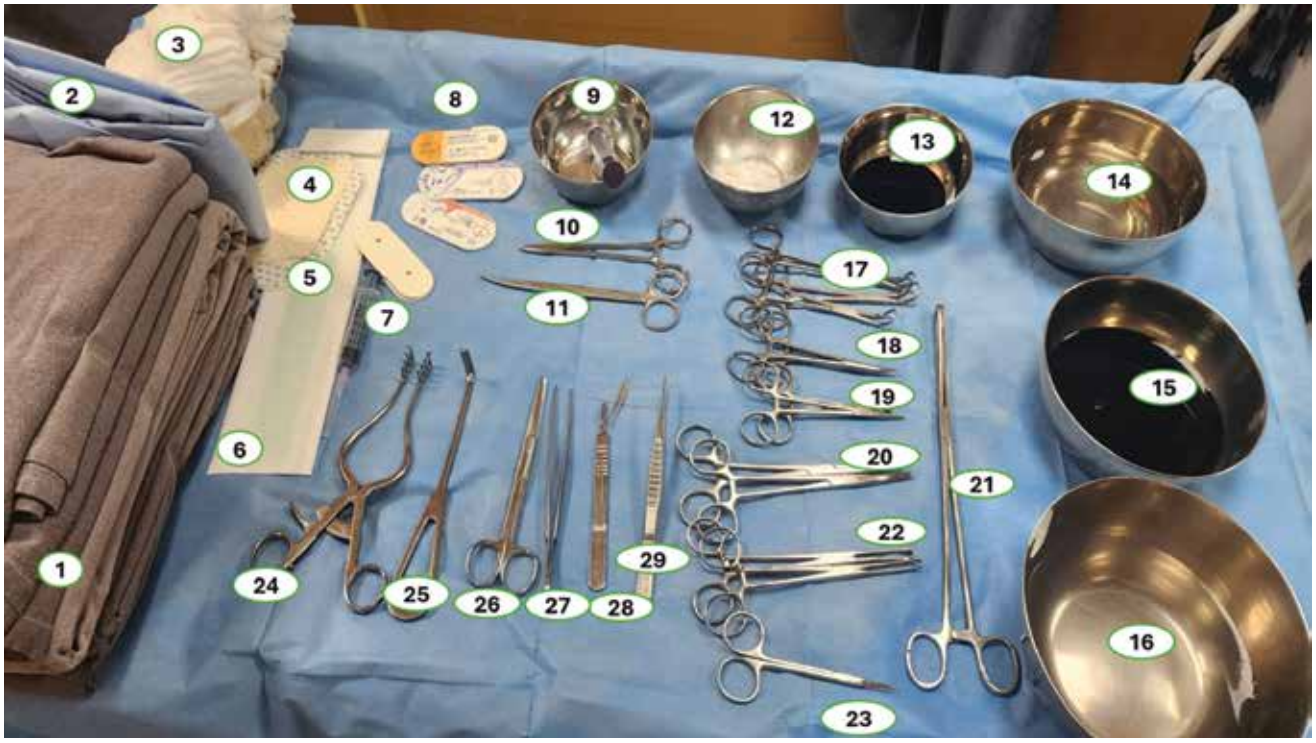


Figure 1: A sterile table with required instruments for permanent pacemaker implant: 1- Linen/Drapes, 2- Image amplifier cover, 3- Gauze, 4- sterile strips for wound closure, 5- transparent adhesive dressings, 6- sterile iodine impregnated surgical field cover, 7- syringe and needle, 8- three types of sutures, 9- local anaesthesia solution,10- needle holder, 11- Metzenbaum scissors, 12- vancomycin powder for pocket irrigation, 13- Betadine for final wound dressing,14- Bowl for sterile saline, 15- Betadine for painting, 16- sterile saline for wetting gauze, 17- Towel clips(Backhaus), 18 and 19- small artery holding forceps, 20- long artery holding forceps, 21- sponge holding forceps, 22- Allis forceps, 23- Iris scissors, 24- Self-retaining retractor(Weitlaner), 25- Retractor(Langenbeck), 26- straight scissors(Mayo), 27- toothed holding forceps, 28- knife with blade, 29- non-toothed holding forceps.

external pacing or have very low heart rates. Prolonged placement of temporary pacing wire is shown to increase the CIED infection rates. When maintained, it should be ensured that it is stable, has a good capture threshold, and is non-traumatic to RV (Fig. 2).

Incision and Pocket formation: Local anaesthetic solution is infiltrated along the incision line and deeply on the location of the pocket. Usually, a deltopectoral incision is preferred. The deltopectoral groove is often visible as a groove between the deltoid muscle

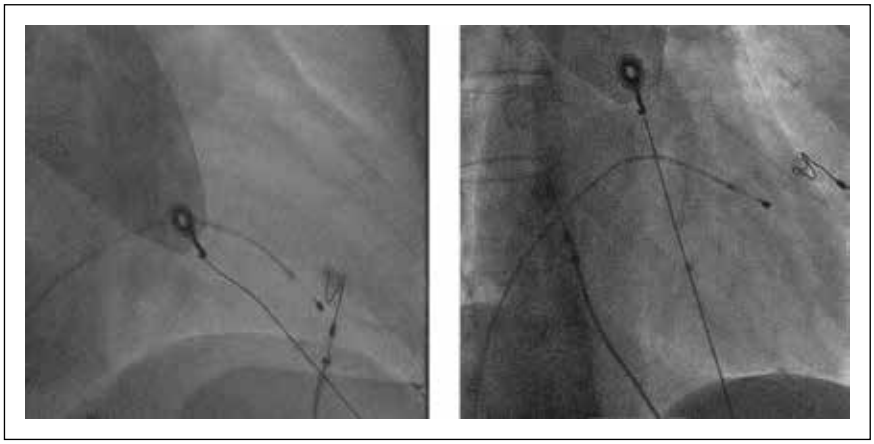


Figure 2: **2A** An adequately positioned temporary pacing wire at the apex. **2B** is an example of unstable positioning of temporary wire. This has a higher risk of dislodgement, loss of pacing and asystole in a dependent patient.

laterally and the pectoral muscle medially. The incision is made approximately 1 cm below the clavicle in the deltopectoral groove, as required for the device's size. Care should be taken not to cross the anterior axillary line. A deltopectoral incision also ensures access to the cephalic venous system for cephalic and axillary vein approaches. Other methods of incisions, like a horizontal incision or an oblique incision, are rarely practised nowadays.

The incision should be in a single line, adequate and confident. If it needs to be extended, an extended scissor or a Weitlaner retractor is used to align and avoid a "dog ear." A layer-by-layer dissection through areolar tissue with the bloodless plane is conducted till the pre-pectoral fascia. We use a Weitlaner self-retaining retractor adjusted to maintain tension at each layer, combined with Metzenbaum curved scissors and non-toothed forceps. This is very helpful for this layer-by-layer dissection. Pre-pectoral fascia may be slightly opened to confirm the muscle layer, as the appearance of fascia can often be deceptive, and the real muscle plane may be even deeper. It is preferable to avoid splitting of pre-pectoral fascia or dissecting along muscle fibres in patients on antiplatelet drugs, as this often leads to multiple bleeding spots across the muscle layer.

CENTRAL VENOUS ACCESS

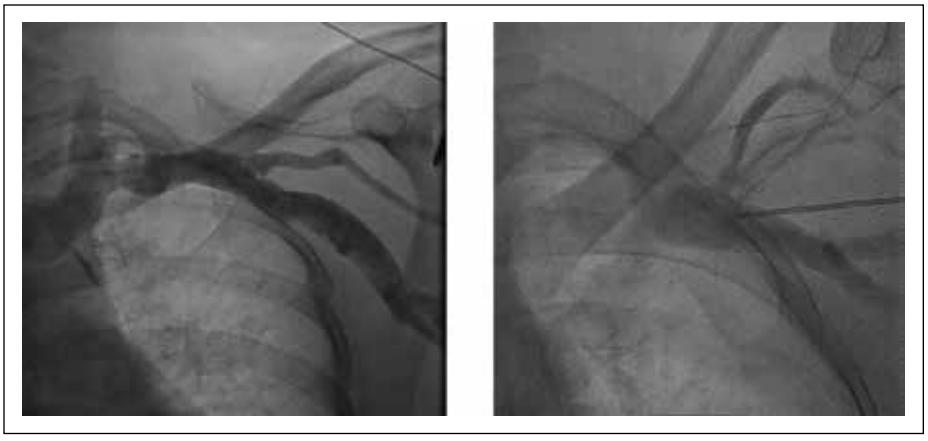
Intrathoracic subclavian puncture: Conventionally, the landmark is the junction of the medial and middle third of the clavicle. The angle between the first rib and clavicle is called the subclavian window. This technique carries some risk of pneumothorax.

Extra thoracic subclavian/axillary vein puncture: This is the most common method of access. A venogram may be done prior (Figures 3, 4 & 5). Then, the needle with a syringe is advanced, aiming towards the junction of the clavicle and the first rib but not crossing the medial border of first rib. Usually, the colour of blood helps identify the venous blood provided the patient is not on supplemental oxygen. Often, with an arterial puncture, the piston is pushed backwards easily with arterial pulsatile force compared to a venous puncture. Some prefer to avoid keeping saline in syringe to help differentiate arterial and venous blood. AP caudal view is sometimes helpful in separating the rib cage from the veins. In the event of venous spasm, a small dose of nitroglycerin injection through the ipsilateral upper limb can help. Prior sedation can also reduce the occurrence of spasm. Once the first guidewire is passed, the rest of the punctures can be taken, keeping the first guidewire as a reference.

If an arterial puncture occurs inadvertently, the needle is removed. If in doubt always attempt a new puncture and never insert the sheath in to the first puncture. Please note that multiple arterial punctures can lead to hematoma formation which can compress the vein making subsequent venous punctures difficult.

Magney's approach: The axillary vein is located at the intersection of the line drawn between the middle of the sternal angle and the tip of the coracoid process. This often serves as an extrathoracic bony landmark for the axillary vein. The axillary vein is targeted here. This technique avoids the entrapment of lead in soft tissue and ligaments when compared to the classic subclavian approach.[7]

Byrd modification: The introducer needle is held perpendicular while directed to the first rib. According to Byrd, the technique involves "manoeuvring the



3A 3B

Figure 3: **3A** A venogram is done prior to puncture or incision to identify any venous abnormalities like LSVC. The presence of a good cephalic vein, like in the above case, is reassuring for a pocket-first approach, as the cephalic vein is available for access when required. **3B** The technique of taking venous access while giving contrast injection through the ipsilateral arm minimises radiation and improves the success.

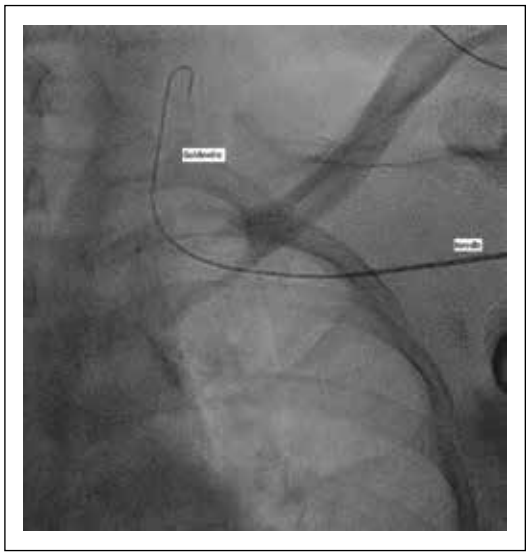


Figure 4: Sometimes, the guidewire goes to a jugular vein or fails to cross a venous valve. Manipulating the guidewire by a combination of rotation, making a loop, pushing forward, or exchanging using a dilator or a glide wire often solves the problem.

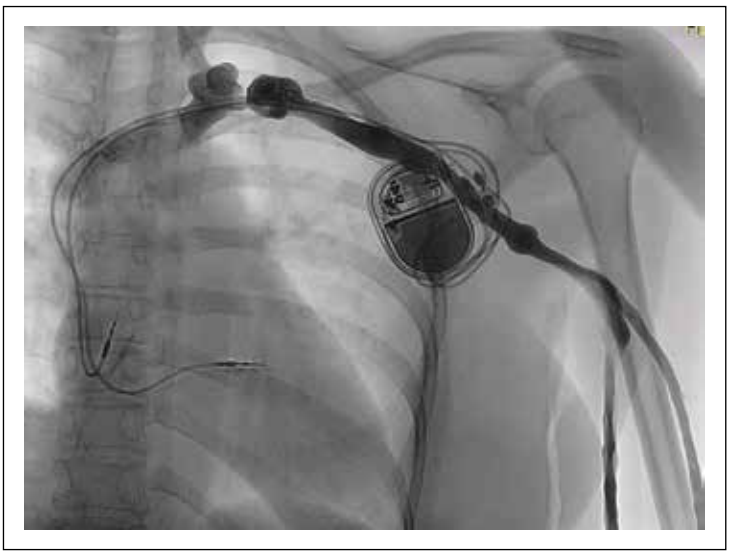


Figure 5: A case of dual chamber pacemaker with an outline of the central venous system using a contrast injection from the left upper limb.

introducer needle from the clavicle to the first rib by a series of partial withdrawals and reinsertions, visualised by fluoroscopy. The needle is advanced posteriorly along the rib until the vein is punctured".[8] Orientation is maintained by touching the rib with each manoeuvre; the needle is "walked" anteriorly and posteriorly, touching the rib with each position until venous blood is aspirated. This reduces the risk of pneumothorax (Fig. 6).

Guidewires should be ensured to dip down to IVC to ensure right-sidedness and avoid putting the sheath in case of an accidental vein-to-artery entry. Sometimes, guidewire passes towards jugular veins, for which pull back and manipulation or an exchange with a glide wire will be helpful.

PREVENTION OF PNEUMOTHORAX

Venography for reference prior to puncture

Venogram in AP caudal view

Ultrasound guidance and/or fluroscopic guidance

Extra thoracic axillary vein approch

Micro puncture needle technique

The cephalic vein cut-down technique

Figure 6: Approches to reduce the incidence of iatrogenic pneumothorax during pacemaker implants.

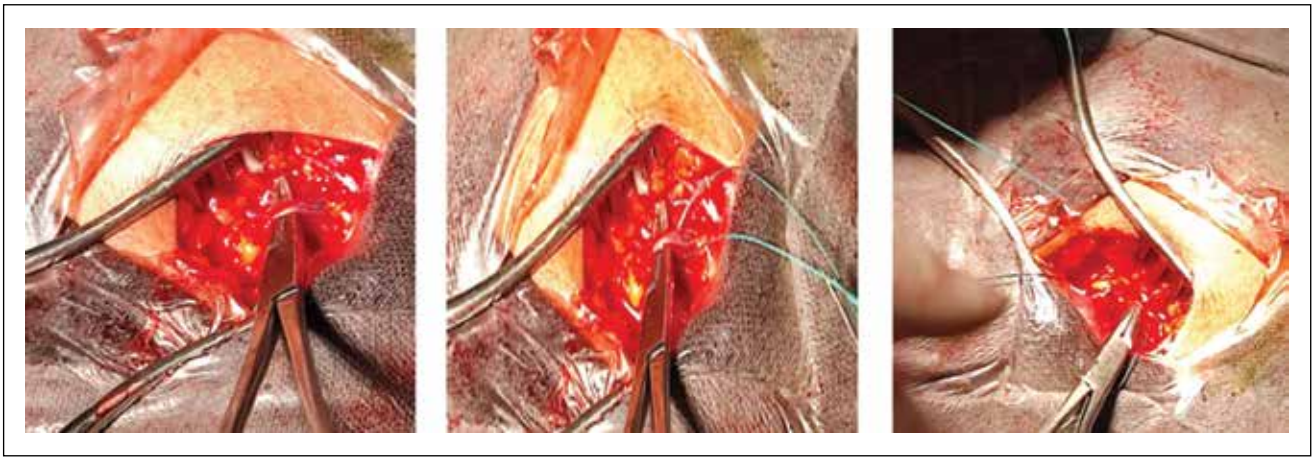
The retained guidewire technique can be helpful in the introduction of multiple guidewires and leads. The only concern is the limited space available for the manoeuvring of each lead independently without the unwanted movement of another lead.

Once all the guidewires are passed, a small artery forceps is used to dissect the entry point. This step is crucial. In the event of undue bleeding, pulsatility or bright blood, an arterial stick should be suspected, the guidewire should be removed, and a fresh puncture should be taken.

CEPHALIC VENOUS ACCESS

Mastering cephalic venous access is imperative for any skilled operator/electrophysiologist. This skill can bail out in a crisis and avoid the embarrassment of switching sides of implantation due to failed access attempts. This is also useful in cases with chest deformity, COPD, and those with a higher risk of pneumothorax.

Technique - The cephalic vein is dissected in the deltopectoral groove. Usually, the vein is in the fatty fascia between the deltoid and pectoralis muscle. Once the vein is visible, it is gently lifted and held with forceps, as shown in the image (Fig. 7). Care should be taken to prevent the avulsion of the veins. Sometimes, tendons or soft tissue can mimic the vein. Correlation of location with the venogram of the cephalic vein, if visible in the prior venogram, will be a helpful addition. Then, two non-absorbable sutures are kept ready loosely without tightening the knot above and below the selected



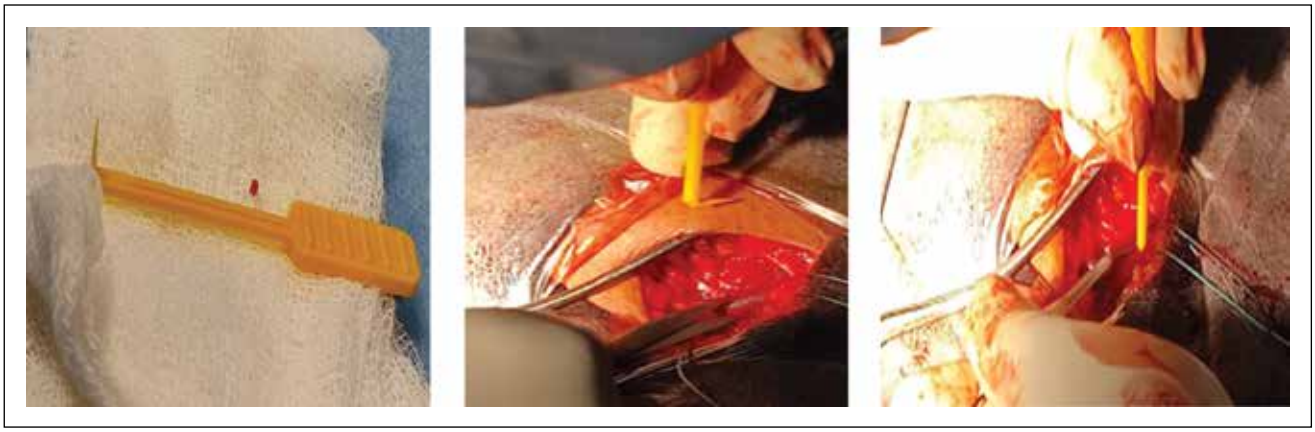
7A **7B** **7C**

Figure 7: **7A** The cephalic vein is dissected and exposed in the deltopectoral groove. **7B** vein is gently lifted and held with the forceps, as shown in the image. **7A** and **7B**, two non-absorbable sutures, are kept ready loosely without tightening the knot above and below the selected segment. (**7C**)

segment. A clamp holds the ends of ligatures. This will be useful to prevent blood loss and ensure visibility if the field is filled with blood once the vein is cut open. It also prevents any retrograde bleeding. Then, the lead may be directly introduced through the venotomy site, or the technique initially described by Ong and Barold may be tried. (Ong- Barold Guidewire technique)[9]

A vein lifter (Fig. 8) is prepared along with the iris forceps. Iris forceps are small forceps with a fine pointed tip for precise grasping of delicate tissue. A careful nick is put on the anterior surface of the cephalic vein, and once venotomy is performed, a soft tip guide wire is introduced into the vein. Once the guidewire is introduced, the sheath-dilator assembly is inserted with a rotatory motion.

A micropuncture needle with a guidewire is a handy alternative option, as the primary and secondary operators need to manage multiple instruments simultaneously at this point to avoid missing the puncture site. If blood rapidly fills the field, the distal tie is tightened immediately. Once the guidewire is passed inside, a sheath can be put in and split into two guidewires per the standard guidewire-sheath exchange technique ***(retained guidewire technique)***. The cephalic vein often accommodates two pacing leads or a defibrillator lead easily. While fixing the lead, the initial suture can be put with the proximal end of the sleeve pushed into the vein. Rest sutures can be placed on the remaining grooves and fixed to the muscle bed as usual.



8A **8B** **8C**

Figure 8: A vein lifter is prepared along with iris forceps (image **8A**). A careful nick is put on the anterior surface of the cephalic vein (**8B**), and a glide wire is carefully introduced into the vein (**8C**)

PLACEMENT OF RIGHT VENTRICULAR LEAD

There is no single proper technique for placement of right ventricular lead. Often, implanters develop strategies based on their own experience, but the basic steps remain the same. It is said that the optimal lead placement requires a *harmonious movement of lead and the stylet in symphony*.[10] (Figures 9 & 10)

While introducing through the peelable sheath, keeping the stylet fully in is recommended while crossing the initial half of the sheath. A supple lead often struggles to cross the initial part, especially when pinched by the operator's left hand to prevent an air embolism. Then, the straight stylet is withdrawn at least 5 cm so that the tip is soft and non-traumatic to the venous wall. While introducing the lead, sometimes lead may hit the lateral superior vena cava wall and get stuck or cause damage to the tip of the lead or venous wall injury. This can be managed by pulling back the sheath and the lead. Once advanced, the lead may fall to the superior vena cava (SVC) and right atrium (RA), and the lead can be further advanced.

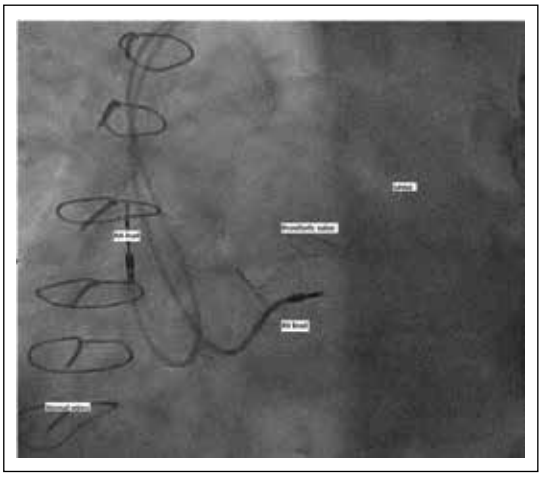


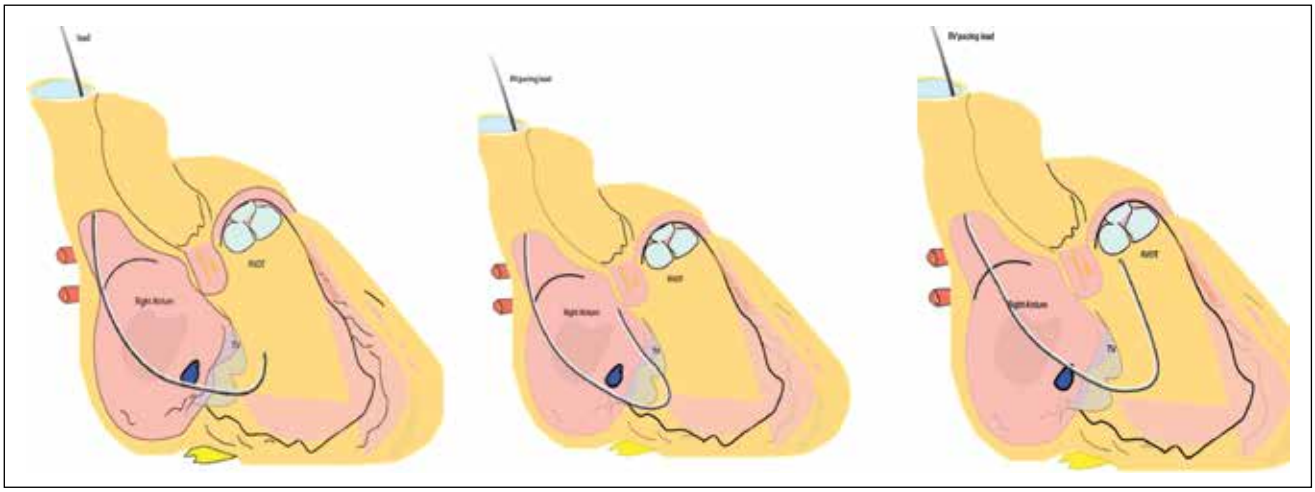
Figure 9: Fluoroscopy image showing the placement of RV lead in mid-septum and RA lead in the right atrial appendage in LAO view.

Sometimes, central veins can be very tortuous, leading to difficulty in advancing the pacing lead. Lead should never be forced against even minor resistance as it can injure vessel walls, especially with defibrillator leads. This problem can be overcome by deep cannulation of the sheath using a dilator and guidewire. By doing so, the lead can often directly enter SVC from the sheath. While pulling out stylets from lead, it is always recommended to hold the proximal end of lead near the sheath with the operator's other hand to prevent an inadvertent pullback of the lead.

Once the lead reaches mid-RA, multiple techniques exist for entering the right ventricle (RV) across the tricuspid valve (TV).

Stylet exchange method

This is a very atraumatic and straightforward method. The straight stylet is exchanged for a J-shaped stylet. Then, in the right anterior oblique (RAO) view under fluoroscopy, TV is crossed, and lead enters the right ventricular outflow tract (RVOT). This ensures entry into the right ventricle. Morphology of concomitant ventricular ectopic corresponding to location may be noted. Sometimes, brief runs of non-sustained VT can be seen in outflow tract locations, which can be managed



10A **10B** **10C**

Figure 10: Drawing of the heart in RAO view with chambers opened up showing methods of crossing the pacing lead across the tricuspid valve. **A-** Direct entry using an angled stylet, **B-** Prolapsing the lead loop across TV, **C-** Inserting a J stylet to cross TV and enter RVOT.

by a slight pull-on lead to change the location, reducing the irritability. A complete absence of ventricular ectopic should raise suspicion of lead entry into the coronary sinus (CS). This can be reconfirmed by reviewing fluoroscopy in the left anterior oblique (LAO) view. The lead crossing vertebral column is more likely lying in the coronary sinus (or rarely across IAS to be in LV). The coronary sinus is angulated towards the left shoulder in LAO view in the younger population and more horizontal in older adults.

Prolapsing the Loop

TV can also be crossed by withdrawing stylet in the mid to low RA and pushing it to form a loop, which, upon further push, prolapses into TV. A caveat here is making a septal curve in stylet while in RA causes difficulty in entry to TV as the curve will hit on tricuspid annulus precluding the entry into the RV.

Once the lead is in the RVOT, J curved stylet is exchanged for a custom-made septal curve. The lead stylet system is pulled down to RV mid-septum. Then, the stylet is wholly pushed in to take a septal angle and slightly pushed forward for an optimal location. A mid-septal location is reconfirmed in RAO and LAO view. Then lead helix is extended using an "A-frame" screw under fluoroscopy. Then, the stylet is withdrawn and exchanged for a straight stylet. Care should be taken to avoid over screwing of the helix (which often rotates back upon itself).

One important caveat here is ensuring that lead has not taken a course through the chordae tendinea. The absence of looping of the lead body across the TV will indicate this. In such a situation, lead will not fall to the mid or lower part of the annulus and stay in the mid to upper part of the annulus. If this is suspected, the lead-stylet assembly is pulled back to the right atrium and then reintroduced.

PLACEMENT OF RIGHT ATRIAL LEAD

There are passive and active fixation right atrial leads. Right atrial leads can be preformed with a J curve, which straightens on inserting stylet, and non-preformed leads. Atrial leads, which are non-preshaped and fixed using active fixation, are most often used in our practice.

These leads have the advantage of customizability using stylets and can be fixed anywhere in the right atrium if desired. The most common indications for placement of a right atrial lead in a non-appendage location are the inability to position in the appendage, suboptimal threshold in the appendage, and in post-cardiac surgery cases where the right atrial appendage is amputated or sutured.

Atrial lead is introduced into the vascular system, like ventricular lead (Fig. 11). Lead is taken to the middle of the right atrium, and a J-shaped stylet is introduced so that lead takes the shape of J. Then, by the slow pushing movement, the lead tip falls into the mouth of the right atrial appendage (RAA). Once the stylet is entirely in, gentle pushing of the lead-stylet assembly usually engages the RAA. This can be confirmed also by prolapsing and reinserting the tip. If this manoeuvre is not successful, pushing the entire system down in the RAO view and then gently withdrawing the whole assembly to mid-RA may help lead to engaging the RAA. If still unsuccessful, anticlockwise rotation of lead and stylet while the entire system is being pulled up can help. A classical to-and-fro (windshield) movement is seen when the lead is abutting the right atrial appendage. A slight pull on the stylet will cause prolapse of the tip of lead into RAA. Sometimes the lead bends while doing this manoeuvre, which requires further advancement of stylet instead of withdrawing. Once an optimal location is achieved, lead can be screwed and fixed. A good current of injury with a reasonable threshold is a good indicator of a good lead placement.

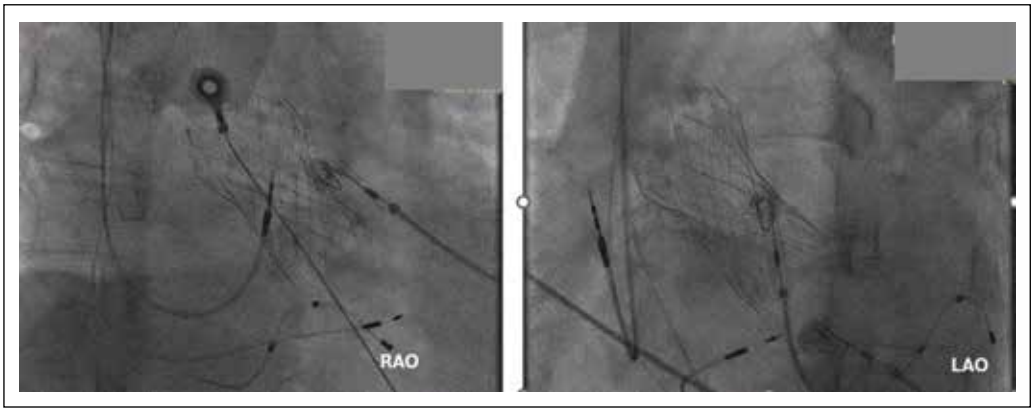


Figure 11: Atrial lead placement in a patient post transcatheter aortic valve implantation. Note the relationship of the right atrial appendage with the aortic root. The lead is positioned anteriorly in the right atrial appendage in LAO view.

Lead can also be fixed in other places on the right atrium if an optimal location near the appendage cannot be obtained. While screwing the lead, stylet should be in. While fixing near annular location, care should be taken to avoid inappropriate sensing of ventricular electrogram in atrial lead. The lead position should be checked in RAO, AP, and LAO views. The lead will be anterior in both RAO and LAO views in an optimally positioned right atrial lead. Atrial J stylet should be removed cautiously and exchanged for the straight stylet. Lead parameters can be checked and then sutured.

ASSESSMENT OF LEAD PARAMETERS

Testing cables are connected using alligator clips to assess the lead parameters. Usually, bipolar characteristics are first evaluated. A black alligator clip is connected to the tip electrode, and a red clip is connected to the proximal electrode. To test in a unipolar fashion, a red alligator clip is attached to tissue by connecting to the retractor and black to tip or ring electrode. Initially, sensing with the current of injury is checked. A complete absence of the current of injury signals the suboptimal lead location.

Sensing parameters: Sensing is measured in millivolts. A P wave of more than one mV and an R wave of more than five mV are generally considered acceptable. In patients with atrial fibrillation, chaotic atrial electrical activity can be noted.

Pacing threshold: This is the minimum energy needed to capture the myocardial tissue electrically upon pacing. A threshold of 1 volt at 0.4 ms pulse width is ideal for both atrial and ventricles. A threshold of less than 2 volts at 0.4 ms pulse width is deemed acceptable to both atrial and ventricles. In the presence of a good current of injury, a threshold of around 2 Volts is often noted to come down to less than 1 volts within 20 minutes. High output pacing is performed in non-septal locations to identify an inadvertent diaphragmatic capture.

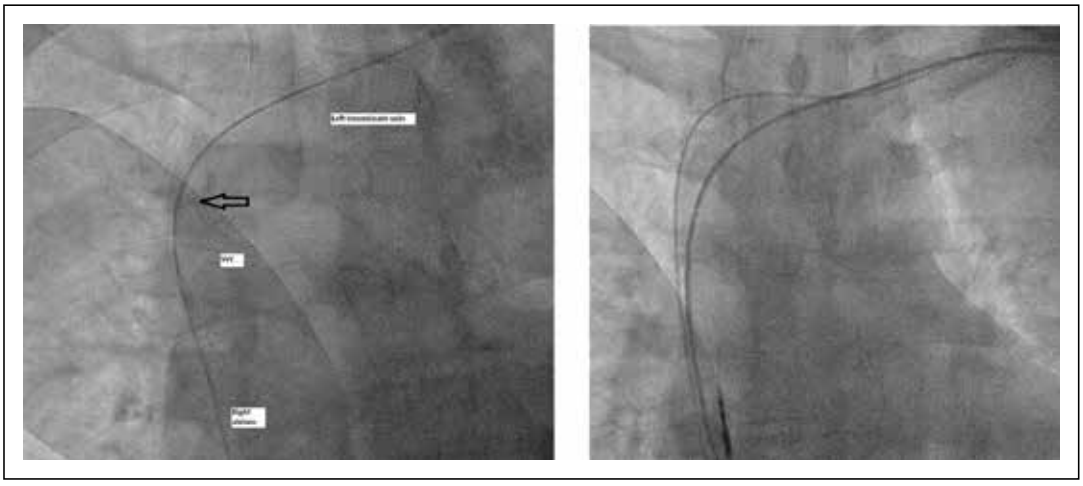
Lead impedance: An impedance ranging from 300 to 1300 is considered normal. A low impedance signals insulation break. Lead fracture (which is very rare at implant) and a loose screw at the proximal connector are common causes for a high impedance situation.

MAINTAINING AN ADEQUATE LOOP

Once an acceptable position is achieved for the lead, the sheath is peeled away, avoiding excess lead movement and maintaining an adequate loop. The best way to make a loop is to push the lead while withdrawing the stylet carefully after then screwing. We prefer to keep a loop sufficient to form almost ninety degrees upon the RA- RV axis and lead resting comfortably without excessive movement at the tricuspid valve level. Atrial lead looping should be just adequate. An inadequate or excessive loop can increase the chances of dislodgement. An ideal atrial loop is usually "open U" shaped, while an excessive loop will be large closed U-shaped, often dipping to IVC or prolapsing into RV (Figures 12 & 13). Adequate care should be taken to keep an extra loop in the paediatric population. In the elderly, adequate loops to account for tortuosity at the innominate vein and RA SVC junction should be considered.

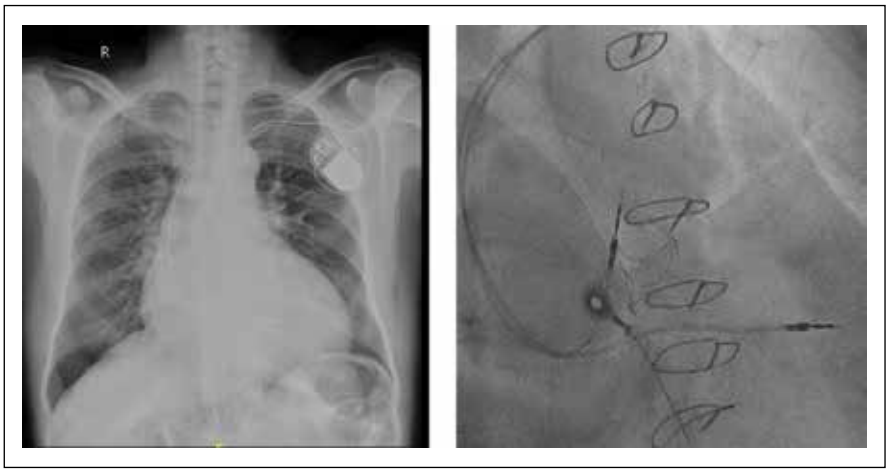
LEAD SUTURING

Fixing the lead is a very crucial step for preventing lead displacements. Leads should be anchored to the



12A **12B**

Figure 12: **12A** In older adults, adequate loops should be considered to account for tortuosity at the innominate vein and RA SVC junction. The arrow mark shows the direction of lead convexity at the RA-SVC junction, which is rightwards, and adequate allowance for tortuosity should be given. Otherwise, once the patient moves upright, the loop inside the heart will reduce. Image **12B** shows the pulling of ventricular lead at the RA SVC junction on day 2.



13A 13B

Figure 13: **13A** An example of an inadequate RV lead loop. **13B** An example of an excessive RA lead loop (see text). This loop was intermittently prolapsing to TV and IVC.

pectoral muscles using non-absorbable sutures. A straight stylet should be inserted to half the length of the lead to strengthen it and prevent a lead fracture. Initially, sutures are put on the grooves of the lead sleeve to tighten it to the lead. If this suture is improper, lead may move within the sleeve. Subsequently, this suture is anchored to nearby muscles, fixing it to the floor. After fixing, a slight tug on the lead is done to check the adequacy of lead suturing. If there is any laxity, additional sutures are put in. At this stage, lead parameters should be rechecked. If the impedance is very high, it is often indicative of an improper circuit than an actual lead fracture. Changing the testing cable or wetting crocodile clips (A-shaped clips) connection frequently reveals normal parameters.

A good current of injury persisting at this point is a favourable sign of good lead positioning, though it is not mandatory. The pacing threshold often improves by this time, even if it was higher initially with a good current of injury. It is an excellent habit to recheck the screws in fluoroscopy for any helix retraction before connecting to the header. Lead helix retraction is fortunately rare.

Connecting lead to the pulse generator and pocket closure

Lead tips are wiped and dried with sponges or cotton. Leads are then connected to the header of the pulse generator individually according to the label provided. Lead serial numbers are reconfirmed, and the tip is pushed under vision beyond the ring in the header. Some companies offer a blue dot at the lead tip to improve visibility. It is critical to avoid over screwing. The pocket may be then irrigated with antibiotics if required.

The leads are coiled and pushed deep and down into the pocket for minimal tension or torsion. The pulse generator is kept inside, taking care to keep leads beneath. The pulse generator is then secured using a stay suture, which should not be over-tightened or very lax to prevent migration of the pulse generator.

Before pocket closure, a fluoroscopy of the pocket (Fig. 14) is usually carried out to ensure the proper location of the pin at the header and to avoid any abrupt angles in the loop (which may predispose to fracture) or any foreign objects in the pocket. A final gauze count check by the scrub nurse is essential.

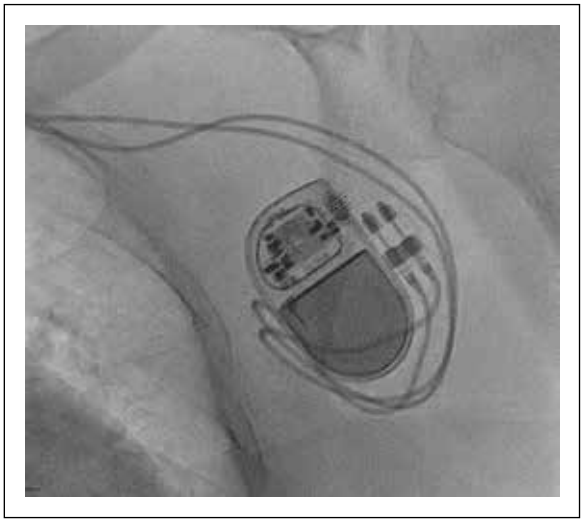


Figure 14: Postoperative fluoroscopy should be used to check the lead loops and depth of the lead connector pin within the header. Errors at lead connection can lead to loss of pacing or high impedance post-procedure. Identification of the problem while the pocket is open can solve the issue quickly.

Figure 15: Use of an antibiotic eluting pouch in a high-risk case. This absorbable envelope made of tyrosine polyacrylate mesh contains 7.6 mg minocycline and 11.9 mg rifampin in a 7.4 cm x 8.5 cm sterilised envelope.

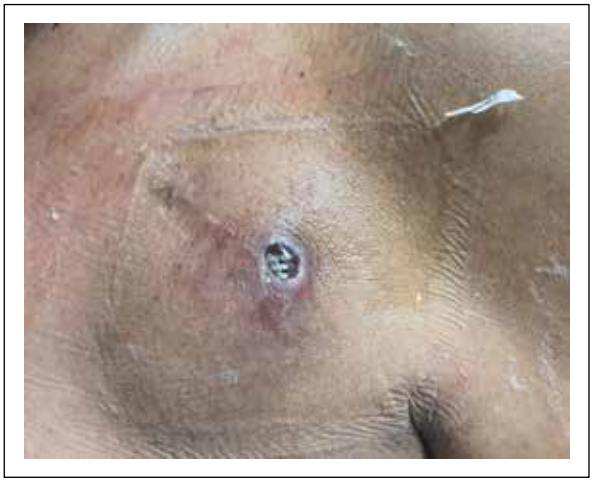
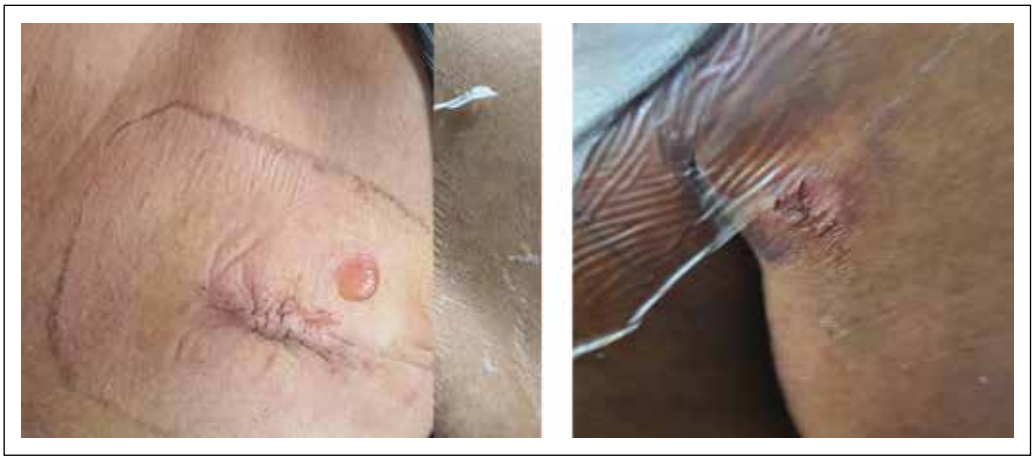


Figure 16: A case of pressure necrosis due to the corner of the pulse generator with secondary infection. Modern pulse generators are often given a customised contour design, so pressure points usually occur only at the corners of the pulse generators(header) of a tight pocket rather than the lower edges. Corners of pulse generators should be secured and isolated without forming pressure points using deep tissue bites and interrupted sutures.

An envelope impregnated with antibiotics, rifampin and minocycline (antibiotic-eluting envelopes) is used to prevent infection in some centres in high-risk patients. (Fig. 15). This resorbable antibacterial pouch prevents the biofilm of pathogens like staphylococcus. This has been shown to provide sustained local delivery of antibiotics at the generator pocket site and appears beneficial in reducing CIED pocket infections.[11]

The wound is often closed in three to four layers. Initial interrupted sutures will isolate the pocket from the rest of the wound. Corners of pulse generators should be secured and isolated without forming pressure points using deeper bites and interrupted sutures.Pressure necrosis and secondary infection can occur (Fig. 16) with an inadequate pocket. Patients with thin chest wall are at an increased risk of this complication.

Subsequently, two layers of continuous sutures with absorbable sutures are put in. Finally, one subcuticular layer of suture is done. An Aberdeen Knot can secure the end of the suture line if the operator is well-versed in the technique. The sterile transparent dressing is applied. Rarely do patients develop allergic reactions to adhesive dressing, which resolve upon change to a different dressing or being kept open. (Fig. 17)



17A **17B**

Figure 17: **17A-** Patient developed a fluid-filled bleb in response to an adhesive dressing, which promptly responded to the removal of the dressing; **17B-** Another patient developed erosion and allergy to the adhesive dressing.

POST-PROCEDURE CARE

The patient is observed and monitored in an ICU for a few hours for the development of a hematoma. An ECG is obtained with and without the use of a magnet. Antibiotics and analgesics are continued.

A postoperative radiograph is obtained to check for any pneumothorax (Fig. 18) (Table 2). In large pneumothorax, often the last cine of fluoroscopy can show evidence of air in the pleura. The device is usually interrogated on postoperative day 1 and then prior to discharge. Any planned pacing rates are set, or hysteresis settings are reviewed. A bedside echocardiogram is carried out to rule out any effusion.

Postoperatively, intravenous antibiotics are continued for 24 hours, and the patient is discharged to home on 2nd or third postoperative day. Usually, more dressings are not required; wound inspection can be done after eight days, and then the wound is kept open. After that, the patient can be reviewed in the pacemaker clinic after a month and then yearly (Fig. 19).

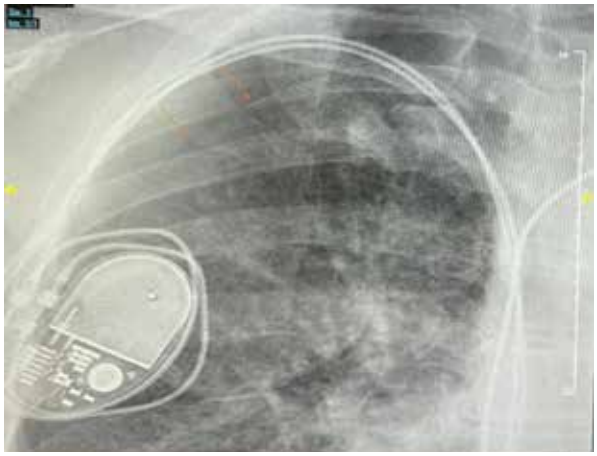


Figure 18: A case of pneumothorax following the upgrade of a pacemaker. Arrow marks highlight the collapsed lung plaeural space interface.

Table 2: Checklist for a post-procedure Xray after CIED implantation

Checklist for a post-procedure Xray after CIED implantation
• Check the lead position for any displacement
• Observe the lead loop length
• Check for any helix retraction
• Look for a pneumothorax or an effusion on both sides; if there is any suspicion, a follow-up chest X-ray is warranted.
• Observe the pocket site for any migration of PG or a loose or inadequate screw, or any foreign object
• Observe for any subcutaneous emphysema

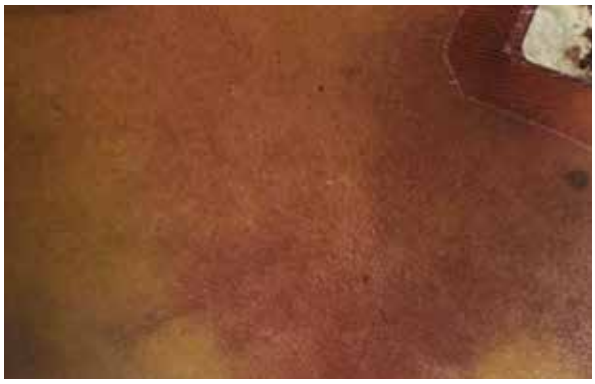


Figure 19: Late onset pocket hematoma and chest wall redness in a case of coagulopathy secondary to hepatic failure in a patient who underwent a pacemaker for symptomatic AV block. Image courtesy of Dr Harsh Kumar Pandey.

SPECIAL CONSIDERATIONS IN CHILDREN

The device should be chosen with the smallest available size in children undergoing pacemaker implantation, and an appropriate implantation method should be considered. An epicardial pacemaker may be ideal for children of small body weight (less than 10 kg). In high-risk cases, device upgrades, and children, it will be imperative to use an up-front micropuncture needle, which can be exchanged later for a conventional guidewire. The use of a micropuncture needle upfront can avoid complications and early venous spasm (Fig. 20). A sufficient loop of the device should be kept to account for the future growth of the heart around the lead.

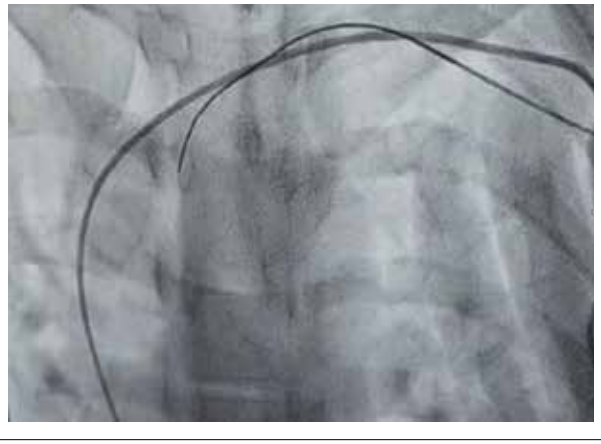
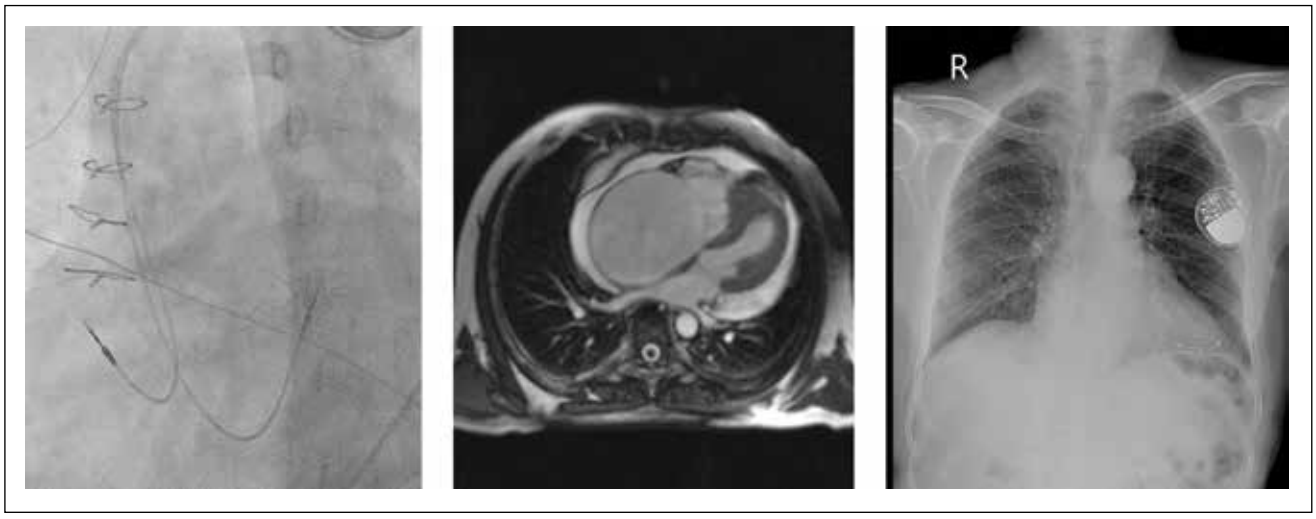


Figure 20: The use of a micropuncture needle with guidewire while upgrading a single chamber pacemaker with limited venous access and collateral formation to a dual chamber pacemaker.



21A 21B 21C

Figure 21: **21A-** In the case of endomyocardial fibrosis, an active fixation lead is placed in the outflow tract septum. Active fixation lead is required for stability at this location, especially in the presence of TR. **21B-** Cardiac magnetic resonance apical 4-chamber image showing endomyocardial fibrosis with dilatation of the right atrium. **21C-** Placement of a lead in the coronary sinus for pacing using an LV active fixation lead in a patient with endomyocardial fibrosis.

In very small patients, the sheath-dilator assembly can reach directly to the right atrium and is carefully manipulated to avoid abutting the atrial wall and resultant injury. Adequate care should be taken in the manipulation of leads with the stylet not fully in considering the thin septum and cardiac walls, especially in very young patients, to avoid perforation.

SPECIAL CONSIDERATIONS IN STRUCTURAL HEART DISEASE

A good transthoracic echocardiogram and a chest X-ray are mandatory before any permanent pacemaker implantation. Preprocedural planning is mandatory for structural heart disease. Severe tricuspid regurgitation can cause difficulty in positioning RV lead in cases of RHD and PAH. Awareness of the presence of dextrocardia helps in planning the position of the lead, and sometimes, an inverted view of fluoroscopy images may be required intra-procedurally. In the presence of endomyocardial fibrosis (EMF), the lead may have to be fixed to the outflow or upper septum or the basal inflow septum (Fig. 21). These locations may require active fixation leads for stability, especially in the presence of TR. Placement of a lead in the coronary sinus for pacing using an LV active fixation lead is another valuable approach for patients with endomyocardial fibrosis. In this approach, the endovascular lead not crossing the tricuspid valve gives an advantage of not worsening the pre-existing TR. Dilated CS tributaries make the procedure relatively easier in these cases.[12]

SUMMARY

Permanent pacemaker implantation is a procedure with a definite learning curve and a meticulous training and technique prevents fatal complications later. A summary of common problems encountered during implantation and their troubleshooting is described below (Table 3).

Table 3: Summary of common problems encountered in pacemaker implantation and troubleshooting

Sl. no.	Problem	Prevention/Solution
1	Difficulty in obtaining venous access	• Adequate hydration prior
		• Good venogram - AP or AP caudal views • Avoiding an arterial puncture • Best try is often the first one. • Puncture during a contrast injection. • In obese making a pocket prior helps get venous access easier • Putting a tracking guidewire through femoral access into the left subclavian
2	Higher risk for pneumothorax	• The above steps to improve the chance of venous access can be tried, ***plus*** • Use a micro-puncture needle • Use of ultrasound-guided access • Use AP caudal view to separate extra thoracic subclavian/axillary vein from rib cage • Use a cephalic vein approach
Sl. no.	**Problem**	**Prevention/Solution**
3	Renal dysfunction/contrast allergy	• Direct access without contrast using bony landmarks • Railroading using a guidewire put from the femoral or ipsilateral arm • Use of ultrasound-guided access • Using renal safer contrast agents in minimal amounts
4	Recurrent arterial puncture	• Use a contrast railroad through the vein for puncture. • Give compression each time during inadvertent arterial puncture. This prevents a large hematoma from compressing the vein, precluding further access. • Use a different needle path next time if an arterial stick occurs
5	Excess back bleed through the sheath.	Avoid oversizing the sheath for the pacing lead and completely peel away the sheath immediately once a good lead position is achieved.
6	Difficulty in advancing guidewire to heart	This can be expected from a venogram with frequent valves in veins or a tortuous course. Manipulating the guidewire or exchange using a dilator or glide wire often solves the problem.
7	Guidewire moving to the left of the spine from subclavian	Avoid putting a sheath; reconfirm and remove the wire. Mainly, this occurs with an arterial entry and wire dipping towards the aorta.
8	Difficulty in advancing the pacing lead at the left innominate SVC junction.	Pull back the whole system, then pull back the peel-away sheath to the subclavian withdrawal stylet and push forward. The lead tip will drop down to SVC.
9	Difficulty in advancing the pacing lead due to vessel tortuosity	Deep cannulation of the sheath using a dilator and guidewire. By doing so, lead often directly enters SVC from the sheath.

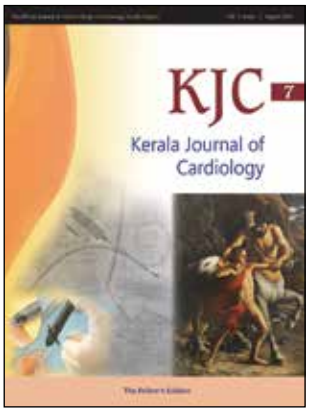
10	Air embolism	• Pinching of the introducer sheath while guidewire-dilator assembly removal and lead exchange prevent inadvertent air entry. • Immediate high-flow oxygen to be administered and call for anaesthesia support to keep the patient monitored
11	Difficulty in crossing TV	• Exclude tricuspid valve disease • Exclude an open helix at the tip, which can catch on soft tissue. • Use various manoeuvres described above (see text on RV lead)
12	Difficulty in reaching RV apex after multiple attempts	Suspect EMF! In these cases, the lead may be required to be placed in the outflow septum or CS.[12] A dedicated stylet curve for the apex also can be helpful.
13	A wrong connection of lead at the header	• This scenario can be prevented by doublechecking the lead labels-length, serial numbers and label of ports and on the pulse generator. • Keeping the leads sewn to the muscle bed in order as atrium above, RV followed by LV and using the same order to connect leads is a practical approach to avoid confusion and mismatch
14	Unable to push the connector pin completely	• Ensure that the pin is being pushed into the correct port in the header. (a quadripolar LV lead to an RV port may be incompatible). • Unscrew the pin at the header and re-attempt. Sometimes new generators come with a screw tightened.
15	Reduction of initial lead loop after pocket closure	Ensure that leads are not pulled while coiling redundant leads into the PG pocket. An adequate pocket prevents this complication. An adequate allowance for tortuous veins should be given to older adults.

ACKNOWLEDGEMENTS

Author thanks his mentor, Prof.Narayanan Namboodiri KK for the motivation and help received while preparing the article.

SELECTED REFERENCES

1. Glikson M, Nielsen JC, Kronborg MB, Michowitz Y, Auricchio A, Barbash IM, et al. 2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy: Developed by the Task Force on cardiac pacing and cardiac resynchronization therapy of the European Society of Cardiology (ESC) With the special contribution of the European Heart Rhythm Association (EHRA). European Heart Journal. 2021;42(35):3427-520.
2. Kusumoto FM, Schoenfeld MH, Barrett C, Edgerton JR, Ellenbogen KA, Gold MR, et al. 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients With Bradycardia and Cardiac Conduction Delay: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2019;140(8):e382-e482.
3. Rajappan K. Permanent pacemaker implantation technique: part I: arrhythmias. Heart. 2009;95(3):259-64.
4. Cooley DA. In memoriam. Tribute to Ake Senning, pioneering cardiovascular surgeon. Tex Heart Inst J. 2000;27(3):234-5.
5. Littleford PO, Spector SD. Device for the rapid insertion of a permanent endocardial pacing electrode through the subclavian vein: preliminary report. Ann Thorac Surg. 1979;27(3):265-9.
6. Birnie DH, Healey JS, Wells GA, Verma A, Tang AS, Krahn AD, et al. Pacemaker or Defibrillator Surgery without Interruption of Anticoagulation. New England Journal of Medicine. 2013;368(22):2084-93.
7. Magney JE, Staplin DH, Flynn DM, Hunter DW. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. Pacing Clin Electrophysiol. 1993;16(11):2133-42.
8. Byrd CL. Clinical experience with the extrathoracic introducer insertion technique. Pacing Clin Electrophysiol. 1993;16(9):1781-4.
9. Ong LS, Barold SS, Lederman M, Falkoff MD, Heinle RA. Cephalic vein guide wire technique for implantation of permanent pacemakers. Am Heart J. 1987;114(4 Pt 1):753-6.
10. al Ee. Clinical Cardiac Pacing, Defibrillation and Resynchronization Therapy. 5th ed. Ellenbogen, editor2016.
11. Xiang K, Catanzaro JN, Elayi C, Esquer Garrigos Z, Sohail MR. Antibiotic-Eluting Envelopes to Prevent Cardiac-Implantable Electronic Device Infection: Past, Present, and Future. Cureus. 2021;13(2):e13088.
12. Sundaram C, Kartik S V, Namboodiri N, Ajitkumar VK. A Novel pacing option in patients with endomyocardial fibrosis: A case series. Indian Pacing and Electrophysiology Journal. 2021;21(5):303-7.



Left Bundle Branch Pacing - How do I do it?

Shunmuga Sundaram Ponnusamy
Associate Professor,
Department of Cardiology, Velammal Medical College,
Madurai, Tamil Nadu.

INTRODUCTION

For decades, right ventricle (RV) is the preferred site for pacing in patients with symptomatic bradyarrhythmia. However, chronic RV pacing has been shown to be associated with dyssynchronous activation of the ventricular myocardium resulting in left ventricular (LV) dilatation and dysfunction.[1,2] Pacing induced cardiomyopathy (PIC) is defined as LV ejection fraction (LVEF) of <50% or absolute decline of LVEF by ≥10% and/or new onset heart failure symptoms after pacemaker implantation.[3] Conduction system pacing has gained significant momentum in the recent years to overcome the limitations of chronic RV pacing. Direct capture of His bundle (HB) or left bundle branch (LBB) results in synchronized activation of the left ventricle providing the electrical and mechanical synchrony.[4,5] Deshmukh et al,[6] first demonstrated the feasibility of permanent His bundle pacing (HBP) in patients with atrial fibrillation and heart failure. However, HBP was associated with high implantation threshold, lead dislodgements, premature battery depletion and inability to correct distal conduction system disease. Huang et al,[7] suggested left bundle branch pacing (LBBP) as an alternative modality to overcome the limitations of HBP

ANATOMY OF CONDUCTION SYSTEM

Sinus node at the superior vena cava-right atrial junction generates electrical impulse of the heart which spreads through three inter-nodal pathways to reach the atrio-ventricular (AV) node. The AV node continues as His bundle (HB) which has two components – the penetrating and branching portion.[8] The penetrating portion of HB arises from the anterior end of the AV node and penetrates the central fibrous body of the heart where the fibers of LBB emerge at the level of non-coronary cusp. The branching portion of HB includes the segment below the origin of posterior most fibers of LBB (posterior fascicle) to the point where HB continues as right bundle branch (RBB) after giving rise to anterior fibers of LBB. The LBB fibers runs inferiorly and anteriorly as broad fan of fibers before dividing into posterior and anterior fascicles that course towards the corresponding papillary muscles.[9]

LEFT BUNDLE BRANCH PACING

LBBP is defined as direct capture of proximal left bundle, anterior fascicle or posterior fascicle along with septal myocardium[10] while LBB area pacing (LBBAP)

Abbreviations: LBBP - left bundle branch pacing; LVSP - left ventricular septal pacing; CRT - Cardiac resynchronization therapy; LLL - lumenless lead; SDL - stylet driven lead; RWPT - R wave peak time; LBBB - left bundle branch block; CMR - cardiac magnetic resonance; LGE - late gadolinium enhancement.

Keywords: Left bundle branch pacing, cardiac resynchronization therapy, septal perforation, heart failure, left bundle branch block

Address for correspondence: Dr Shunmuga Sundaram Ponnusamy, Associate Professor, Department of Cardiology, Velammal Medical College Hospital and Research Institute, Madurai, Tamil Nadu, India - 625009, Email: shunmuga.pgi@gmail.com

includes LBBP and LV septal pacing.[11] The procedure involves deploying the lead deep inside the proximal interventricular septum to capture the broad fan of left bundle fibers.

IMPLANTATION TECHNIQUE

Huang et al,[7] first reported the technique of LBBP in a patient with left bundle branch block (LBBB) as an alternative to overcome the limitations of HBP. Preprocedural echocardiography should be performed to assess the ventricular function, interventricular septal thickness, presence of scar, and valvular regurgitation. Cardiac magnetic resonance (CMR) imaging is an optional imaging modality in cardiomyopathy patients to delineate the extent of the septal scar which is a major determinant of procedural success. As the technique involves placing the lead in the proximal interventricular septum, a delivery catheter is necessary to deploy the lead. The delivery catheters most commonly used are pre-shaped with fixed curvatures (primary curve to enter into the RV and a secondary curve that direct towards the septum) (table-1) though deflectable catheters are also available. The lead most commonly used for LBBP is the lumen-less lead [LLL] with plenty of clinical evidence though conventional stylet driven leads (SDL) are also tried with almost similar results. The 3830 lumen-less bipolar lead (SelectsecureTM, Medtronic Inc, Minneapolis) is 4.1F sized with an inner-cable design and excellent tensile strength.[12] The lead has silicone inner insulation, polyurethane outer insulation, MP35N nickel alloy conductors with 2 electrodes at the lead tip made of titanium nitride coated platinum alloy. The length of the electrically active helix (cathode) is 1.8mm length with inter-electrode distance of 9mm.

Table 1: Delivery catheters and leads for left bundle branch pacing

Delivery Catheters	Pacing leads
Fixed Curve	**Lumenless lead**
C315 His (Medtronic)	3830 Selectsecure
Locator 3D (Abbott)	
Selectra 3D (Biotronik)	
SSP (Boston Scientific)	
Deflectable	**Stylet driven leads**
C304 Selectsite (Medtronic)	Tendril (Abbott)
Agilis HisPro (Abbott)	Ultipace (Abbott)
	Solio S (Biotronik)
	Ingevity (Boston Scientific)
	Fineline II Steriod EZ (Boston Scientific)

Continuous recording of 12-lead electrocardiography during implantation is necessary for the procedure. Intracardiac electrograms can be recorded with the help of an electrophysiology system or pacing system analyzer (PSA). Pacing lead electrograms will be generated by connecting it to the electrophysiology system in unipolar configuration with high- and low-pass filter settings of 0.5 and 500 Hz respectively, to obtain unfiltered electrogram for monitoring the current of injury (COI) while filtered unipolar electrograms are obtained with high-and low-pass filter settings of 30 and 300 Hz respectively to record the LBB potential.[13] A quadripolar catheter can be placed across his bundle (HB) to continuously record the potential throughout the procedure (figure-1). Alternatively, the pacing lead can be used to delineate the extent of the HB. The target site for lead deployment is identified by pacing the right side of the interventricular septum 1-1.5cm distal to the HB towards the RV apex to obtain a paced QRS morphology notched QS ('W' pattern) in lead-V1 along with discordant QRS complexes in lead-aVR and aVL (figure-1). A predominantly positive paced QRS in lead-II predicts capture of the proximal left bundle as opposed to a negative QRS which predicts posterior fascicular capture. Though classically described, 'W' pattern is not mandatory as it may not be seen in 20% of the patients. The delivery catheter should be held firmly with counter-clockwise torque, with the hub of the sheath pointing towards 4 O' clock to 5 O' clock position to orient it perpendicular to the septum. Fluoroscopically tip of the lead should be perpendicular to the septum in LAO 25^0-30^0, ie. lead tip usually looks towards 3 O' clock position in this view. Both the lead and gloves should be dry (free of blood, fluid or contrast) for achieving effective rotations to deploy the lead. After identifying the target site on the right side of the septum, the lead is deployed by one of the two techniques:

1. Conventional approach – gradual deployment by interrupted rotations with continuous monitoring of the paced QRS morphology and unipolar pacing impedance
2. Premature ventricular complex (PVC) guided approach[14,15,16] - rapid deployment with continuous monitoring of the PVC morphology

In the conventional approach, the pacing lead is deployed gradually by interrupted rotations with monitoring of three important parameters: paced QRS morphology (notch on the nadir of QS in lead-V1 ascends up to form R-wave), unipolar pacing impedance (gradually increase before it drops by 100-200 ohms as the lead reaches the LV sub-endocardium) and current of injury (COI) on the lead electrogram (figure-1). In the PVC guided approach, the lead is deployed by rapid rotations. The movement of the lead can be appreciated in left anterior oblique

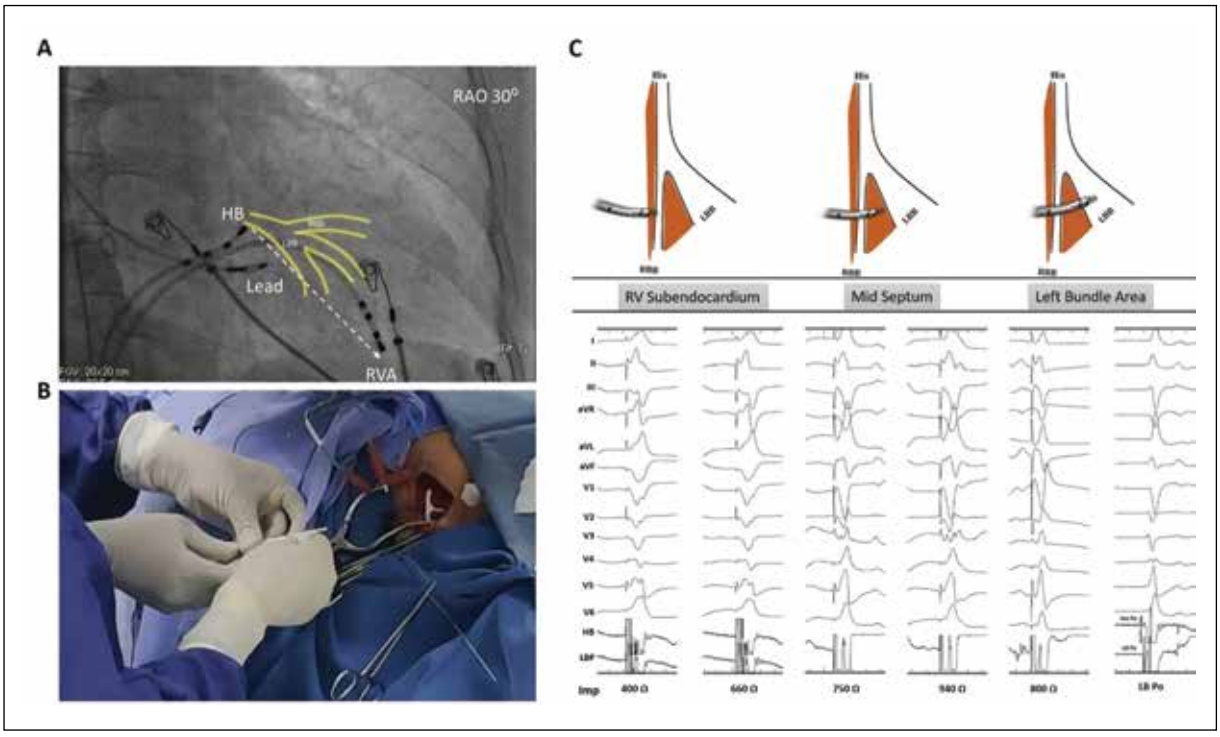


Figure 1: Left bundle branch pacing. A – Fluoroscopy in right anterior oblique view showing the target zone. The sheath is positioned 1-1.5 cm below His bundle along an imaginary line connection distal his signal towards the right ventricular apex. B – The lead is deployed by giving rotations with both the hands and the sheath is counter-clockwise torqued with the hub of sheath pointing towards 4 O' clock position. C – As the lead is deployed the notch on the nadir of the QRS in lead V1 gradually ascends to form the R-wave along with reduction in QRS duration. Note the gradual rise in unipolar pacing impedance before it falls by 100-150 ohms as the lead reaches the LV sub-endocardium

(LAO) fluoroscopy view. Rapid penetration results in generation of PVCs the morphology of which changes from wide QS morphology to narrow qR/rSR in lead-V1 as the lead traverses from right to left side of the septum (figure-2). Template/fixation beat[15,16] is defined as a PVC with RBBD pattern and a QRS duration of <130ms. Rotations should be stopped immediately on observing a template beat. It predicts LBB area capture

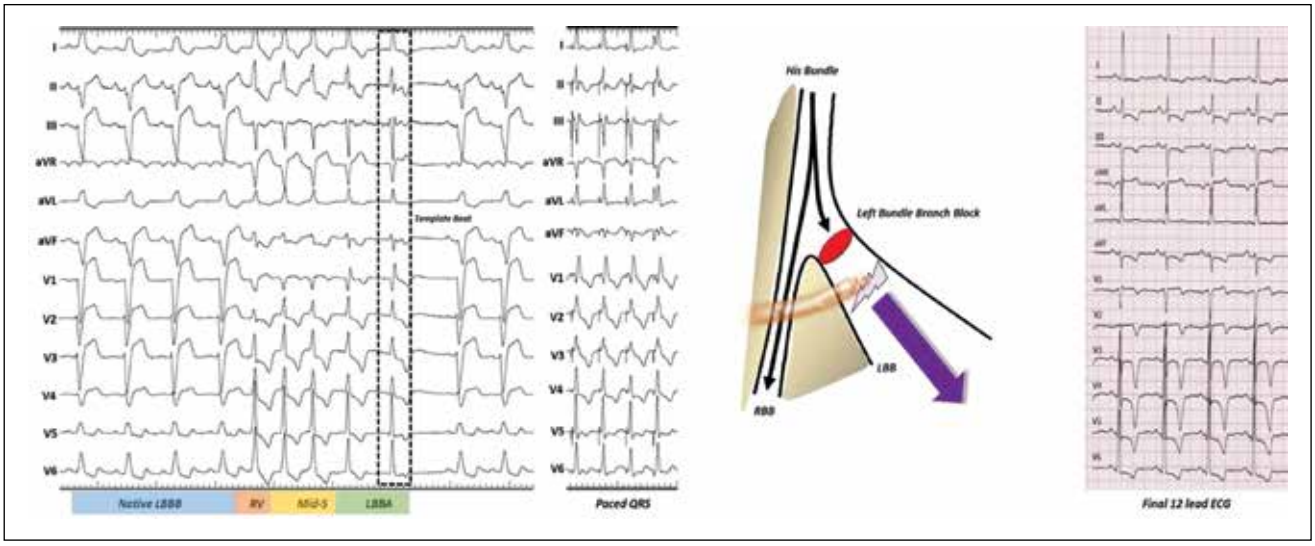


Figure 2 – Premature ventricular complex (PVC) guided LBBP. A – PVCs are generated during rapid rotations as the lead traverses from right to left side of the septum. Note the change in PVC morphology from QS to qR in lead. A PVC with qR/rSR' pattern is called as 'Template beat'. B – Paced QRS morphology mimics the template beat. C – In a patient with LBBB, LBBP results in complete correction of QRS morphology. D – Post LBBP paced ECG with AV delay optimization showing tiny R in lead-V1 and T-wave memory

with specificity of 97.3% and sensitivity of 96.4%.[16] It is observed in 90.5% of patients with lumen-less pacing lead.[17] Template beat guided LBBP predicts minimal myocardial injury, less fluoroscopic time and avoids septal perforation during lead deployment. M-beat,[17] a subset of template beat with M-pattern (rsR') in lead-V1, slurred S-wave in lead-V6 and rounded terminal R/R' component in lead-aVR has a sensitivity of 96.7% and specificity of 58.6% for predicting selective capture of LBB.

Stylet driven leads (SDL) requires pre-deployment of helix before septal positioning. Stylet may provide additional stiffness for SDL facilitating easy penetration. Continuous pacing during deployment is feasible with SDL while it may require additional revolving connector pin for lumen-less lead. The distal end of the SDL is non-isodiametric as compared to the iso-diametric distal tip of the lumen-less lead. Extended helix can spontaneously retract back during lead deployment. Helix locking tools (Abbott, Plymouth) are available which can be used to extend the helix before deployment and to lock it during deployment thereby preventing the retraction.

LBB Capture Confirmation Criteria

Confirmation of conduction system pacing is essential to provide synchronized activation of the ventricle and to avoid pacing related complications. Criteria for confirming the LBB capture has been proposed18 but not validated in any major trials. As left bundle branch fibers are pre-excited, right bundle branch delay (RBBD) pattern in the 12-lead electrocardiography is the hallmark of LBBP. However, it also seen in 23-44% of patients with LVSP. Hence, in addition to RBBD pattern, one or more of the following criteria has to be satisfied to confirm the capture of LBB

(a) Demonstration of LBB potential – In patients with sinus rhythm with normal LBB activation, a sharp high frequency potential can be recorded if the lead is deployed in LBB area though it does not prove direct LBB capture (figure-3). In patients with baseline LBBB morphology, potential may either be absent or concealed within the terminal part of the ventricular electrogram. His corrective pacing (figure-3) by either dual lead technique or by a temporary quadripolar catheter could unmask the potential by restoration of LBB activation. In a retrospective study by Su et al,[19] LBB potential could be demonstrated in 98.3% (115/117) of patients with sinus node dysfunction and symptomatic AV block (QRS duration <120ms). Based on the electrophysiological properties, LBB potential was classified into 2 types[20] (1) Type-A or manifest potential (64%) in which a high frequency potential was noted immediately after lead deployment (2) Type-B or concealed potential (36%) in which the potential was initially concealed within the slurred negative COI and resurged over the next few minutes gradually to form a sharp high frequency biphasic potential. Interestingly type-B potential was observed when the lead was deployed in the proximal left conduction system as evidenced by the longer PV duration. The appearance of type-B potential could be considered as an end point for giving further rotation as selective capture pattern was noted at near threshold value in all patients. Concealed (type-B) potential should be potential should be considered in patients with slurred negative LBB COI before giving additional rotations or repositioning the lead at a different site.

(b) Demonstration of abrupt decrease in stimulus to peak of R-wave duration ≥10ms with short and constant RWPT – The R-wave peak time, measured from the onset of the pacing artefact to the peak of R-wave in the lateral leads of the ECG (V5/V6) indicates the rapidity of the LV free wall activation. Continuous monitoring of the RWPT during implantation will show abrupt shortening of RWPT by ≥10ms during transition from LVSP to LBBP and it remains constant irrespective of the pacing output (figure-4).[21] The absolute value of RWPT below which LBB capture could be confirmed is still not

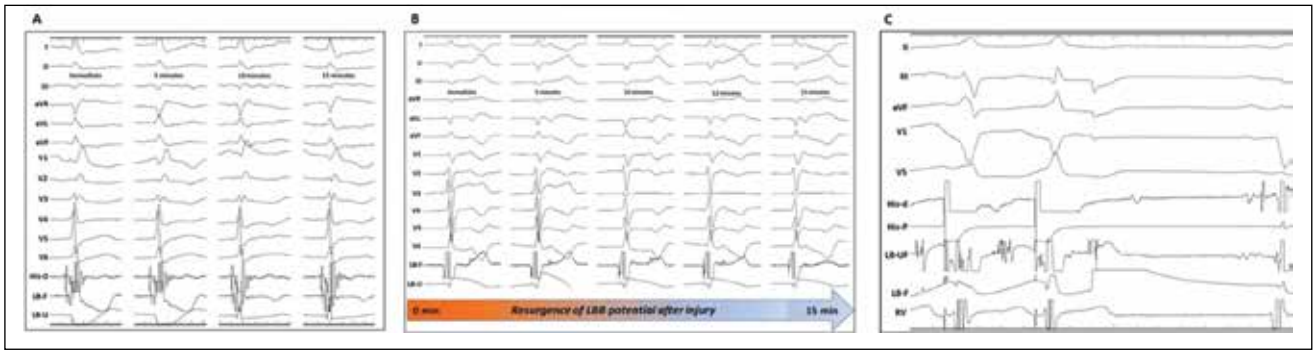


Figure 3: LBB potential during implantation. A – Type A (manifest) potential which will be seen immediately on deploying the lead. B – Type B (concealed) potential which will be concealed within the negative current of injury and resurges over the next few minutes. C – Unmasking of LBB potential by His corrective pacing in a patient with native LBBB

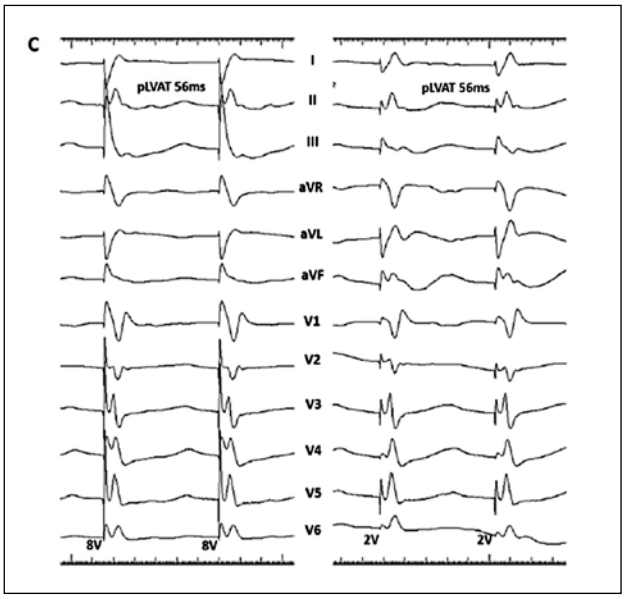


Figure 4: Short and constant R-wave peak time/peak left ventricular activation time at high and low output.

known. Huang et al[21] demonstrated RWPT of 75ms in patients with baseline non-LBBB morphology has sensitivity of 82% and specificity of 95% and for patients with baseline LBBB morphology RWPT of 85ms has sensitivity of 76% and specificity of 93% for confirming LBB capture.

(c) Output dependent change in QRS morphology – During capture threshold assessment, the gradual reduction in pacing output will show transition from non-selective to selective or non-selective to septal LBB capture. Non-selective capture of both LBB and septal myocardium is characterized by RBBD in 12-lead ECG, short and constant RWPT at high and low pacing output in lead-V6 and the lead electrogram showing pacing artefact and ventricular electrogram together without an iso-electric interval. Selective capture of LBB is characterized by change in QRS morphology from qR to rSR' in lead-V1, increase in amplitude of S-wave in lead-V6, rounded configuration of terminal R' wave in lead-aVR with the pacing lead showing distinct interval between ventricular electrogram and the pacing artefact (figure-5). During the transition from non-selective to selective at near-threshold pacing output, the RWPT remains constant. Non-selective to septal transition, characterized by reduction or loss of R-wave in lead-V1 along with sudden prolongation of RWPT by

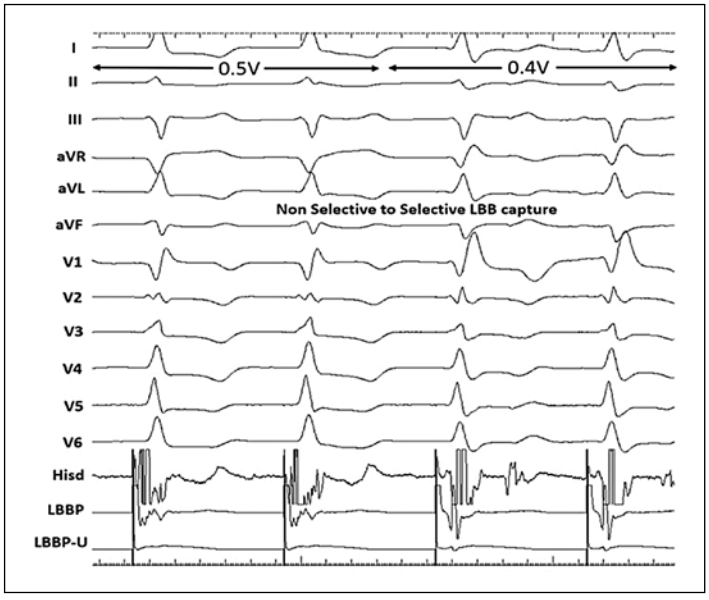


Figure 5: Non-selective to selective capture transition as the output is reduced from 0.5V to 0.4V. Note the change in QRS morphology along with distinct pacing lead electrogram separated from the pacing artefact.

>10ms as the pacing output is reduced gradually, occurs due to (1) higher LBB capture threshold as compared to myocardial threshold; (2) the location of pacing lead away from the LBB area with conduction system capture occurring only at high output. These two scenarios can be differentiated by pacing at high and low output, where the RWPT is constant in the former group while it prolongs by >10ms as the output is reduced in the latter group requiring few additional rotations to reach the target zone.

(d) Physiology based ECG criteria – Marek et al[22] proposed this criterion based on the concept that capture of LBB results in restoration of physiological activation of lateral wall of the left ventricle. As per these criteria in patients with non-LBBB morphology QRS onset to RWPT equals the RWPT during native rhythm and stimulus to RWPT equals the LBB potential to RWPT in lead-V6. Similarly in patients in baseline LBBB morphology stimulus to RWPT in lead-V6 will be less than the difference between intrinsicoid deflection time (IDT) and transeptal conduction time (TCT). The IDT is measured from the earliest onset of QRS in any lead to the beginning of the final rapid downslope in lead-V6 and TCT is measured from the onset of QRS to the beginning of the first notch in the lateral leads (lead-I/aVL)

(e) Demonstration of retrograde His bundle potential and anterograde left conduction system (LCS) potential – His bundle potential or LCS potential can be recorded during LBBP by placing a temporary quadripolar catheter in his bundle location or a multi-electrode catheter on the left side of the interventricular septum. Retrograde his potential can be demonstrated during LBBP in all patients with baseline non-LBBB morphology and in 18% of patients with LBBB morphology.

(f) V6-V1 interpeak interval[23] – The duration of intrinsicoid deflection in lead-V1 is a surrogate of RV activation delay and lead-V6 a surrogate of LV activation delay. The V6-V1 interpeak interval measures the relative delay in the activation of RV as compared to LV and can be used to differentiate LVSP from LBB capture. During non-selective to selective capture, RV activation is delayed to due to loss of septal myocardial capture and LV activation remains unchanged. On the contrary during non-selective to LVSP, LV activation is delayed due to loss of LBB capture and RV activation through the septal myocardium remains unchanged. Hence during LVSP, the time to intrinsicoid deflection in both lead-V1 and V6 is delayed due to delayed activation of LV and RV. The V6-V1 interpeak interval will be shortest during LVSP, intermediate during non-selective LBB capture and longest during selective LBB capture. A cut-off of >33ms has the sensitivity of 71.8% and specificity of 90% for differentiating non-selective capture from LVSP and a cut-off of >44ms has 100% specificity for confirming selective LBB capture.

(g) Programmed deep septal stimulation[24] – The conduction velocity and effective refractory period (ERP) of the septal myocardium and the LBB are different. Programmed stimulation through the LBBP lead in unipolar configuration results in three different responses (1) diagnostic response type-1 (myocardial) – seen in patients with conduction system ERP greater than septal myocardial ERP. As

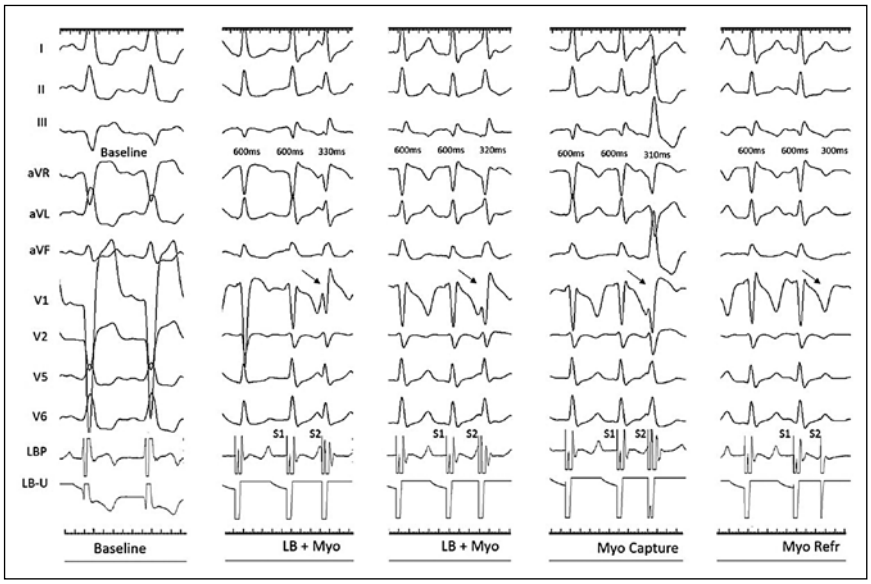


Figure 6: Programmed deep septal stimulation. At 310ms coupling interval, there was a change in QRS morphology with loss of R-wave in lead-V1 along with prolongation of QRS duration suggestive of loss of LBB capture.

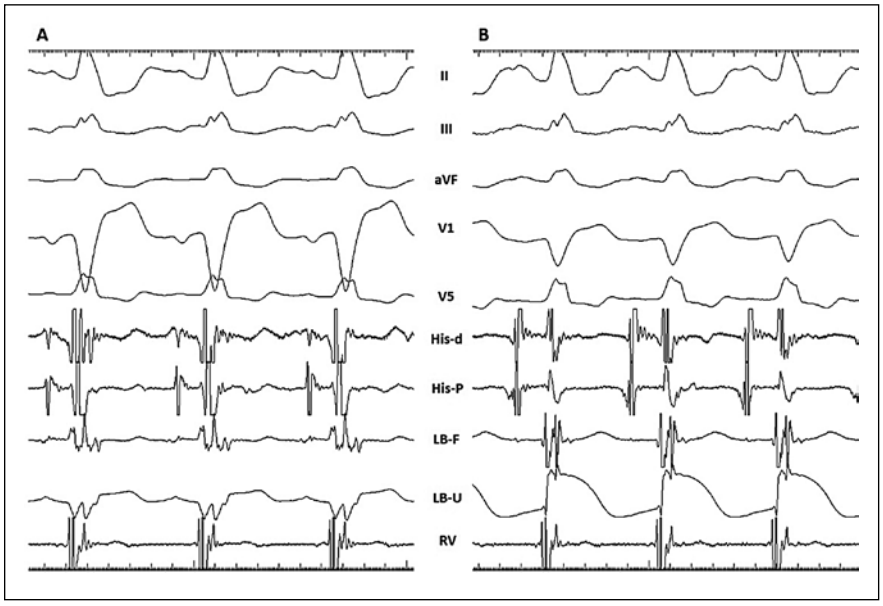


Figure 7: Septal perforation during implantation. A – Unfiltered unipolar electrogram (LB-U) showed QS morphology with no significant current of injury (COI) suggestive of septal perforation. B- Hence the lead was positioned at a different site with good COI and capture threshold.

the coupling interval is gradually reduced, there will be a change in QRS morphology and duration suggestive of LVSP due to loss of conduction system capture (figure-6); (2) diagnostic response type-2 (selective LBB) – with the gradual reduction in coupling interval, there will be a selective capture of LBB characterized by rSR' pattern in lead-V1, increase in amplitude of S-wave in lead-V6 along with an iso-electric interval between the pacing artefact and the onset of QRS complex. Selective capture is more often noticed when the extra-stimulus is delivered during intrinsic rhythm rather than after 8-beat basic drive. (3) non-diagnostic response – with gradual reduction in coupling interval, there will be a minor change in QRS morphology not suggestive of type-1 or type-2 pattern. This response can be seen if both LBB and myocardium has nearly similar ERP or if the pacing lead is away from the LBB area.

Septal perforation

The most important complication to recognize at the time of implantation is the septal perforation. The incidence of acute septal perforation during implantation varies between 3.2% to 14.1%13.[25,26] It should be recognized promptly and the lead should be repositioned at a different site to avoid long term thrombo-embolic complications. In a retrospective study Ponnusamy et al[13] identified septal perforation in 30 out of 212 patients (14.1%) who underwent successful LBBP. Sudden drop in current of injury (COI) and unipolar impedance of <450 ohms identified septal perforation. Unfiltered unipolar electrograms should be used rather than bipolar electrograms as the latter might give false re-assurance due to anodal COI. Two different patterns of unfiltered unipolar electrograms are noted during septal perforation (1) type-I (QS pattern) due to complete perforation of the lead into the LV cavity (figure-7) and (2) type-II (RS pattern) due to partial perforation of the lead tip into the cavity. Shali et al[27] showed the ratio of COI between the tip and the ring would indicate the depth of the lead inside the septum and a very low ratio would indicate micro-perforation of the pacing lead. Due to smaller size, the surface area of the septal perforation due to LLL will be less and close spontaneously without demonstrable shunt while SDL perforation may result in larger area predisposing for shunts and cameral fistulas.[28,29]

LEAD REPOSITIONING

The need for lead repositioning during implantation includes septal perforation, inability to penetrate deep inside the septum and inability to demonstrate LBB capture despite penetration. Frequent repositioning may result in excessive myocyte injury. In a retrospective study[30] which analyzed the troponin release in patients who underwent successful LBBP, the mean number of attempts for successful lead placement was 2.5±1.9. Significant elevation of troponin was noted in 49.4% of patients who underwent LBBP as compared to 69.1% of patients who underwent supra-ventricular tachycardia (SVT) ablation (p=0.02). Myocyte injury during LBBP using lumen-less leads were minimal and asymptomatic and no long-term adverse outcomes were noted. For repositioning the lead, a gentle counter-clockwise

rotation along with traction will be sufficient to retract the lead back from the septum. In a retrospective study[13] which studied the electrophysiological characteristics of septal perforation, all 30 patients who had septal perforation during implantation underwent successful repositioning after extraction without helix damage. During a mean follow-up of 9.9±6.7 months, the pacing parameters remained stable and echocardiography showed no residual ventricular septal defect, shunt or fistula. It is important to identify a different site to reposition the lead to avoid dislodgement by (a) fluoroscopic land-mark; (b) pace mapping on the right side of the septum to show different paced QRS complexes in inferior leads; (c) demonstrating template/fixation beats; (d) monitoring the movement of the lead in left anterior oblique fluoroscopic view. Similar paced QRS complexes, absent template beat and hyper-transmission of the rotations to the lead tip usually indicates same entry site and should be avoided.

Septal Behavior during implantation

Septal scar is considered as the major limiting factor for successful LBBP. The lead may not penetrate the septum in some patients even without structural heart disease. In a cadaver model, Jastrzebski et al,[31] demonstrated 4 different lead behaviors during deployment based on the torque build-up and the resulting penetration (a) helix-only penetration due to entanglement effect (43.1%); (b) helix-only penetration due to endocardial barrier effect without entanglement (19.6%); (c) drill effect (9.8%) with only moderate penetration; (d) screwdriver effect (27.4%) with progressive penetration. In-human penetration may be different due to constant interaction of perfused septum with the blood pool. Ponnusamy et al,[32] assessed the behavior of the lumenless lead during rapid rotations and the physiological property of the interventricular septum during LBBP. Lead movement inside the septum was assessed by lead traverse time (LTT). Based on the septal behavior, three different responses were noted. Type-I response (normal/firm septum) was noted in 93.7% (n=239) of patients characterized by constant and progressive movement of the lead inside the septum. Neither perforation nor further change in PVC morphology beyond M-beat were observed despite additional few un-intentional rotations indicating the protective mechanism of the LV sub-endocardium. Type-II response (soft/cheesy septum) was noted in 3.5% (n=9) of patients characterized by hyper-movement of the lead without resistance due to altered texture of the septum and poor LV sub-endocardial barrier predisposing for perforation into the LV cavity. Type-III response (hard/scarred septum) was noted in 2.8% (n=7) of patients characterized by inability of the lead to penetrate the septum despite multiple attempts. Understanding these responses will help in achieving an optimal lead positioning during implantation and avoiding dislodgements during follow-up

Though scar can be identified by trans-thoracic echocardiography, cardiac magnetic resonance (CMR) imaging with late gadolinium enhancement (LGE)

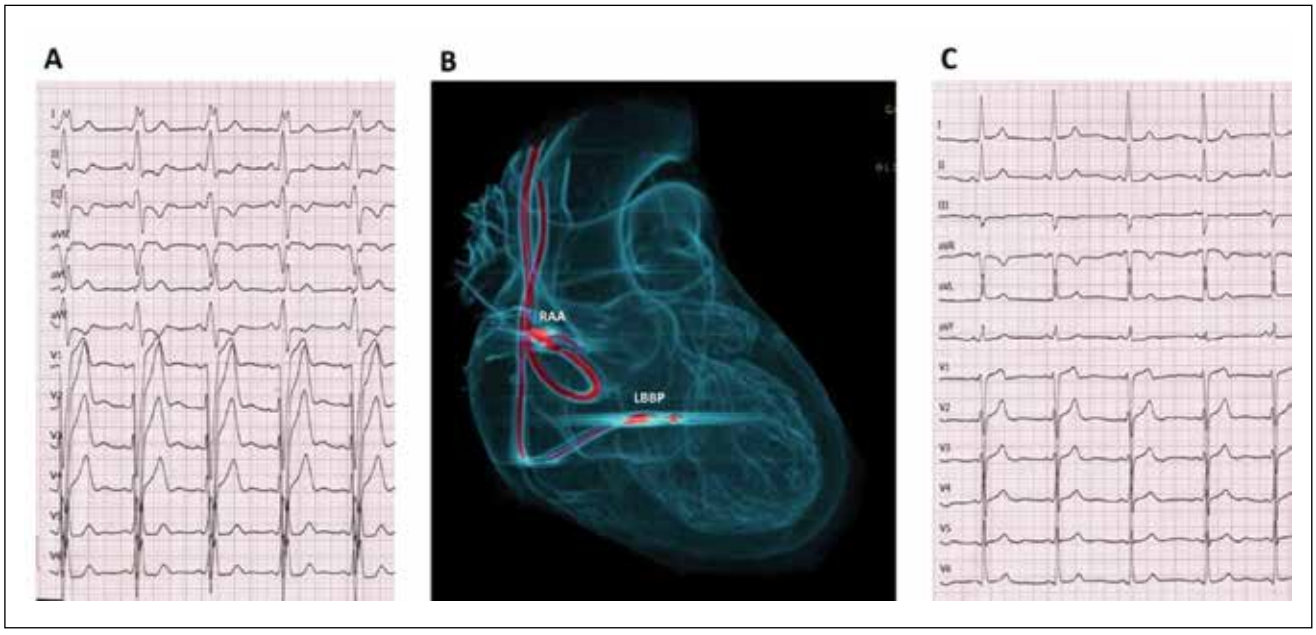


Figure 8- LBBP optimized dual chamber pacemaker (LOT DDD). A – Baseline QRS showing complete left bundle branch block. B – Contrast tomographic angiography image showing the LBBP lead in interventricular septum below the non-coronary cusp. C – Post LBBP ECG after AV delay optimization showing narrow QRS duration with masked RBB delay pattern due to native AV node fusion.

assessment will help in evaluating the distribution, extent and quantification of the scar, tailoring the treatment strategy and to assess the long-term prognosis in CRT eligible patients. Presence of scar over the infero-lateral wall of the LV results in sub-optimal response to BVP as it may result in bizarre paced QRS morphology and pre-dispose to ventricular arrhythmias. Hence LBBP could be considered as preferred CRT strategy in these patients. A retrospective observational study[33] showed that the presence of transmural scar in the LBBP zone defined as overlapping areas of basal antero-septum and infero-septum (segment 2 and 3; American Heart Association 17 segment model) predicted LBBP procedural failure with 100% sensitivity and specificity. Hence BVP or LBBP optimized CRT (LOT CRT) could be considered as a preferred strategy. In a prospective study (MADURAI LBBP study),[34] patients were risk stratified into low (<10%) or high scar burden (>10%) based on LGE quantification by CMR imaging. Patients with low-scar burden received LBBP optimized dual chamber pacemaker (LOT-DDD) without ICD while those with high-scar burden received LOT ICD or LOT CRT-D. Primary composite endpoints of death, HF hospitalization and mortality were noted in 3.8% of low-scar burden group as compared to 33.3% in high-scar burden group (p <0.0001). Normalization of LV function (LVEF ≥50%) was noted in 80% of patients with low-scar burden as compared to 33.3% in high-scar burden group at the end of 12 months follow-up.

ENDPOINTS FOR FURTHER ROTATION

The pacing lead has to be deployed just beneath the LV sub-endocardium to capture the LBB fibers. Additional rotations after reaching the LBB area might result in perforation into the LV cavity. The parameters which can be considered as endpoints for giving rotations include, demonstration of non-selective to selective capture transition, observing M-beat during PVC guided lead deployment, type-B (concealed) LBB potential, short and constant RWPT at high and low pacing output and unipolar pacing impedance nearing 450 ohms. Additional rotations should be avoided after observing these parameters as it may result in perforation.

TROUBLESHOOTING

The success rate for LBBP varies between 80.5% to 97%.[25,35,36] The reasons for procedural failure include inadequate sheath support, improper sheath-septal orientation, inability to penetrate the septum and cheesy septum. If the basal septum is scarred, left posterior or anterior fascicle can be targeted by repositioning the sheath in the mid-septum. Septal leaflet of the tricuspid valve might prevent the deep septal positioning of the lead. The sheath should be advanced towards the RV apex before bringing it back into the target site to avoid pinning the tricuspid leaflet into the septum. The RBB delay pattern due to LBBP can be corrected by optimizing the AV delay to achieve fusion with native AV node conduction, (Fig. 8) anodal capture or by placing additional lead in the RV septum. It is essential to confirm LBB capture and differentiate it from LVSP to provide better resynchronization therapy (table-2)

Table 2: Difference between LBBP and LVSP

Parameters	LBBP	LVSP
Paced QRS (V1)	qR in ~100% (?masked RBBD) Absent terminal S-wave	qR in 44% Terminal S-wave in 60%
RWPT (V6) - differential pacing	Short and constant	Different at different output
RWPT (V6) - absolute value	<75ms in non-LBBB <85ms in LBBB	Prolonged
LB potential	+	+/-
Retrograde His potential	+	-
Capture transition	NS to Selective NS to Septal	No transition
V6-V1 interpeak interval	>33ms	<33ms
Physiology based ECG criteria	Native RWPT=paced RWPT	>10ms difference
Programmed deep septal stimulation	Change in QRS morphology, axis	No change

Complications

Acute septal perforation into the LV cavity has to recognized immediately and corrected by repositioning the lead at a different site. Iatrogenic RBB injury by the delivery catheter or the pacing lead can be avoided by keeping the delivery catheter below the His bundle during mapping as the RBB courses anterior and superior to the LBB. Septal hematoma, coronary artery injury, septal coronary artery fistula and lead dislodgements are the reported complications of LBBP. Distal conductor fractures are reported more frequently with SDLs.[37] Loss of conduction system capture during follow-up has been reported in 4.6% with 1.5% requiring a re-do procedure.[38] There are concerns regarding the feasibility and safety of extraction of the lead from the LBB area though a recent large multicenter study[39] demonstrated a high success rate for the extraction of LBBAP leads (dwell time of <3 years) with a low need for mechanical extraction tools and minimal complication. The author has also shown that re-implantation in the conduction system was feasible after lead extraction in majority of the patients.

Future directions

LBBP is an excellent alternative modality of pacing to provide cost-effective resynchronization therapy. However, there are no dedicated tools designed for LBBP. Improvement in the tools and procedural techniques will help in increasing the acute procedural success and adoption rate of the procedure. Leadless LBBP is an exciting area where blends the two recent innovations in the field of pacing. Elliott et al[40] showed the feasibility of deploying the leadless WiSE-CRT over the LV septum to capture the LBB fibers. The most physiological form of pacing can be provided by biological pacemakers by reprogramming the somatic cells or pluripotent cells to generate spontaneous action potential.[41]

CONCLUSION

Last decade witnessed a revolution in the pacing technology by providing physiological activation of the ventricle through direct capture of His bundle or left bundle branch fibers. LBBP has several advantages over HBP as it provides better pacing parameters with excellent lead stability. Though the studies have shown excellent short and mid-term outcomes, randomized multicenter trials are warranted to establish the long-term safety and clinical outcomes of LBBP.

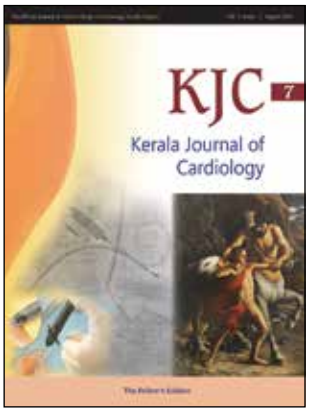
Disclosures:

SSP - Consultant
Research support - Medtronic
Consultant - Abbott

REFERENCES

1. Sweeney MO, Hellkamp AS, Ellenbogen KA, et al. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. Circularion 2003;107(23):2932-7.
2. Gebauer RA, Tomek V, Salameh A, et al. Predictors of left ventricular remodeling and failure in the right ventricular pacing in the young. Eur Heart J 2009;20(9):1097-104
3. Ponnusamy SS, Syed T, Vijayaraman P. Pacing induced cardiomyopathy: recognition and management. Heart 2023; heartjnl-2022-321723. doi: 10.1136/heartjnl-2022-321723.
4. Abdelrahman M, Subzposh FA, Beer D, et al. Clinical outcomes of His bundle pacing compared to right ventricular pacing. J Am Coll Cardiol. 2018;71(20):2319-330
5. Sharma PS, Patel NR, Ravi V, et al. Clinical outcomes of left bundle branch area pacing compared to right ventricular pacing: Results from the Geisinger-Rush Conduction system pacing registry. Heart Rhythm. 2022;19(1):3-11
6. Deshmukh P, Casavant DA, Romanyshyn M, et al. Permanent, direct His-bundle pacing: a novel approach to cardiac pacing in patients with normal His–Purkinje activation. Circulation 2000;101:869–77.
7. Huang W, Su L, Wu S, et al. A novel pacing strategy with low and stable output: pacing the left bundle branch immediately beyond the conduction block. Can J Cardiol 2017;33:1736.e1–3. https://doi.org/10.1016/j.cjca.2017.09.013; PMID: 29173611.
8. Tawara S. Das Reizleitungs system des Saügetierherzens. Jena: GustavFischer, 1906;135–8.
9. Hudson REB. Surgical pathology of the conducting system of the heart. Br Heart J 1967;29:646–70. https://doi.org/10.1136/hrt.29.5.646; PMID: 6039160.
10. Ponnusamy SS, Arora V, Namboodiri N, et al. Left bundle branch pacing: A comprehensive review. J Cardiovasc Electrophysiol 2020;31(9):2462-73
11. Burri H, Jastrzebski M, Cano O et al. EHRA clinical consensus statement on conduction system pacing implantation; endorsed by APHRS, CHRS and LAHRS. Europace 2023;25:1208-36.
12. Ponnusamy SS, Vijayaraman P. My preferred approach to left bundle branch pacing: Lumenless lead. Heart Rhythm O2. 2022;4(2):147-53.
13. Ponnusamy SS, Basil W, Vijayaraman P. Electrophysiological characteristics of septal perforation during left bundle branch pacing. Heart Rhythm. 2022;19(5):728-34
14. Ponnusamy SS, Vijayaraman P. Left bundle branch pacing guided by premature ventricular complexes during implant. HeartRhythm Case Rep.2020;6(11):850-3
15. Ponnusamy SS, Ganesan V, Syed T, et al. Template Beat: A novel marker for left bundle branch capture during physiological pacing. Circ Arrhythm Electrophysiol. 2021;14(4):e009677.
16. Jastrzebski M, Keilbasa G, Moskal P, et al. Fixation beats: A novel marker for reaching the left bundle branch area during deep septal lead implantation. Heart Rhythm. 2021;18(4):562-9

17. Ponnusamy SS, Basil W, Vijayaraman P. M-beat – A novel marker for selective left bundle branch capture. J Cardiovasc Electrophysiol. 2022;33(8):1888-92
18. Ponnusamy SS, Vijayaraman P. Evaluation of Criteria for Left bundle branch Capture. Card Electrophysiol Clin 2022;14:191-202
19. Su L, Xu T, Cai M, et al. Electrophysiological characteristics and clinical values of left bundle branch current of injury in left bundle branch pacing. J Cardiovasc Electrophysiol 2020;31(4): 834–42.
20. Ponnusamy SS, Ganesan V, Ramalingam V, Nachammai P, Vijayaraman P. Electrophysiological characteristics of left bundle branch potential during implantation. Heart Rhythm. 2023;20(11):1595-96
21. Wu S, Chen X, Wang S, et al. Evaluation of the criteria to distinguish left bundle branch pacing from left ventricular septal pacing. J Am Coll Cardiol EP 2021;7(9):1166–77.
22. Jastrzebski M, Keilbasa G, Curila K, et al. Physi- ology-based electrocardiographic criteria for left bundle branch capture. Heart Rhythm 2021;18(6): 935–43.
23. Jastrzebski M, Burri H, Kielbasa G, et al. The V6-V1 interpeak interval: a novel criterion for the diagnosis of left bundle branch capture. Europace 2022 Jan 4;24(1):40–7. https://doi.org/10.1093/ europace/ euab164.
24. Jastrzebski M, Moskal P, Bednarek A, et al. Pro- grammed deep septal stimulation - a novel maneu- ver for the diagnosis of left bundle branch capture during permanent pacing. J Cardiovasc Electrophy- siol 2020;31:485–93.
25. Vijayaraman P, Subzposh FA, Naperkowski A, et al. Prospective evaluation of feasibility and electrophysiologic and echocardiographic characteristics of left bundle branch area pacing. Heart Rhythm 2019;16:1774–1782.
26. Su L, Wang S, Wu S, et al. Long-term safety and feasibility of left bundle branch pacing in a large single-center study. Circ Arrhythm Electrophysiol. 2021;14(2):e009261. doi:10.1161/CIRCEP.120.009261. Epub 2021 Jan9.
27. Shali S, Wu W, Bai J et al. Current of injury is an indicator of lead depth and performance during left bundle branch pacing lead implantation. Heart Rhythm. 2022;19:1281-88
28. Pooter JD, Ozpak E, Calle S, et al. Initial experience of left bundle branch area pacing using stylet-driven pacing leads: A multicentre study. J Cardiovasc Electrophysiol. 2022;33:1540-9
29. Jastrzebski M, Kielbasa G, Cano O, et al. Left bundle branch area pacing outcomes: the multicentre European MELOS study. Eur Heart J. 2022;18:ehac445. Online ahead of print
30. Ponnusamy SS, Patel NR, Naperkowski A et al. Cardiac troponin release following left bundle branch pacing. J Cardiovasc Electrophysiol. 2021;32(3):851-55
31. Jastrzebski M, Moskal P, Holda MK et al. Deep septal deployment of a thin, lumenless pacing lead: a translational cadaver simulation study. Europace. 2020;22(1):156-61.
32. Ponnusamy SS, Ganesan V, Anand V, et al. Observations of interventricular septal behavior during left bundle branch pacing. J Cardiovasc Electrophysiol. 2023;34(11):246-54.
33. Ponnusamy SS, Murugan M, Ganesan V, Vijayaraman P. Predictors of procedural failure of left bundle branch pacing in scarred left ventricle. J Cardiovasc Electrophysiol 2023;34(3):760-4.
34. Ponnusamy SS, Ganesan V, Ramalingam V, et al. Magnetic resonance imaging based dual lead cardiac resynchronization therapy: A prospective left bundle branch pacing study (MADURAI LBBP study). Heart Rhythm. 2023;20(8):1119-27
35. Ponnusamy SS, Muthu G, Kumar M, et al. Mid-term feasibility, safety and outcomes of left bundle branch pacing – single center experience. J Interv Card Electrophysiol 2021;60:337–46. https://doi.org/10.1007/ s10840-020-00807-w; PMID: 32623624.
36. Li Y, Chen K, Dai Y, et al. Left bundle branch pacing for symptomatic bradycardia: implant success rate, safety, and pacing characteristics. Heart Rhythm 2019;16:1758–65. https://doi.org/10.1016/j.hrthm.2019.05.014; PMID: 31125667.
37. Pooter JD, Ozpak E, Calle S, et al. Initial experience of left bundle branch area pacing using stylet-driven pacing leads: A multicentre study. J Cardiovasc Electrophysiol. 2022;33:1540-9
38. Ponnusamy SS, Ganesan V, Vijayaraman P. Loss of capture during long term follow-up after left bundle branch pacing. JACC Clin Electrophysiol. 2023;9(3):418-20
39. Vijayaraman P, Trivedi RS, Koneru JN et al. Transvenous extraction of conduction system pacing leads: An international multicenter (TECSPAM) study. Heart Rhythm. 2024 May 9:S1547-5271(24)02381-6. doi: 10.1016/j.hrthm.2024.04.054.
40. Elliott MK, Jacon P, Sidhu BS, et al. Technical feasibility of leadless left bundle branch area pacing for cardia resynchronization: a case series. Eur. Heart J. Case Rep. 5, ytab379.doi:10.1093/ehjcr/ytab379.
41. Komosa ER, Wolfosn DW, Bressan M, Cho HC, Ogle BM. Implementing biological pacemakers: Design criteria for successful transition from concept to clinic. Circ Arrhythm Electrophysiol. 2021 Oct;14(10):e009957.



My Angioplastic Techniques in Chronic Total Occlusions

S M Ashraf
Professor & Head, Department of Cardiology,
Govt. Medical College, Kannur, Kerala.

INTRODUCTION

Chronic Total Occlusion (CTO) make up 15- 18% of all significant coronary lesions observed from different studies. Mechanism of CTO formation is by occlusion resulting from tight stenosis, followed by several changes over time including expansion of thrombus, hardening of plaque and thrombus, calcification, intraplaque-intrathrombus recanalisation/angiogenesis, and development of collaterals.

Success of CTO PCI is dependent on guide wire crossing which is based on the presumed mechanism of CTO and also pathological changes after occlusion.

Before taking the patient on cath table, check patient characteristics like age, sex, left and right ventricular function, pulmonary pressure, creatinine clearance, mitral regurgitation, diabetes and history of previous PCI. Study the CTO segment and look for CTO length, tortousity, microchannels, presence of side branch, tapered or blunt proximal end, calcification, distal end of CTO, whether bifurcation at its end, bridging or hetero collaterals, and availability of CT coronary images.

Access site: TransFemoral (TF) or Trans Radial (TR) - Which route is better?

Better take femoral approach for complex CTO especially in females where radial size is lesser. TF is also ideal in situations like LCx CTO, need for larger guide, and in retrograde PCI using epicardial collateral.

Introducer sheath in CTO PCI: In tortuous vessel, use 40-45 cm long sheath. Here use extra stiff wire, and make a small curve at sheath tip and use rotating movement. It gives 1 Fr additional back up support and also make less risk of vessel wall injury and possible prevention of cholesterol embolism.

Success of CTO PCI is dependent on Guide Catheter (GC) Selection: 7 Fr GC allows almost all procedures except simultaneous use of micro catheter, balloon and ivus catheter in CTO and also not allow rotablation with a burr size > 2.25 mm. 6Fr GC wont allow simultaneous use of miicrocatheter and ivus. When performing retrograde CTO PCI, we can use two 6 Fr Guide catheters for both donor and recipient vessel or also can be used as ping pong technique.

Address for correspondence: S M Ashraf, Professor & Head, Department of Cardiology, Govt. Medical College, Kannur, Kerala.
Email: ashsmfz@gmail.com

For RCA CTO, guide catheter used are JR or Short AL and the choice depends on morphology of CTO vessel and method of intervention whether antegrade vs retrograde. AL GC gets support from entire sinus of valsalva including opposite wall and the aortic valve. Common problem with JR GC in CTO RCA is, GC may initially be coaxial with CTO segment but it disengages during wire manipulation. But frequent use of micro catheter, Guide extension catheters like guidelner or Guidezilla and anchoring balloon technique make JR a comfortable GC in RCA CTO. In anchoring method, use side branch which is not close to ostium since it won't interfere with coaxiality between GC and main vessel. AL type GC is useful for anomalous RCA CTO also.

DOSING OF HEPARIN

Measure ACT every 30 minutes. Start with 5000 units or according to patient's body weight and do ACT after initial 10 minutes. If not prolonged, repeat the dose (80% initial dose) and still value remain same after 5-10 minutes, then suspect HIT. If prolonged more than 400 seconds after initial dose, suspect contamination with contrast and take repeat sample.

FLUOROSCOPY

Don't move the table for assessing collateral or CTO segment and take a long cine angiogram. Focus on ROI. ROI (Region of Interest) is defined as the occluded region of coronary artery from the point at the tip of guide wire to a peripheral landmark or the site of presumed bend.

Selecting angiographic views

Study angio cine in two standard orthogonal projection prior to start CTO PCI and do contralateral injections by isocentering the occluded segment. In case of ISR CTO with distal reformation near to stent edge, contralateral shoot s not needed.

For Retrograde CTO, septal or epicardial collaterals have to be visualised in specific projections en facing collaterals, mainly antegrade and retrograde.

Antegrade CTO Approach

There are important Guidewire crossing strategies to follow.

1. **Exploration strategy:** If there is microchannel within a relatively large vessel, we should find its entrance and insert the guidewire. My preference here is Fielder XTR wire.Once the entrance has been identified, then we must track the microchannel. Dont try to penetrate the CTO with a wire which is selected for tracking because that attempt may cause subintimal entry even if doesnt have a stiff tip.
2. **Exploration with penetration strategy:** Advance the guidewire to explore relatively soft site prior to hard CTO segment like loose tissue tracking. At the entry to hard CTO, we should search for a point where guidewire can penetrate the cap with as little pressure as possible. If we find deflection of tip, stop here and use another wire with higher tip load, fore example I use Gia Next 2 or 3 here and will repeat exploration.
3. **Penetration with exploration strategy:** In CTO with no microchannel or no central soft tissue, then use harder wire first itself. use microcatheter with workhorse wire. My favourite wire is runthrough wire for advancing microcatheter and exchanged with hardwire. Gia Next 2/3 to start and we shouldnt push with force because wire will deflect into subintimal space. Here we should advance the wire slowly with little force while exploring to find the correct direction.
4. **Penetration with exploration by Fixed Point Guidewire Rotation:** FPGR

If guidewire becomes blocked by a hard tissue within the lumen and then abruptly moves forward when pushed forcibly, its tip will usually have entered the subintimal space. After slightly advancing the guidewire either of the two projections will often show that it has been deflected. If so, we should pull the guidewire back and search for the place where the wire was initially obstructed. While keeping the guidewire tip at the blockage to prevent subintimal deviation, we should orient the tip in opposite direction. Then explore to find the direction in which the GW can be advanced while rotating the tip within 90 degree on either side.

ROLE OF MICROCATHETER (MC) IN CTO

While attempting guidewire crossing, usage of microcatheter has become important for success. Position of the microcatheter (MC) tip is the most important factor. When manipulating GW towards a CTO through MC, we should not place the tip of the MC near the entrance of the occlusion. Positioning the tip of MC about 5 mm from the entry will improve back up for GW. However, if the distance is too short, the MC will bias the GW towards the larger curvature of a curved vessel and increase the risk of guidewire whipping. So better to keep the micro catheter tip at 1 to 1.5 cm from the entry to ensure good manipulability of the guide wire.

What to do if subintimal entry has happened? (Fig. 1)

(a) The guidewire enters the subintimal space relatively easily. In this situation, the guidewire has been advanced into the subintimal space without any

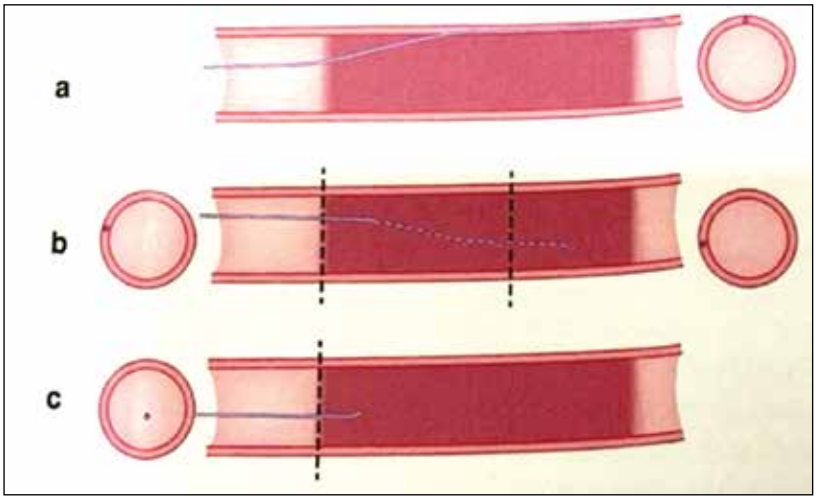


Figure 1: Subintimal entry of wire.

resistance, so the point at which the wire actually enters the subintimal space is difficult to determine.

(b) If it is expected to be possible to track the true lumen from the entry of the CTO, we should pull the GW back to a most proximal point possible within the lesion and orient it in the opposite direction to explore for the correct route.

(c) If this manoeuvre fails to advance the guide wire through the true lumen, you should completely withdraw the GW from the lesion and find a new entry point that is more likely to allow successful crossing of the CTO or else try for parallel wiring technique with a different wire.

INFLUENCE OF CALCIFIED PLAQUE AT THE OCCLUSION (Fig,2)

(a) The tip of the guidewire may enter preexisting plaque and become blocked by a calcified area of the plaque.

(b) Alternatively, the tip of the guidewire may be obstructed by calcification at the core of the lumen where final occlusion occurred. My personal choice here is Confienza series if occlusion length is not long and course of vessel is relatively straight.

Presence of positive/ negative remodelling in CTO segment:

Occlusion of a segment with positive remodelling. If there is marked positive remodelling, it may feel as if the guide wire is not crossing the lesion through the true lumen.

Negative remodelling of the occlusion with graphic example is given below. (Fig. 3)

This shows an occluded coronary artery with extreme negative remodelling, which means that a guidewire advanced through plaque readily deviates into the subintimal space.

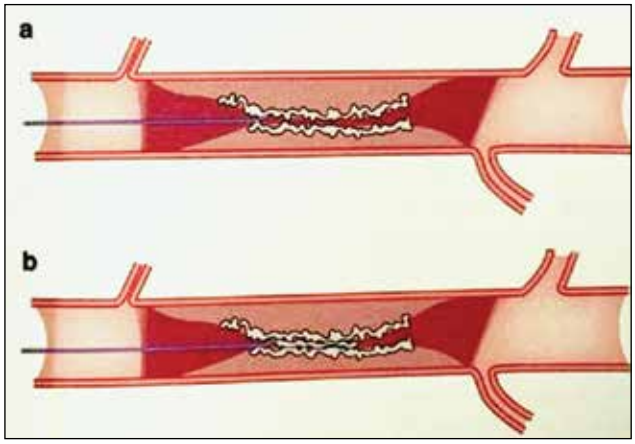


Figure 2: Influence of calcified plaque.

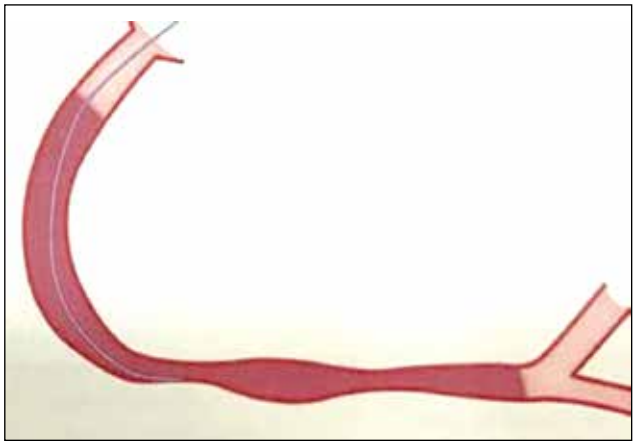


Figure 3: Effect of re-modeling.

Additional techniques like Parallel wiring technique, IVUS guided wiring, and subintimal tracking - reentry techniques are some of the examples in selected CTO intervention

Retrograde Approach for CTO PCI:

My primary approach is always antegrade. Retrograde if we meet the following requirements.

1. If large dissection flap has been created in a CTO after failure of antegrade approach.
2. If the proximal cap of a CTO is located at a large coronary ostium.
3. If an antegrade wire is deflecting to extravascular space in a long CTO segment.
4. Presence of ideal collaterals
5. After antegrade attempt

Selection of Collateral Channel:

1. Select a septal channel before an epicardial channel
2. Select a channel with fewer severe bends
3. Avoid a channel that joins the target vessel just distal to the occlusion.
4. Septal collateral is preferred because of less risk of tamponade, less tortousity and easy tracking. A collateral channel to RCA from first septal branch often joins atrioventricular branch. If such a channel is found, we can safely advance a wire from septal branch directly towards distal RCA through channel and penetrate the distal cap of the occlusion.

Selection of Guide Catheter in retrograde CTO PCI:

Short guide catheter is needed in many retrograde CTO PCI cases. We can also shorten GC by cutting 7 F Guide catheter (1 & 2) and connect both cut ends with 6 F outer sheath(3) and tightly connect two ends (5,6). (Fig. 4)

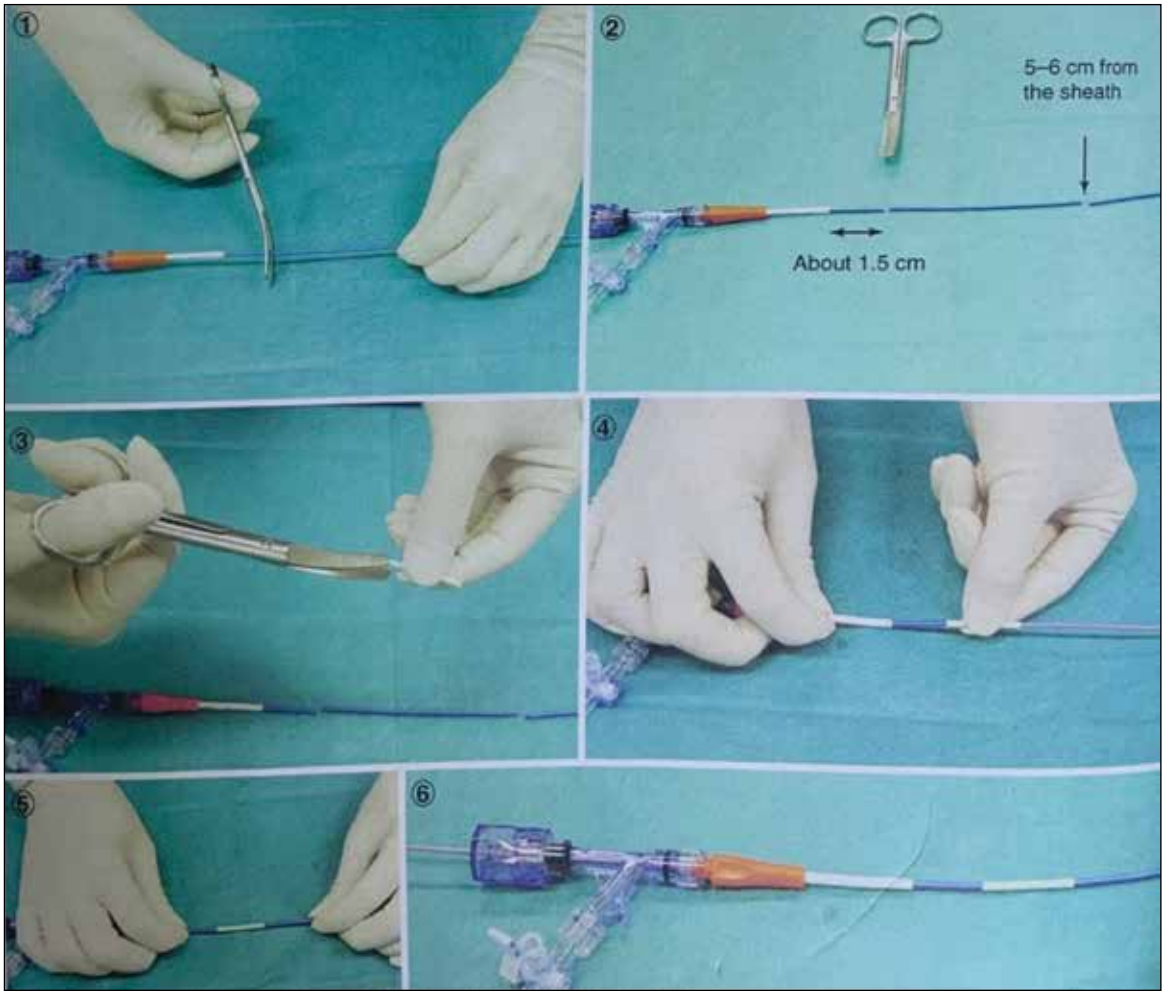


Figure 4: Guide catheter shortening.

Micro catheter (MC) in Retrograde PCI:

Special precautions should be taken.

A retrograde MC should have a length of 150 cm. For tip injection ideally tip of MC should be soft and tapered, in that case Corsair and Caravel are the best. other alternative is finecross MC.

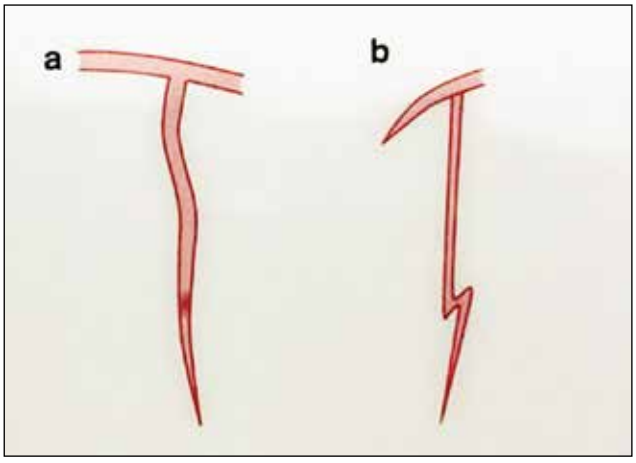


Figure 5: Variation of collateral channel appearance in different fluoroscopy projections. .

Role of Fluroscopy and Contrast Imaging in Retrograde PCI:

Optimal imaging projection is needed for en facing collaterals.

Example of variation of channel appearance in different fluoroscopy projections. (Fig. 5)

A channel that appears linear (a) in one projection may be tortuous (b) in another projection.

How to track a collateral channel:

1. Use minimal force when advancing the guidewire into the channel, and never push it hard.
2. Primarily view the channel in a projection perpendicular to its longitudinal axis.
3. Always keep the tip of GW parallel to the channel while advancing it, especially as it passes through an acute bend.
4. Advance GW with as little force as possible and only when it is oriented in the correct direction.
5. Exchange the GW for another with more slipperiness if the resistance is too much to advance it without employing strong force.

CTO Penetration strategies in Retrograde Approach:

Regular strategies are

1. Direct crossing method
2. Kissing wire technique
3. Reverse CART Technique
4. Kissing Reverse CART technique
5. Rendezvous Technique

Contemporary Reverse CART technique:

When to switch to reverse CART? Situations like

1. a retrograde GW fails to enter true lumen.
2. At least one GW is blocked by hard plaque.

Three most important advantages of Reverse CART technique include

1. No enlargement of distal dissection
2. Antegrade balloon inflation gives better landmark for retrograde wire entry
3. No need for IVUS

How to do Reverse CART : A Simplified description

This technique involves enlarging false lumen and true lumen near proximal end of occlusion by antegrade GW. Proximal part of occlusion is then dilated by small antegrade balloon. Retrograde GW is advanced to bring it into contact with antegrade balloon. The balloon is deflated and retrograde guidewire is introduced into space and taken to proximal true segment.

Trouble shooting in retrograde CTO PCI:

1. GW induced perforation and laceration of channels.
2. Fail to externalise retrograde wire.
3. RG3 wire related Bradycardia and hemodynamic collapse.
4. Donor vessel thrombosis.
5. Failure of advancing retrograde microcatheter GW entrapment.

Recanalisation strategy after Crossing CTO:

1. If CTO is crossed through false lumen, use simpler approach - Predilation followed by DES.

2. Post CTO recanalisation of occlusion segment, if distal vessel shows small caliber size with negative remodelling, then dilate with 0.5 mm larger than vessel diameter with lesser 2-4 atm pressure.
3. CTO recanalisation with circumferential calcium, then use Calcium debulking strategy like Rotablation, if not circumferential calcium, then scoring balloon is enough.

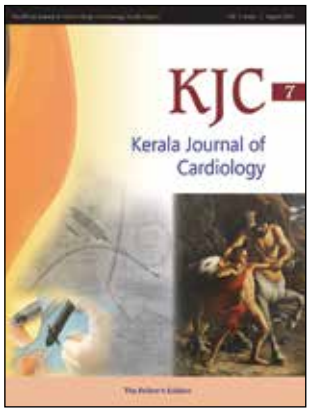
When to stop procedure in CTO:

There may be technical reasons to stop the procedure and also safety aspects too. Important take home messages are -

1. To avoid radiation damage, restrict below 40-60 minutes fluroscopy.
2. To avoid contrast induced nephropathy (CIN), restrict contrast volume. Total contrast volume advised is individualised and ideally better to keep below 100 ml. Contrast media exposure more than 4- 5 ml/kg body weight or 300 ml divided by Serum Creatinine (mg per dl.) are having high risk of CIN.
3. We can do second attempt after 4-6 weeks or other options like medical management and surgical approach can be sought after discussion with heart team.

CONCLUSION

CTO PCI success depends on proper preparation, pre planning, keeping rules of CTO PCI, handling of hardwares, prevention of complications, perseverance and realisation of when to stop the procedure.



Left Main Coronary Artery Interventions - Challenges and Recommendations

Vishnu Kesavan
Consultant Cardiologist, Rajagiri Hospital,
Aluva, Kochi, Kerala.

INTRODUCTION

Percutaneous coronary intervention (PCI) has emerged as the preferred treatment for patients with coronary artery disease (CAD). However, the optimal intervention strategy for unprotected left main coronary artery (LMCA) disease, which poses a high risk of adverse cardiovascular events, remains uncertain. However, the confidence of interventional cardiologists in performing LM interventions has increased significantly over the past two decades, particularly with the use of drug-eluting stent (DES)-based PCI and adjunctive pharmacotherapy. Given the large amount of myocardial tissue at risk and the complexity of bifurcation PCI in most LMCA interventions, the procedure is an uphill battle.

In this chapter, we will discuss the challenging anatomy of LMCA, recent evidence on LMCA intervention, and the significance of imaging in LMCA intervention.

PART - I. APPROACH TO LMCA INTERVENTIONS

ANATOMY OF LMCA/COMPLEXITY IN LMCA

It is widely understood that the left main artery is responsible for supplying approximately 60% of the myocardium in the dominant circulation. However, in cases where the left-dominant system is present, this percentage can increase to up to 90%.[1] While the LMCA can be divided into ostium, shaft, and distal segments with bifurcation, the occurrence of focal atherosclerotic lesions in the LMCA is infrequent. A vast majority of distal LMCA lesions extend well into the bifurcation, thereby necessitating complex bifurcation intervention. In fact, up to 80% of distal LMCA lesions require such interventions due to their extension into bifurcation. Bifurcation lesions, like water flowing across a divider, tend to deposit their maximum debris on areas with low shear stress. This typically occurs on the lateral wall opposite to the carina, resulting in the disease process extending beyond the ostium of the left anterior descending artery (LAD) and circumflex (Cx).[2] This process of plaque extension to branch vessels can be well demonstrated by intravascular imaging, making it a necessary tool in LMCA intervention.[3]

Address for correspondence: Vishnu Kesavan, Consultant Cardiologist, Rajagiri Hospital, Aluva, Kochi, Kerala. Email: vishnukesavan2k7@gmail.com

EVIDENCE FOR LMCA INTERVENTION

Since the introduction of DES PCI IN 2000, many randomized trials like LEMANS[4], SYNTAX LMCA[5], PRECOMBAT[6], EXCEL[7], and NOBLE[8] changed the approach to LMCA intervention (Table 1). Although LEMANS study had a small sample size of around 50 patients, the PCI arm demonstrated a tendency to improve the left ventricular ejection fraction, which increased the confidence of interventional enthusiasts.[4]

Two studies, SYNTAX and PRECOMBAT, conducted randomized trials with around 300 patients to compare the effectiveness of PCI and CABG after 1-5 years of follow-up. Both studies were able to demonstrate noninferiority of PCI over CABG in patients with intermediate and low SYNTAX score.[5,6]

There were two studies named NOBLE(8) and EXCEL[7] that each had more than 500 patients. However, these studies had conflicting results, which made the PCI group face further difficulties. EXCEL involved 957 patients where the primary outcomes included death, MI, and Stroke. After five years of follow-up, the study showed that PCI was not inferior to CABG. NOBLE had 592 patients, with primary endpoints death, nonprocedural MI, stroke, and repeat revascularization. After five years of follow-up, the NOBLE study showed that PCI was inferior to CABG.

Several metanalyses, conducted by Ahmed et al.[12], Kuno et al.[13], D'Ascenzo et al.[14], and Sabatine et al.[15],have shown that PCI with DES have similar long-term mortality rates as those who undergo CABG. The findings of these meta-analyses and the EXCEL study have influenced the latest 2021 ACC/AHA guideline, which now recommends class IIa for LMCA PCI, if PCI can achieve revascularization equivalent to CABG.[16]

In the process of choosing between PCI and CABG, it is prudent to consider pertinent guidelines and meta-analyses. Following thorough deliberation and consultation with the heart team, a well-founded decision can be confidently reached.

Table 1: Randomized trials of PCI with DES Vs. CABG for LMCA disease[4–8]

	LEMANS	SYNTAX LM	PRECOMBAT	EXCEL	NOBLE
PCI/CABG, n/n	52/53	357/347	300/300	948/957	592/592
Follow Up years	10	10	10	5	5
Diabetes,%	18	25	32	29	15
Bifurcation %	58	61	64	81	81
SYNTAX Score, mean	Not reported	30	25	21	22
Stent	BMS & DES (35%)	DP-PES	DP-SES	DP-EES	BP-BES &DP-SES
IVUS	Recommended	Infrequent	91%	77%	74%
FFR guidance	Not reported	Infrequent	Not reported	9%, Recommended	Recommended
Primary endpoint	Change in LVEF	Death, MI, Stroke, repeat revascularisation-5 year follow up & All cause death-10 year	Death, MI, Stroke, or TVR	Death, MI, or Stroke	Death, nonprocedural MI, Stroke, or repeat revascularisation
Key Finding	A trend towards higher LVEF at ten years	PCI was noninferior to CABG at 1 and 5 years in terms of death, MI, repeat revascularisation or Stroke. No significant difference in all cause death at 10 years	PCI was non inferior to CABG at 1,5 and 10 years	PCI was non inferior to CABG at 3 & 5 years	PCI was inferior to CABG at 5 years

BMS- bare-metal stent; BP-BES biodegradable polymer biolimus -eluting stent; CABG- coronary artery bypass grafting; DES- drug-eluting stent; DP-EES- durable polymer Everolimus-eluting stent; DP-PES- durable polymer paclitaxel-eluting stent; DP-SES durable-polymer sirolimus-eluting stent; EXCEL- Evaluation of Xience Everolimus Eluting Stent vs Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization; FFR- fractional flow reserve; IVUS- intravascular ultrasound; LEMANS- Left Main Stenting; LVEF- left ventricular ejection fraction; MI- myocardial infraction; NOBLE- Nordic-Baltic-British Left Main Revascularization; PCI- percutaneous coronary Intervention; PRECOMBAT- Premier of Randomized Comparison of Bypass Surgery versus Angioplasty Using Sirolimus-Eluting Stent in Patients with Left Main Coronary Artery Disease; SYNTAX- Synergy Between Percutaneous Coronary Intervention with TAXUS and Cardiac surgery; SYNTAX-LM- left main sub study of the SYNTAX (Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery); TVR- target vessel revascularization.

Guideline Recommendation for PCI of left main coronary artery

Diagnosis of LM CAD (2018 ESC) (2023 ACC/AHA & 2021 SCAI)

1. 50% stenosis diagnosed by invasive coronary angiography is significant LMCAD.
2. Use IVUS for evaluation of intermediate LM CAD (Class IIa)
3. Use FFR for assessing significance of intermediate coronary artery lesions (Keep in mind the possibility of error in cases downstream coronary lesion) (Class I)
4. Invasive angiography for risk stratification is not needed if non-invasive imaging shows significant LMCA disease (Class III)

Revascularisation of LMCAD as per 2018 ESC guideline (Table 2)

1. Revascularisation should be strongly considered in significant LMCAD (Class1)
2. Stratify patients by SYNTAX score to predict outcome prior PCI(Class1)
3. Consider CABG for Intermediate (23-32) and high (≥33) SYNTAX score LMCAD (Class 1)
4. Consider PCI for Low SYNTAX score LMCAD-(Class 1)
5. Can consider PCI for intermediate SYNTAX score LMCAD (Class IIa)
6. PCI is not recommended for high SYNTAX score LMCAD (Class III)

Revascularisation of LMCAD as per 2021 ACC/AHA/SCAI guideline (Table2)

ACC/AHA/SCAI guidelines are more subjective and rely more on heart team assessment of coronary complexity rather than SYNTAX score alone.

1. A class IIa recommendation is conferred for percutaneous coronary intervention in patients with low to intermediate risk anatomy (SYNTAX score ≤ 33) if stenting can yield comparable revascularization outcomes to coronary artery bypass grafting.
2. CABG is preferred for patients with high anatomic complexity or significant multivessel disease is there along with LMCAD (Class I) (E.g., Trifurcation lesion, complex bifurcation lesion, ostial LMCA disease, severe calcification)
3. In complex coronary anatomy also PCI can be considered if patient is a poor candidate for surgery (Class IIa) (E.g., Poor distal targets for grafts, severe left ventricular dysfunction, severe lung disease)

PHYSIOLOGICAL/IMAGING ASSESSMENT OF LMCA

It is evident that comprehensive planning of all left main percutaneous coronary interventions (PCI) cannot rely solely on 2D angiography. Factors such as angulation, eccentricity, foreshortening, bifurcation anatomy, overlapping segments, and the absence of a reference segment can impede the accurate assessment of severity. [17]

FFR in LMCA intervention

Physiological assessment through fractional flow reserve (FFR) is extensively employed to gauge the severity of angiographic lesions (Table 4). However, the exclusion of left main (LM) lesions in most randomized FFR studies poses a challenge in categorizing the significance of FFR for these lesions. It is noteworthy that isolated LMCA lesions devoid of downstream coronary involvement are exceedingly uncommon, rendering FFR less dependable in the presence of sequential or diffuse coronary involvement. The intricate interplay of serial lesions presents a particularly formidable scenario, with a notable probability that distal stenoses may disrupt flow and subsequently impact the pressure gradient across the left main coronary artery (LMCA).

Table 2: Recommendation Guideline for PCI of Left main Coronary artery[10,11,16]

Guidelines	Class of recommendation	Level of Evidence
2018 ESC/EACTS	I: LMCA disease with SYNTAX score ≤22 IIa: LMCA disease with SYNTAX score 22-33 III: LMCA disease with SYNTAX Score ≥33	A
2021 ACC/AHA	IIA: For SIHD with significant LMCA to whom LMCA PCI can provide equivalent revascularisation as possible with CABG	B
ACC- American College of Cardiology, AHA- American Heart Association, ESC- European Society of Cardiology, SIHD- Stable Ischemic Heart Disease, STS- Society of Thoracic Surgeons, LMCA- Left Main Coronary Artery, PCI- Percutaneous Coronary Intervention.		

Imaging/IVUS in LMCA intervention

Intravascular ultrasound (IVUS) plays a crucial role in assessing plaque morphology, plaque extension to branch vessels, and the minimum lumen area (MLA) to determine the significance of the lesion (Table 3).

Studies conducted in the United States utilizing IVUS have revealed that an MLA of ≤5.9 mm^2 is indicative of a physiologically significant lesion, as evidenced by a fractional flow reserve (FFR) of less than 0.75, with a sensitivity and specificity of 93% and 94%, respectively.[18] In studies conducted on the Asian population, the LMCA calibre has been measured at 4.5 mm^2. While body surface area and sex exhibit minimal impact on LMCA calibre, ethnicity emerges as a significant factor, particularly in relation to the proximal vessel.

Upon amalgamating the findings from these two ethnic groups, it is postulated that an MLA > 6mm^2 represents a safe threshold for non-intervention, while an MLA <4.5mm^2 necessitates active intervention. An MLA falling within the range of 4.5-6.0 mm^2 is categorized as a grey area, mandating the utilization of physiological assessment (FFR) to inform the final decision-making process IVUS plays a key role post-PCI for assessing malposition, under expansion, edge dissection, and neo carina. As per the recent (2021) SCAI/ACC/AHA guideline deferment of revascularisation can be considered in left main coronary artery diseases with minimal lumen area (MLA) of ≥6 to 7.5 mm^2. Smaller cut-off of 4.5 to 4.8 mm^2 may be better suited for Asian patients due to smaller baseline coronary vessel size.

The left main (LM) bifurcation is segmented into four sections to conduct a comprehensive analysis of restenosis predictors: all assessed by IVUS pullback from LAD.[19]

1. Ostial left anterior descending artery (LAD) (5 mm-segment distal to the carina),
2. Polygon of confluence (POC) (confluent zone of the LAD and left circumflex artery (LCX) on longitudinal IVUS image),
3. Proximal LMCA above the POC (5-mm segment just proximal to the POC),
4. Ostial LCX (5-mm segment distal to the carina), assessed by LCX pullback.

Minimum stent area criteria for preventing future restenosis have been proposed by Kang S J et al, which gives us the "5-6-7-8 rule" in LMCA bifurcation stenting.[19]

As per their findings, a minimal stent area (MSA) of 5.0mm^2 in LCx, 6.3mm^2 in the proximal LAD, 7.2mm^2 in the Polygon of Confluence (POC), and 8.3mm^2 in the distal LMCA is significantly associated with reduced incidence of future restenosis.[19] A reduced intravascular ultrasound minimal stent area (IVUS-MSA) within any of these segments correlated with a heightened incidence of angiographic in-stent restenosis (ISR) and clinical major adverse cardiac events (MACE). Thus, correcting under expansion with these optimal IVUS criteria using IVUS guidance during LMCA stenting procedures may reduce cardiac events after DES treatment for unprotected LMCA disease.

IVUS plays a crucial role in post PCI stent optimisation and assessment of complications like edge dissection. Carinal shift can be easily identified by IVUS, where necessary intervention makes the bifurcation stenting less cumbersome.

Recent ACC/AHA/SCAI guidelines recommend using IVUS (class IIa) to reduce the ischemic events when PCI is performed for LMCAD.[3] Current ongoing trial of IVUS in LMCA PCI, the OPTIMAL study, aims to provide strong recommendations for IV imaging.[20]

Table 3.Role of IVUS in LMCA PCI.[21]

Pre PCI	Post PCI
Confirm the significance of the lesion	Stent optimisation
Assess the lesion characteristics	To assess complications (eg; Dissection)
To know the distal extend of lesion and to plan bifurcation strategy (distal LMCA)	
Mark the stent landing zone	

Table 4.Role of FFR in LMCA PCI.[21]

Pre PCI	Post PCI
To assess the functional significance of angiographic Intermediate or ambiguous LMCA lesion	Assessment of jailed branches after LMCA PCI

How to approach Bifurcation lesion in LMCA.?

Bifurcation stenting strategy can be broadly classified as either provisional bifurcation strategy or dedicated two-stent techniques. Each approach offers distinct advantages and considerations that should be carefully evaluated to determine the most suitable strategy for each patient.

Rationale for provisional Bifurcation stenting in Left main lesions.

The concept of provisional stenting addresses LM-MV disease, primarily focused on LM-LAD stenting. In a left-dominant system with a significant LCx lesion where the LCx originates with an angulation of over 90 degrees, we should proceed with LM-LCx stenting and plan for LAD provisionally. In both situations, provisional stenting allows for reassessment of the side branch and provides the option of using a second stent if needed. This approach confers the added advantage of averting target lesion failure or target lesion revascularization by minimizing unnecessary manipulation of the MV stent scaffold.

The DEFINITION trial define complex bifurcation lesions requiring dedicated 2 stent strategy as a bifurcation lesion with >70% stenosis in SB and lesion extending >10 mm in case of ULM bifurcation.[22] The trial encompasses only 30% of the total patient population, indicating that 70% of cases allow for the implementation of a provisional bifurcation strategy. The consensus statement of the European Bifurcation Club (EBC) recommends employing a two-stent strategy for the treatment of bifurcation lesions featuring significant side branch (SB) disease. As outlined by the EBC, significant SB disease is characterized by a vessel with a diameter equal to or greater than 2.75 mm, along with a lesion extending beyond 5mm from the carina, as per the findings of the Nordic-Baltic IV study.[23,24]

Routine kissing balloon inflation of the side branch ostium lacks established efficacy through trial. Instead, post-dilation of the side branch ostium should be contemplated in instances of notable side branch compromise following main branch stenting.

Rationale for two stent technique in LMCA bifurcation

When considering distal LMCA stenting, the choice between the Provisional and 2-stent techniques often presents a complex decision. Previous trials in Bifurcation PCI have demonstrated a higher failure rate associated with the upfront 2-stent strategy, primarily due to its elevated rate of repeat revascularization.

The EBC-MAIN (European Bifurcation Club Left Main Study) showed that the stepwise layered provisional approach was linked to a numerically lower (but not significantly lower) occurrence of major adverse cardiac events (MACEs) (a combination of death, MI, and target lesion revascularization) compared to planned dual stenting.[25] The findings of the DEFINITION II and DK CRUSH V trials indicate a preference for the planned 2-stent strategy (DK CRUSH) over provisional stenting, particularly for complex bifurcation lesions (see table 5 for comparison).[26] The EBC MAIN study encompassed patients with less complex bifurcation lesions, and short side branch lesions in comparison to the patients included in the other two dedicated bifurcation studies (Table 5).

In a recent network meta-analysis involving 5,711 patients who underwent treatment using 5 distinct bifurcation PCI techniques (provisional, crush, culotte, T-stenting/T-stenting and protrusion, and DK crush), DK crush demonstrated a lower incidence of major adverse cardiac events (MACEs) in comparison to provisional stenting, attributed to reduced target lesion revascularization. Conversely, no advantage of the other 2-stent techniques over provisional stenting was evident.[27]

Table 5:RCT-Stenting strategy for distal LMCA bifurcation[21]

	DKCRUSH V trial[26]	**EBC MAIN Trial**[25]
Design	Provisional Vs DK crush	Provisional Vs up front 2 stents
Number of patients	482	467
Diabetes, %	27.2	27.4
Operator experience	≥300 PCI/y ≥20 LMCA PCI	≥150 PCI/y
Mean SYNTAX score	30.6	22.9
Distal bifurcation angle	78	81.3
Length of side branch lesion	16.4	6.9
Complex bifurcation, %	31.5	Not classified
Use of IVUS guidance	Not mandated,41.7%	Not mandated, 32.5%
Up front 2 stent strategy	DK crush	Culotte (53%), T/TAP (33%), DK crush (5%)
Conversion rate to 2 stents in provisional strategy, %	47	22
Stents used in the study	Xience V, Endeavor -Resolute, Firebird 2	Resolute Onyx
Primary endpoint	Target lesion failure-Composite of cardiac death, target vessel MI or target vessel revascularisation	Death, MI, or target vessel revascularisation
Key findings (Provisional Vs 2 stents)	1yr-10.7% Vs 5.0%; p=0.02 3yr-16.9% Vs 8.3%; p=0.006	1yr-14.7% vs 17.7%; p=0.34
DK-double kissing, DKCRUSH V-double kissing crush vs provisional stenting for left main bifurcation, TAP-T and protrusion, EBC MAIN-European bifurcation club left main study RCT-Randomised controlled trial.		

PART - II. TECHNICAL CONSIDERATIONS FOR LMCA INTERVENTIONS

Fluoroscopic View- The spider view is conventionally employed in LMCA stenting to mitigate geographic miss and excessive stent protrusion to the LMCA. However, the straight caudal view should also be duly utilized due to its minimal foreshortening, thereby averting errors in stent length selection, and ensuring precise placement. The LAO cranial view is optimal for profiling the LMCA ostium as it distinctly demarcates the boundary between the SOV and LMCA ostium. In summary, as with any other fluoroscopic procedure, it is imperative to employ at least two orthogonal views to effectively guide the procedure.[1]

Stent selection- When selecting a stent for bifurcation PCI, it is crucial to consider the maximum expansion limit of the platform. This consideration is particularly significant for two-stent techniques such as TAP and culotte with a sizable side branch (SB), as the stent in the SB may encounter constraints due to the limited expansion of the main branch (MB) stent cell. This constraint may result in the "napkin ring sign" and elevate the risk of target lesion failure (TLF).[23]

Selection of technique- The management of ostial and shaft lesions is generally uncomplicated for an experienced operator, particularly with the assistance of intravascular ultrasound (IVUS) and fractional flow reserve (FFR) for functional segment evaluation. In the case of distal left main coronary artery (LMCA) lesions, provisional stenting is currently the preferred approach among most operators due to its lower technical complexity. Compromise of the side branch (SB) may occur after stenting the main branch (MB) as a result of plaque or carina shift, leading to potential ambiguity regarding the significance of SB jailing. Utilizing FFR measurements for the assessment of SB stenosis significance can mitigate the need for unnecessary complex additional procedures.[28]

1. PROVISIONAL BIFURCATION TECHNIQUE

Wiring the branches

Start with the difficult branch and insert the second wire carefully to avoid tangling. Place a wire in the side branch systematically to open the bifurcation angle for easier access. This wire lowers the risk of side branch blockage and can be used as a marker.

Pre-dilation

Pre-dilation of the main branch (MB) is based on clinical and anatomical conditions. Optimal MB lesion preparation is recommended. Routine side branch (SB) dilation is not recommended except in severe ostial stenosis, calcified SB, or difficult SB access, where pre-dilation with a small balloon may be necessary.

Stent selection

Choose stent diameter based on distal MV size. Larger stent can cause dissection and carinal shifting, leading to SB blockage. Select a DES with careful consideration of the expansion limit since we need to perform Proximal optimization according to Proximal MV diameter.

Proximal Optimisation Technique (POT)

The proximal optimization technique (POT) is a method proposed to enhance the results of stent scaffolding for bifurcation lesions. It is a simple technique that involves inflating a short balloon in the main vessel, just before the carina, to an appropriate size. This technique offers many advantages, such as reducing the risk of side branch compromise due to carina displacement, improving stent apposition in the proximal main vessel (pMV), and making it easier to access the side branch after the stent implantation in the main vessel (Figure 1).

How to perform POT...?

Implant the MV stent sufficiently proximal to the SB to accommodate a short, large diameter balloon sized to the PM at least 6 or 8 mm in length. Position the distal marker of this short balloon in front of the carina and inflate to an appropriate size (Figure 1).

Rewiring SB/Wire exchange

Following a percutaneous coronary intervention (PCI) on the main vessel (MV), the subsequent step involves the exchange of the guidewire or recrossing of the side branch (SB) with a wire to dilate the SB ostium, if necessary. Guidewire exchange typically involves pulling back the MV wire or using a third wire, inserted in the MV, just distal to the carina, to insert it into the SB through the most distal cell. This facilitates the projection of struts in the ostial segment of the SB opposite the carina (Figure 2). Subsequently, the jailed wire is removed under fluoroscopy from the SB and inserted into the distal MV segment, preferably with a loop to avoid crossing under a strut. Although this manoeuvre is relatively safe, it may cause deep intubation of the guiding catheter, which can result in dissection or longitudinal stent distortion, particularly in the context of a left main (LMCA) PCI.

While pulling the wire with the right hand, the guiding catheter is closely controlled with the left hand to avoid deep intubation.

Assess the SB

Should I stent SB..?

As the next step, a decision should be made regarding the treatment of SB stenting. Consider SB stenting in the following cases.

1. When there is significant impairment of SB flow (Thrombolysis in Myocardial Infarction flow grade <3)
2. In the presence of a major SB dissection
3. When the SB is diseased and large enough to cause significant residual ischemia or
4. When future access to the SB may be important.

PCI strategy for SB after provisional MV stenting:

T-stenting, T-stenting and small protrusion (TAP), or culotte are the possible SB strategy for provisional bifurcation stenting. Choosing the appropriate technique depends on the bifurcation angulation. T-stenting is typically preferred for T-shaped angles, while TAP or culotte is recommended for Y-shaped angulation (to achieve optimal scaffolding of the SB ostium.[9]

In cases where SB access is performed through the distal strut, optimal SB scaffolding can be achieved, allowing for the execution of T-stenting. However, if the SB ostium is inadequately covered by the MV stent, an overlapping technique, such as TAP, culotte, or internal crush, may be required. In the context of TAP, the deployment of the SB stent is accomplished while maintaining an un-inflated balloon in the MV. This strategic approach allows for the stent to only slightly protrude into the MV, thereby achieving complete coverage of the bifurcation and creating a short neo carina.[9]

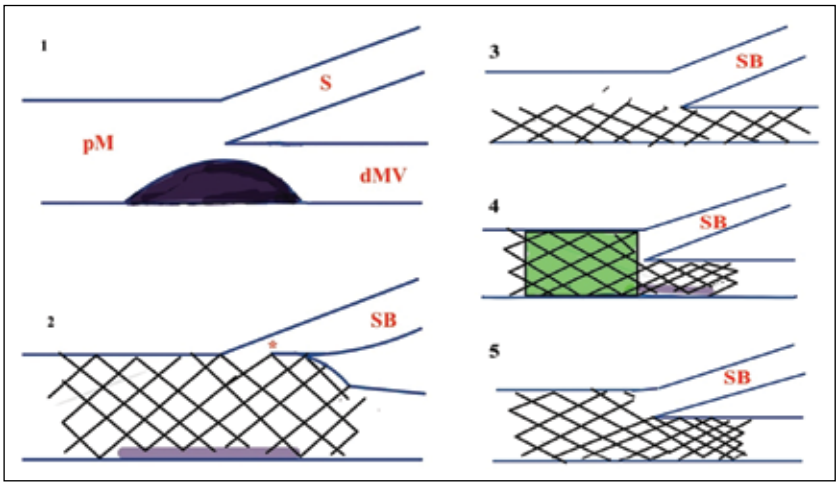


Figure 1: Proximal optimisation technique: 1-2, The stent is sized to the proximal reference diameter of the main vessel. Stent displacement will displace the carina thereby compromising flow into the side branch (SB).3, Stent is sized to the distal main vessel reference diameter (dMV), following deployment proximal part of stent is malopposed. 4-5,Demonstrate POT (Short balloon sized to the proximal main vessel (pMV) is positioned just up to the carina and inflated resulting in good stent apposition without carina shift)

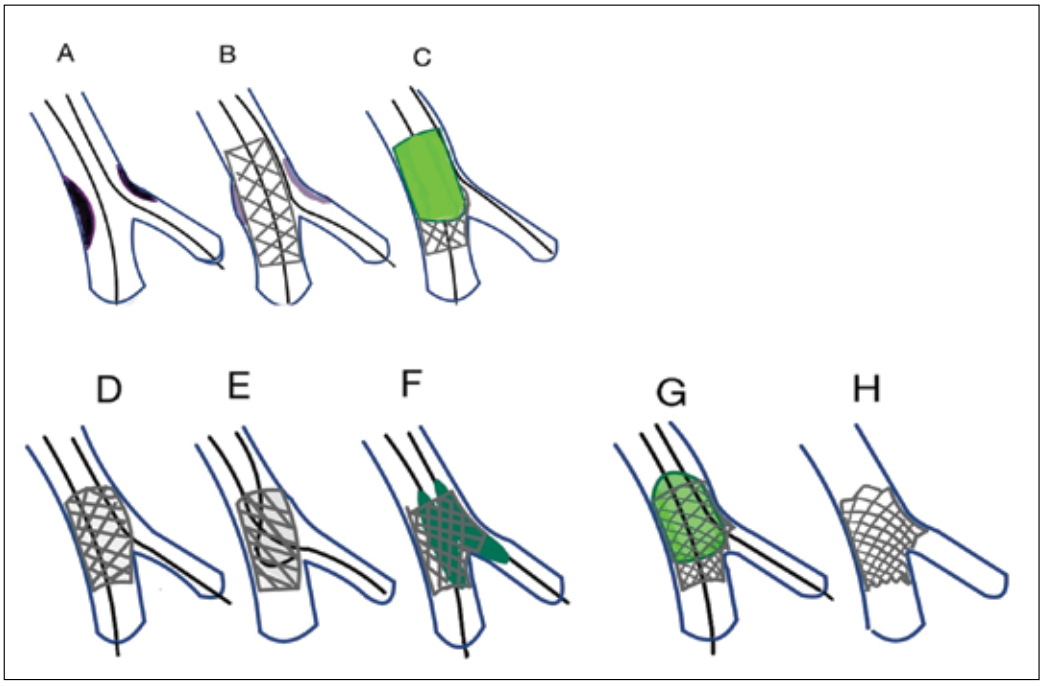


Figure 2: Provisional Bifurcation strategy. A) First step involves insertion of a wire into each of the distal branch. B) Stenting of the main branch with a diameter selected according to distal main diameter. C) The proximal optimization technique with a short balloon with a diameter adapted to proximal main diameter. D) After POT. E) The jailed wire is withdrawn carefully to avoid abrupt guiding catheter intubation, and subsequently advanced into the distal main branch by forming a U-shaped loop. (F) Kissing balloon inflation is carried out with 2 short balloons, preferably noncompliant with a diameter compatible with both distal branches. G) Final POT. H) Final result

2. TWO STENT TECHNIQUES

A. CULOTTE

Culotte is used in bifurcation lesions where the sizes of the distal main vessel and side branch are almost similar, and there is an acute angle between them.

Two stents of equal size were placed in the main branch (MB) and the side branch (SB) with an overlapped segment in the MB before the bifurcation. This procedure is called Culotte (Word Meaning-Wide short trousers). It ensures complete coverage of the carina and the ostium of SB, as well as a more uniform drug distribution.

However, this technique requires a long segment of double layers of metal proximally (Figure 3).

Culotte steps

1. Wire both SB and MV
2. Predilate the SB/More angulated branch
3. Stent SB with proximal strut extending well into pMV
4. POT
5. Recross into MV via distal strut and open the struts
6. Stent the MV (Nonangulated segment) with proximal overlapping.
7. POT.
8. Recross the SB at distal strut.
9. Final KBI
10. Final POT (Avoid neo carina)

B. DK CRUSH (Double kissing crush)

The DK Crush modification is a technique used to improve the success rates of final KBI (FKBI). It involves adding a first KBI after the deployment of the SB stent (Figure 4). The purpose of this is to clear crushed stent struts away from the SB ostium and increase the likelihood of successful recross after MV stenting. Although the first description of DK Crush recommended 4 to 5 mm of SB stent protrusion, the most contemporary technique (Figure 4) recommends approximately a 2-mm protrusion.[26]

The DK Crush steps

1. Stenting the SB (with 1 to 2 mm protrusion in the MV).
2. MV balloon crush
3. Non-distal wiring of SB access through the crushed stent, and SB strut dilation.
4. First KBI
5. Removing the SB stent balloon and wire
6. Stenting the MV
7. POT
8. Re-SB wire access (non-distal)
9. Final KBI
10. Final POT.

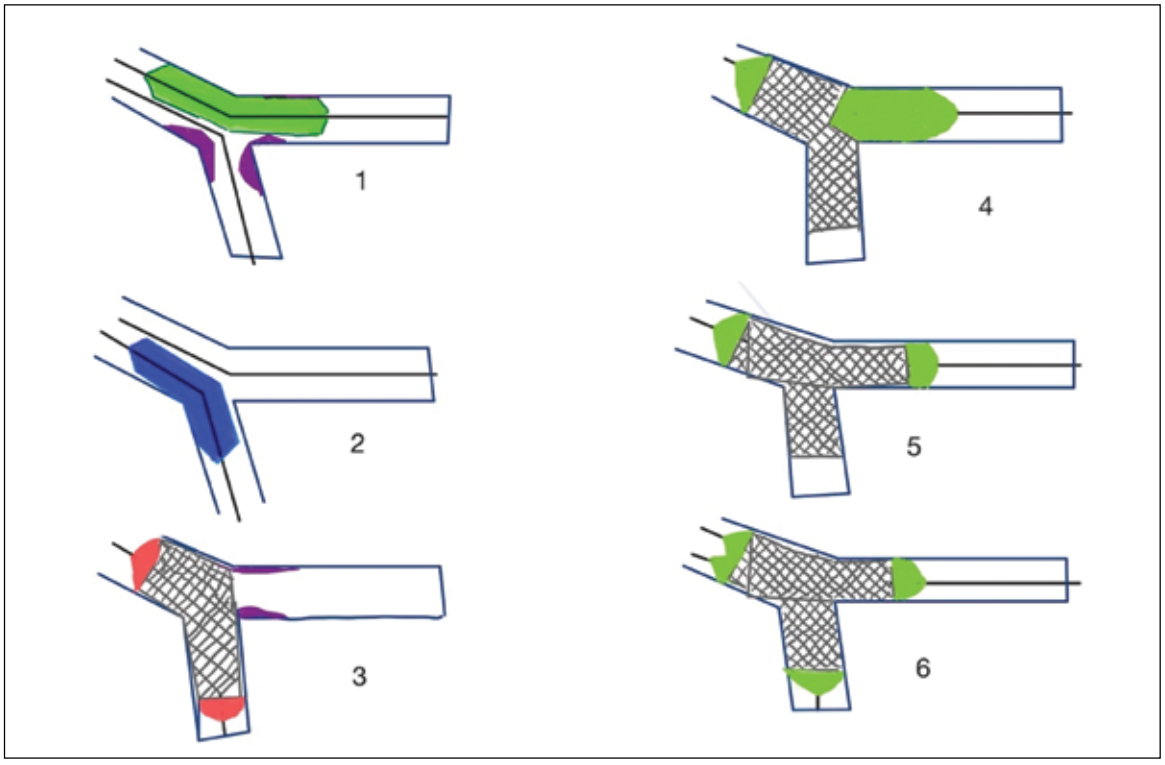


Figure 3: Culotte technique.1,2. Both branches are wired and dilated. 3. Deploy stent in more angulated branch. 4. Do POT. Recross the stent and dilate the distal strut. 5. Place second stent across the unstented branch (remove wire from angulated branch) and deploy (overlap with previous stent). 6. Do POT. Recross to angulated branch at distal strut. Final kissing balloon dilatation. Final POT (not shown in figure).

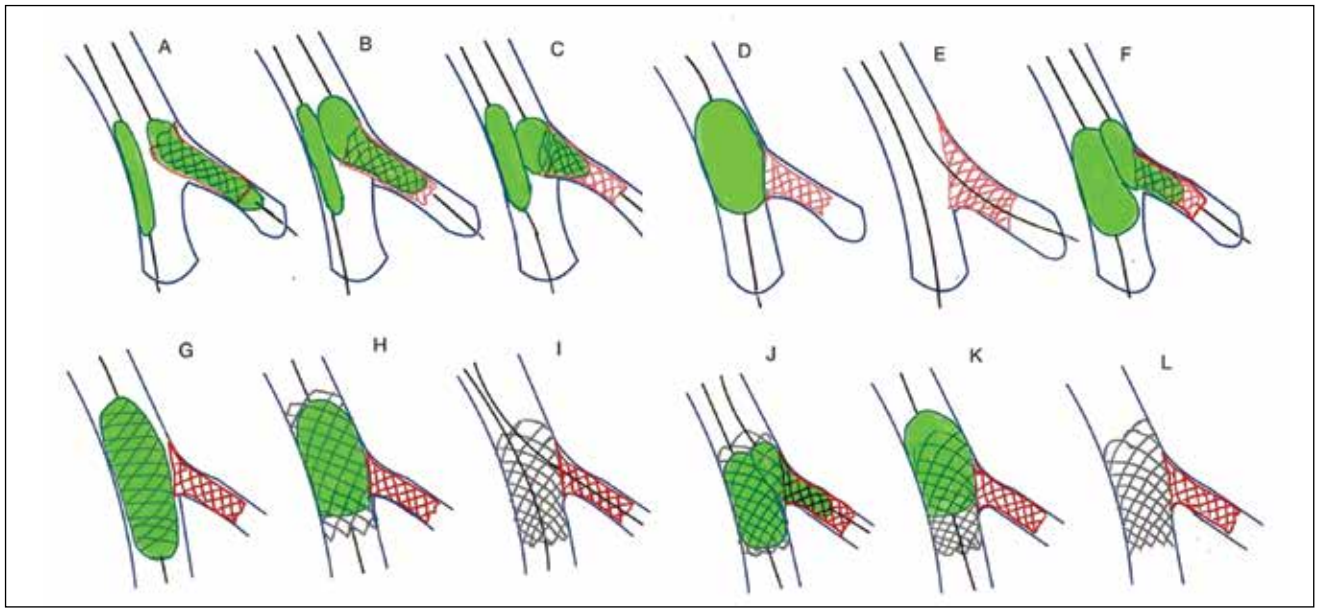


Figure 4: DK crush technique. A: Wire both the vessels and prepare the lesion. The side branch (SB) stent protruding 2-3 mm into the proximal main vessel (MV) is deployed while an uninflated balloon is positioned in the MV; B & C: Optimise the SB stent- slightly withdraw stent balloon and inflate it at a higher pressure. D: Crush the stent by MV balloon after the SB balloon and wire are removed; E: Wire the SB through a non-distal cell; F: First kissing balloon inflation (KBI) after sequential inflation of the two balloons; G: MV stenting after the SB balloon and wire are removed; H: Second POT; I: Wire the SB through a non-distal cell for the second time; J: Second KBI; K: Final POT; L: Final result.

Note: We optimise the SB ostial scaffold in DK crush before deploying the MV stent with an additional KBI. This process involves an additional crush and a SB recross before deploying the MV stent (Steps 2 to 5). The recrossing is done via non-distal struts and POT before recrossing, like other crush techniques.

Critical Points in crush techniques[29]

1. Using smaller balloons for crushing may result in **incomplete crushing**, which in turn increases the risk of the wire slipping inside the lumen of the SB stent instead of passing through the intended two crushed layers. If such a scenario occurs, the first KBI (kissing balloon inflation) would inadvertently lead to the re-expansion of the SB stent.
2. **Step Crush/POT crush-** It is possible to compress the SB stent further using a short balloon that is the same size as the proximal MV. Careful attention should be given to keeping the short balloon proximal to the carina to prevent injury to the distal MV.
3. Consider using **balloon anchoring** in the MV if it is difficult to advance balloons across the crushed stent
4. KBI should be performed using short balloons that are sized 1:1 to the distal MV and SB. **Sequential high-pressure inflation, followed by simultaneous deflation**, is recommended.

Which two stent strategy?

It is essential to choose between the two stent techniques based on factors such as lesion geometry, complexity, bifurcation angle and operator experience. Crush techniques are preferred over culotte in upfront 2-stent bifurcation strategies when there is a significant size disparity between the side branch (SB) and distal main vessel (MV).

The DK crush technique, which involves first KBI, is especially advantageous as it allows the wire to be retained across the MV throughout the procedure. This technique provides an excellent ostial scaffold in the SB and allows for easy recross. Additionally, intentional protrusion of about 2mm of SB stent into MV ensures full SB ostial coverage in case of inadvertent foreshortening of SB stent.

It is worth noting that the DK crush technique is the only upfront 2-stent technique to be reflected in guidelines, with a Class IIb recommendation in the European Society of Cardiology revascularization guidelines.[9] Although mini crush and nano crush involve fewer steps and less procedural complexity, there is a chance of unsuccessful SB access after MV stenting, which can be avoided by consistently performing the DK crush strategy.

DK culotte

The DK crush technique is recognized for yielding a superior scaffold in the side branch ostium, attributed to the implementation of the double kissing procedure. A derivative of the culotte technique, the DK culotte combines the double kissing with the conventional culotte. In vitro studies have demonstrated that the DK culotte concept delivers an exceptional metal scaffold in the side branch ostium.

LMCA PCI in Acute Coronary Syndrome

Unprotected left main (ULM) coronary artery disease is encountered in 3%-10% of coronary angiograms and is associated with high mortality. The survival of patients with ULM disease presenting with acute coronary syndromes (ACS) depends on different variables and is lowest in those with cardiogenic shock (CS).[30] The presence of cardiogenic shock or hemodynamic instability may require the employment of percutaneous coronary Intervention (PCI), despite its potential to complicate primary PCI.

Patients with left main (LMCA) lesions who experience hemodynamic instability have a decreased chance of survival. To prevent mortality during procedures, mechanical circulatory support is necessary. There are several mechanical circulatory devices available, including the intra-aortic balloon pump (IABP), Impella, and extracorporeal membrane oxygenation (ECMO). These devices can help unload the ventricle during percutaneous coronary Intervention (PCI) and facilitate revascularization.[31]

Even though 2011 ACCF/AHA /SCAI guideline give class 2a recommendation for LMCA PCI for STEMI the updated guidelines do not specifically mention the ACS-LMCA scenario.[32].Reasonable outcomes can be obtained in complex LMCA lesions even in acute settings with current PCI techniques and imaging guidance. Randomized studies involving ACS in LMCA lesions need to be conducted to solve this puzzle.

Mechanical Support in LMCA PCI

Over the past two to three decades, there has been significant progress in coronary intervention techniques. The availability of low-profile balloons and atherectomy devices has widened the scope of percutaneous interventions.

The goal of MCS in high-risk PCI is to provide sufficient forward cardiac output to maintain myocardial flow and end organ perfusion and to unload the left ventricle during the procedure. Intra-aortic balloon pump (IABP) has been the most widely used mechanical assist device in hemodynamically unstable patients. Even though IABP helps in afterload reduction, it didn't show any survival benefit in randomised trials like IABP shock II which included patients with AMI and cardiogenic shock.[33]

Impella is a continuous non-pulsatile micro axial pump which helps to unload the ventricle during complex PCI. It improves cardiac output, decreases pulmonary capillary wedge pressure, decreases myocardial oxygen demand. Impella device has been studied in an elective high risk PCI population against preprocedural IABP in the PROTECT II study.[34] It showed lower rate of composite MACE with Impella compared to IABP at 90 days. The FDA has approved Impella devices for use in cardiogenic shock after AMI and for use in urgent and elective high-risk PCI like unprotected LMCA -PCI (Impella 2.5 and Impella CP ≤ 6 hours).[35]

Tandem Heart LV assist device is a continuous flow centrifugal pump wherein oxygenated blood is drawn from the left atrium, propelled by a magnetically driven six-blade impellar, and delivered to femoral artery via an arterial canula. This device has also been used with good short-term success as an adjunctive tool for high-risk PCI.[36]

In short, cardiogenic shock complicating AMI and complex high-risk coronary intervention is associated with a high incidence of morbidity and mortality. Mechanical circulatory support device selection should be carefully individualised using a specialised, multidisciplinary team approach.

CONCLUSION

According to the existing clinical evidence, both coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) demonstrate equivalent efficacy in managing patients with left main coronary artery (LMCA) disease and low to intermediate anatomic complexity. Nevertheless, the long-term comparative effectiveness of CABG and PCI in specific patient cohorts remains uncertain. Subsequent follow-up data from pivotal trials such as EXCEL and NOBLE are anticipated to facilitate a more streamlined decision-making process.

Q &A

1. Which one of the following randomized controlled trials represent study on left main coronary intervention.

   a) PRECOMBAT

   b) LEMANS

   c) NOBLE

   d) EXCEL

   e) All the above

Ans: e

2. Identify the left main intervention trial (RCT)which failed to demonstrate the non-inferiority of PCI over CABG.?

   a) LEMANS

   b) SYNTAX

   c) NOBLE

   d) EXCEL

   e) Both c & d

Ans: c

3. Identify the false statement regarding mechanical circulatory support n LMCA disease

   a) Balloon occlusion during PCI for LMCA disease can cause hemodynamic collapse

   b) Mechanical circulatory devices should be used prophylactically in all left main PCI

   c) Cardiogenic shock with LMCA disease is associated with high morbidity and mortality.

   d) Myocardial stunning from cardiogenic shock in LMCA may not recover rapidly even after successful PCI.

   e) All are true

Ans: b

4. Which one of the following represent Carinal angle.?

   a) A

   b) B

   c) C

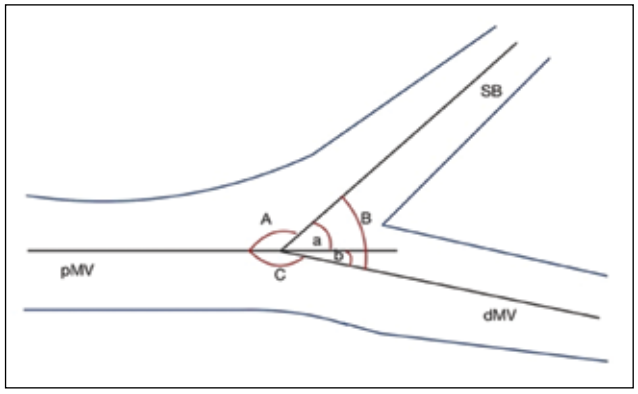
   d) a

   e) b

Ans: d

5. Which one of the following are incorrect regarding the advantages of POT.?

   a) Make SB access easier after MV stent implantation



   b) Reduce risk of SB compromise due to carina displacement

   c) Use long and large size balloon possible.

   d) Important in both 1stent and 2 stent bifurcation strategies

Ans: c

6. Which among the following technique/techniques you will consider for SB PCI after a MV stenting in provisional bifurcation strategy.?

   a) T stenting

   b) TAP

   c) Culotte

   d) Any of the above

   e) None of the above

Ans: d

7. Which among the following represent a 2 stent technique for SB stenting.?

   a) T/TAP

   b) Crush technique

   c) Culotte

   d) b & c

   e) All the above

Ans: e

8. Which among the following 2 stent technique/ techniques can be used for optimizing SB stenting in situations where a single stent was planned beforehand.?

   a) T/TAP

   b) Crush technique

   c) Culotte

   d) a& c

   e) All the above

Ans: d

9. Which one of the following is/are TRUE regarding DK crush technique.?

   a) Need to recross SB stent twice

   b) POT is not mandatory before first recross as the proximal main vessel has no stent struts. POT still can help as a step crush

   c) POT before second SB recross is mandatory as it facilitates non distal crossing

   d) Adding first KBI clear crushed stent struts away

from the SB ostium and increase the likelihood of successful recross after MV stenting

e) All the above

Ans: e

10. The crush technique is commonly performed via a 7F catheter system, but the following crush techniques can be performed even with a 6F system. Choose the appropriate answer from the following.?

a) Nano crush

b) Mini crush

c) DK crush

d) a+b

e) Any of the above

Ans: e

11. Which one of the following mandate distal stent strut crossing of MV stent while rewiring SB for KBI.?

a) T stenting

b) Culotte

c) DK crush

d) Mini crush

e) a+b

Ans: e

12. Which one of the following techniques does not mandate non-distal crossing of MV stent while performing SB rewiring.?

a) T stenting

b) DK crush

c) Mini crush

d) Nano crush

e) All the above

Ans: a

REFERENCE

1. Pellegrini D, Ielasi A, Tespili M, Guagliumi G, De Luca G. Percutaneous Treatment of Left Main Disease: A Review of Current Status. J Clin Med. 2023 Jul 28;12(15):4972.
2. Papafaklis MI, Bourantas CV, Theodorakis PE, Katsouras CS, Fotiadis DI, Michalis LK. Association of endothelial shear stress with plaque thickness in a real three-dimensional left main coronary artery bifurcation model. Int J Cardiol. 2007 Feb 7;115(2):276–8.
3. Oviedo C, Maehara A, Mintz GS, Araki H, Choi SY, Tsujita K, et al. Intravascular ultrasound classification of plaque distribution in left main coronary artery bifurcations: where is the plaque really located? Circ Cardiovasc Interv. 2010 Apr;3(2):105–12.
4. Buszman PE, Kiesz SR, Bochenek A, Peszek-Przybyla E, Szkrobka I, Debinski M, et al. Acute and Late Outcomes of Unprotected Left Main Stenting in Comparison With Surgical Revascularization. J Am Coll Cardiol. 2008 Feb 5;51(5):538–45.
5. Thuijs DJFM, Kappetein AP, Serruys PW, Mohr FW, Morice MC, Mack MJ, et al. Percutaneous coronary intervention versus coronary artery bypass grafting in patients with three-vessel or left main coronary artery disease: 10-year follow-up of the multicentre randomised controlled SYNTAX trial. The Lancet. 2019 Oct 12;394(10206):1325–34.
6. Ahn JM, Roh JH, Kim YH, Park DW, Yun SC, Lee PH, et al. Randomized Trial of Stents Versus Bypass Surgery for Left Main Coronary Artery Disease: 5-Year Outcomes of the PRECOMBAT Study. J Am Coll Cardiol. 2015 May 26;65(20):2198–206.
7. Stone Gregg W., Kappetein A. Pieter, Sabik Joseph F., Pocock Stuart J., Morice Marie-Claude, Puskas John, et al. Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease. N Engl J Med. 2019 Nov 7;381(19):1820–30.
8. Mäkikallio T, Holm NR, Lindsay M, Spence MS, Erglis A, Menown IBA, et al. Percutaneous coronary angioplasty versus coronary artery bypass grafting in treatment of unprotected left main stenosis (NOBLE): a prospective, randomised, open-label, non-inferiority trial. The Lancet. 2016 Dec 3;388(10061):2743–52.
9. Authors/Task Force members, Windecker S, Kolh P, Alfonso F, Collet JP, Cremer J, et al. 2014 ESC/EACTS Guidelines on myocardial revascularization: The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. 2014 Oct 1;35(37):2541–619.
10. Fihn SD, Blankenship JC, Alexander KP, Bittl JA, Byrne JG, Fletcher BJ, et al. 2014 ACC/AHA/AATS/PCNA/SCAI/STS Focused Update of the Guideline for the Diagnosis and Management of Patients With Stable Ischemic Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines, and the American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. 2014 Nov 4;64(18):1929–49.

11. Neumann FJ, Sousa-Uva M, Ahlsson A, Alfonso F, Banning AP, Benedetto U, et al. 2018 ESC/EACTS Guidelines on myocardial revascularization. Eur Heart J. 2019 Jan 7;40(2):87–165.
12. Ahmad Y, Howard JP, Arnold AD, Cook CM, Prasad M, Ali ZA, et al. Mortality after drug-eluting stents vs. coronary artery bypass grafting for left main coronary artery disease: a meta-analysis of randomized controlled trials. Eur Heart J. 2020 Sep 7;41(34):3228–35.
13. Kuno T, Ueyama H, Rao SV, Cohen MG, Tamis-Holland JE, Thompson C, et al. Percutaneous coronary intervention or coronary artery bypass graft surgery for left main coronary artery disease: A meta-analysis of randomized trials. Am Heart J. 2020 Sep 1;227:9–10.
14. D'Ascenzo F, De Filippo O, Elia E, Doronzo MP, Omedè P, Montefusco A, et al. Percutaneous vs. surgical revascularization for patients with unprotected left main stenosis: a meta-analysis of 5-year follow-up randomized controlled trials. Eur Heart J - Qual Care Clin Outcomes. 2021 Nov 1;7(5):476–85.
15. Sabatine MS, Bergmark BA, Murphy SA, O'Gara PT, Smith PK, Serruys PW, et al. Percutaneous coronary intervention with drug-eluting stents versus coronary artery bypass grafting in left main coronary artery disease: an individual patient data meta-analysis. The Lancet. 2021 Dec 18;398(10318):2247–57.
16. Lawton JS, Tamis-Holland JE, Bangalore S, Bates ER, Beckie TM, Bischoff JM, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022 Jan 18;79(2):e21–129.
17. Isner JM, Kishel J, Kent KM, Ronan JA, Ross AM, Roberts WC. Accuracy of angiographic determination of left main coronary arterial narrowing. Angiographic--histologic correlative analysis in 28 patients. Circulation. 1981 May;63(5):1056–64.
18. Jasti V, Ivan E, Yalamanchili V, Wongpraparut N, Leesar MA. Correlations between fractional flow reserve and intravascular ultrasound in patients with an ambiguous left main coronary artery stenosis. Circulation. 2004 Nov 2;110(18):2831–6.
19. Kang SJ, Ahn JM, Song H, Kim WJ, Lee JY, Park DW, et al. Comprehensive intravascular ultrasound assessment of stent area and its impact on restenosis and adverse cardiac events in 403 patients with unprotected left main disease. Circ Cardiovasc Interv. 2011 Dec 1;4(6):562–9.
20. De Maria GL, Testa L, de la Torre Hernandez JM, Terentes-Printzios D, Emfietzoglou M, Scarsini R, et al. A multi-center, international, randomized, 2-year, parallel-group study to assess the superiority of IVUS-guided PCI versus qualitative angio-guided PCI in unprotected left main coronary artery (ULMCA) disease: Study protocol for OPTIMAL trial. PloS One. 2022;17(1):e0260770.
21. Park S, Park SJ, Park DW. Percutaneous Coronary Intervention for Left Main Coronary Artery Disease. JACC Asia. 2022 Apr;2(2):119–38.
22. Chen SL, Sheiban I, Xu B, Jepson N, Paiboon C, Zhang JJ, et al. Impact of the complexity of bifurcation lesions treated with drug-eluting stents: the DEFINITION study (Definitions and impact of complEx biFurcation lesIons on clinical outcomes after percutaNeous coronary IntervenTIOn using drug-eluting steNts). JACC Cardiovasc Interv. 2014 Nov;7(11):1266–76.
23. Lassen JF, Holm NR, Stankovic G, Lefèvre T, Chieffo A, Hildick-Smith D, et al. Percutaneous coronary intervention for coronary bifurcation disease: consensus from the first 10 years of the European Bifurcation Club meetings. EuroIntervention J Eur Collab Work Group Interv Cardiol Eur Soc Cardiol. 2014 Sep;10(5):545–60.
24. Burzotta F, Lassen JF, Banning AP, Lefèvre T, Hildick-Smith D, Chieffo A, et al. Percutaneous coronary intervention in left main coronary artery disease: the 13th consensus document from the European Bifurcation Club. EuroIntervention J Eur Collab Work Group Interv Cardiol Eur Soc Cardiol. 2018 May 20;14(1):112–20.
25. Hildick-Smith D, Egred M, Banning A, Brunel P, Ferenc M, Hovasse T, et al. The European bifurcation club Left Main Coronary Stent study: a randomized comparison of stepwise provisional vs. systematic dual stenting strategies (EBC MAIN). Eur Heart J. 2021 Oct 1;42(37):3829–39.
26. Chen SL, Zhang JJ, Han Y, Kan J, Chen L, Qiu C, et al. Double Kissing Crush Versus Provisional Stenting for Left Main Distal Bifurcation Lesions: DKCRUSH-V Randomized Trial. J Am Coll Cardiol. 2017 Nov 28;70(21):2605–17.
27. Di Gioia G, Sonck J, Ferenc M, Chen SL, Colaiori I, Gallinoro E, et al. Clinical Outcomes Following Coronary Bifurcation PCI Techniques: A Systematic Review and Network Meta-Analysis Comprising 5,711 Patients. JACC Cardiovasc Interv. 2020 Jun 22;13(12):1432–44.
28. Lee CH, Choi SW, Hwang J, Kim IC, Cho YK, Park HS, et al. 5-Year Outcomes According to FFR of Left Circumflex Coronary Artery After Left Main Crossover Stenting. JACC Cardiovasc Interv. 2019 May 13;12(9):847–55.
29. Raphael CE, O 'Kane Peter D., Johnson TW, Prasad A, Gulati R, Sandoval Y, et al. Evolution of the Crush Technique for Bifurcation Stenting. JACC Cardiovasc Interv. 2021 Nov 8;14(21):2315–26.
30. S P, P A, M O, Jc S, A M, R V, et al. Clinical outcomes after PCI for acute coronary syndrome in unprotected left main coronary artery disease: insights from the Swiss Acute Left Main Coronary Vessel Percutaneous Management (SALVage) study. EuroIntervention J Eur Collab Work Group Interv Cardiol Eur Soc Cardiol [Internet]. 2011 Oct 30 [cited 2024 May 9];7(6). Available from: https://pubmed.ncbi.nlm.nih.gov/21986328/
31. Showkathali R, Yalamanchi RP. Contemporary Left Main Percutaneous Coronary Intervention: A State-of-the-art Review. 2023 Feb 13 [cited 2024 May 9]; Available from: https://www.icrjournal.com/articles/contemporary-left-main-percutaneous-coronary-intervention-state-art-review

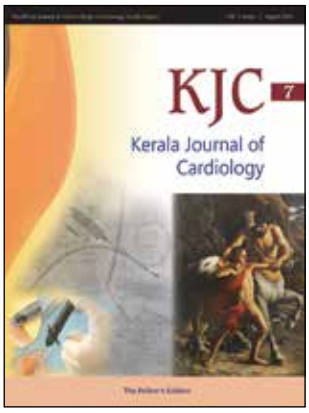
32. Gn L, Er B, Jc B, Sr B, Ja B, B C, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Circulation [Internet]. 2011 Dec 6 [cited 2024 May 9];124(23). Available from: https://pubmed.ncbi.nlm.nih.gov/22064601/

33. Thiele Holger, Zeymer Uwe, Neumann Franz-Josef, Ferenc Miroslaw, Olbrich Hans-Georg, Hausleiter Jörg, et al. Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock. N Engl J Med. 2012;367(14):1287–96.

34. O'Neill WW, Kleiman NS, Moses J, Henriques JPS, Dixon S, Massaro J, et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study. Circulation. 2012 Oct 2;126(14):1717–27.

35. Schreiber T, Wah Htun W, Blank N, Telila T, Mercado N, Briasoulis A, et al. Real-world supported unprotected left main percutaneous coronary intervention with impella device; data from the USpella registry. Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv. 2017 Oct 1;90(4):576–81.

36. Aggarwal B, Aman W, Jeroudi O, Kleiman NS. Mechanical Circulatory Support in High-Risk Percutaneous Coronary Intervention. Methodist DeBakey Cardiovasc J. 2018;14(1):23–31.



Bifurcation Angioplasty - The Editors' Cut

Abhilash S P
Professor, Cardiology
Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerala.

1. Use a minimum 7 Fr guide to reduce complexities subsequently.
2. Wire the more angulated vessel first. This will reduce the chances of wire entangling.
3. Routine side branch (SB) ostial pre-dilatation is not mandatory for provisional strategy.
4. Always choose the main branch (MB) stent based on distal MB vessel size. A proximal optimisation technique (POT) is mandatory for the MB stent in all bifurcation lesions. No need to remove SB wire during MB stenting or during POT. Always use a new wire for SB jailing. Radio opaque part of the jailed wire should be always beyond the carina. Be extra careful if there is calcium.
5. POT balloon to be chosen based on proximal MB size or use the formula → 2/3rd the size of SB+MB diameters. If available, use IVUS to do all the sizing and to identify the landing zones (Plaque burden less than 50%). Undersize IVUS size of vessels by 0.25 to 0.5 mm when choosing stents.
6. MB stent should be at least 8-10 mm proximal to the carina to accommodate the shortest POT balloon (Usually POT done by 6 or 8 mm NC balloon. Always remember that larger balloons used for POT as in LMCA will have significant overhang and place the MB stent with sufficient length proximal to carina to accommodate this overhang).
7. Recrossing to a SB should be preceded by POT in all techniques of bifurcation stenting. In the first recrossing of DK crush, there is no stent proximal to do POT other than the crushed stent and hence many operators avoid a POT. But doing a POT prior to the first recrossing here as well ensures a good crush of the SB stent and avoids the new wire going between partially crushed struts of the SB stent. (This POT is known as the step crush in DK crush. Initial crush might not be complete because the balloon used for crushing would be chosen according to distal MB size)
8. The wire being used for recrossing can be the MB wire (If there is no distal dissection in MB stent edge) or a 3rd wire. Use a hydrophilic/coated wire for easier recrossing.
9. POT prevents wire entering through the sides of the stent if a 3rd wire is used for recrossing and it also facilitates distal recrossing. The recrossing is always "distal" in all techniques (provisional T/TAP, culotte) except crush techniques. Distal recrossing avoids excess metal at the carina in all techniques (provisional T/TAP, culotte) except crush techniques in which lack of metal coverage of carina is the concern. In addition, distal crossing minimises the SB stent protrusion into MB in provisional T/TAP stenting.
10. Crush techniques (Mini crush, DK crush) are better done with "non distal" recrossing. Even though it was originally recommended as "proximal recrossing" for crush techniques, too much proximal recrossing could be problematic for

Address for correspondence: Dr. Abhilash S P, Bhavani, TC 7/491 (6), NLRA 333, Neerazhi Lane, Ulloor, Thiruvananthapuram - 695 011.
E-mail: abhispin@gmail.com

advancing balloon/stent into MB after side branch pre-dilatation. A "non-distal" or "mid" crossing makes most sense for crush techniques. Please note that same principles apply to both the first and the second recrossing in all two stent strategies.

11. Whenever SB stent is positioned, prior to the deployment of the stent always ensure that a balloon is placed in the MB across the SB stent except in culotte technique. This will ensure just enough protrusion of the SB stent into MB and will avoid difficulty in tracking balloon/stent into MB after SB stenting.
12. Whenever a wire is likely to be crushed between two metals, remove that wire before stenting. In all other situations, side branch wire need not be removed. A potential exception could be when a wire is getting crushed between a calcified coronary and metal. It is preferable to remove the wire in the SB in calcified coronaries before the deployment of MB stent.
13. In DK crush, some operators do not remove SB wire before the first crush with the balloon. The argument is first crush is always done with a balloon sized to the distal MB and will never result in complete crush of the SB stent and hence the SB wire will not get trapped. However, author's preference is to remove the SB wire before any crush between metals including the first crush in DK crush.
14. In provisional stenting, PCI can end with MB stenting and POT. No dilatation/opening of struts across SB is routinely recommended.
15. If SB is compromised (acute closure/less than TIMI 3 flow), recrossing and pre dilatation followed by POT is advised. (POT-SB dilatation-POT). If still SB results are not acceptable, kissing balloon inflation (KBI) is advised. If the results do not improve after KBI or if there is dissection of SB, second stent is to be planned to the SB.
16. In all two stent strategies, KBI followed by final POT is mandatory.
17. If KBI is done at any point in stenting, it should be followed by POT to the MB (except the first KBI in DK crush technique).
18. If KBI cannot be done, POT-SB dilatation-POT is a reasonable alternative.
19. Final POT balloon must be placed proximal to carina in all two stent strategies. An exception to this rule is the final POT in provisional two stent strategy. Here the POT balloon should be placed proximal to the neo-carina formed by the SB stent.
20. Usage of imaging like IVUS is strongly encouraged and will help to assess the results of the stenting viz. area achieved, under expansion, mal apposition, edge dissections and geographic miss.

TEN COMMANDMENTS IN BIFURCATION PCI

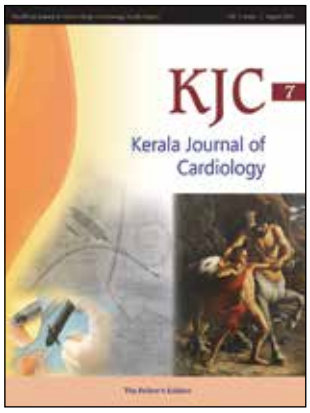
I	Always choose the MB stent based on distal main vessel size
II	A POT is mandatory for the MB stent in all bifurcation lesions
III	MB stent should be at least 8-10 mm proximal to the carina to accommodate the shortest POT balloon
IV	Every recrossing to a SB should be preceded by a POT
V	The recrossing is "distal" in all techniques (provisional T/TAP, culotte) except crush techniques
VI	Crush techniques (Mini crush, DK crush) are better done with "non distal" recrossing.
VII	Whenever SB stent is positioned, prior to the deployment of the stent always ensure that a balloon is placed in the MB across the SB stent except in culotte technique
VIII	Whenever a wire is likely to be crushed between two metals, remove that wire before stenting
IX	In all two stent strategies, KBI followed by final POT is mandatory
X	If KBI is done at any point in stenting, it should be followed by POT to the MB

KJC Pearls

Chiron Teaches Art and Medicine Too...!

Unlocking the Secrets of Cardiovascular Implantable Electronic Devices: A Must-Know Guide for Cardiology Fellows! Page: 78

Syncope in a Young Male – A Case Report Page: 100



Unlocking the Secrets of Cardiovascular Implantable Electronic Devices: A Must-Know Guide for Cardiology Fellows!

Saikiran Kakarla
BCHIC Fellow, BRICS Cardiovascular Health Innovation Centre, Xiamen University, China. (Former Asst. Professor, SCTIMST, Thiruvananthapuram, Kerala).

INTRODUCTION

There is a rapid increase in the insertion of implantable devices with rising complexities for a broad range of indications globally. The Asia Pacific Heart Rhythm Society (APHRS), in its official 10th edition white book 2022, mentioned that 44588 devices per billion people (PBP) were implanted in India in 2021. This number includes the 5742 PBP of high-energy devices (implantable cardioverter defibrillators (ICDs) and cardiac resynchronisation therapy defibrillators (CRT-D)). There was an increase of 15.9% in pacemaker implantation in 2021 compared to 2020 in India.[1] The share of new ICD and CRT implantation rates was4.0 and 2.9 per million inhabitants in 2021.[1] It is important to note that this represents only a fraction of the data that has been published. A chest radiograph is an invaluable tool in assessing the CIEDs in the immediate post-implantation period and on follow-up in predicting and diagnosing complications. Hence, it is imperative to say that there is a definitive need for the cardiologist to know about those devices' complications and radiological appearances. This review helps clinicians update their knowledge of the appearance of CIEDs and complications on chest radiographs.

ANATOMY OF CIED

Typically, conventional CIED can be divided into two main parts: the pulse generator and the leads, whereas a leadless pacemaker is a well-known exception.

1. PARTS OF THE USUAL DEVICE

A) Pulse generator (Fig.1,2)

The pulse generator contains electrical circuitry with a capacitor, a programmed computer for heart rhythm monitoring and providing appropriate pacing support in times of need along with a battery (which usually lasts for 5 – 12 years that is subjective to the device type and utility). It is designed to detect the heart's intrinsic rhythm and send an electrical impulse to the heart, if necessary, within its programmed settings. The size and circuitry vary depending on the type of the device and manufacturer (Fig.1). Apart from the typical left infraclavicular location for the pulse generator, the right infraclavicular area, axilla, and epigastric location are also seen (Fig.2).

Address for correspondence: Saikiran Kakarla, BCHIC Fellow, BRICS Cardiovascular Health Innovation Centre, Xiamen University, China.
Email: doctorsaikirankakarla@gmail.com

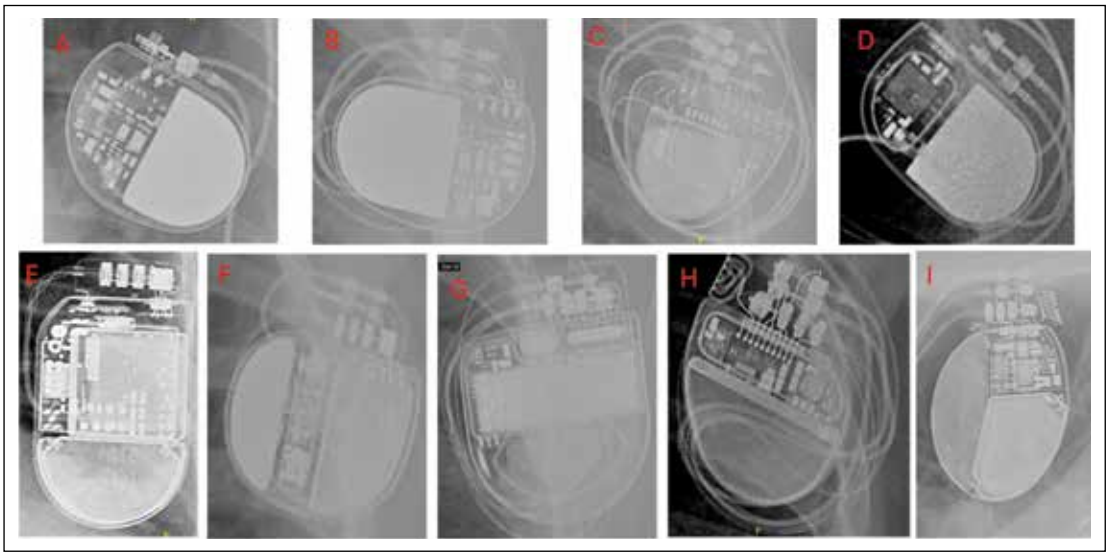


Fig.1: Different pulse generators available in the current market showing varying sizes of capacitors, batteries, and cans. Medtronic single chamber pulse generator (A), Medtronic double chamber pulse generator (B), Medtronic bipolar CRT-P pulse generator (C), Biotronik double chamber pulse generator (D), St Jude Medical Single chamber DF4 AICD pulse generator (E), Boston Scientific double chamber DF4 AICD pulse generator(F), Medtronic CRT-D pulse generator (G), Boston Scientific CRT-P pulse generator (H), Boston Scientific DF1 dual-chamber pulse generator (I)

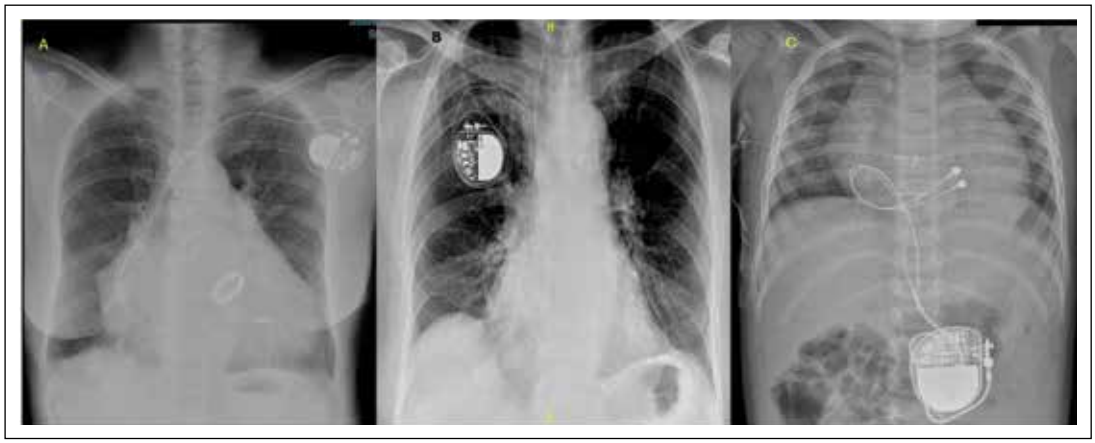


Fig. 2: Different locations of the pulse generator left infraclavicular location (A), right infraclavicular location (B), epigastrium location (C)

B) Electrodes and Leads (Fig.3)

The insulated wires connecting electrodes to a generator are called pacemaker leads. In contrast, the electrode is the uninsulated terminal of the lead connected to the heart. Defibrillator electrodes can be identified on chest radiographs as having coils compared withusual electrodes. Lead tips are held in place within the heart actively or passively.

Active fixation is accomplished using a screw tip, which is readily visible on conventional chest radiographs (Fig.3, Fig.4A).

The radiolucent tines passively fixate the ends of the leads caught in the RV trabecular lining (Fig.4B).

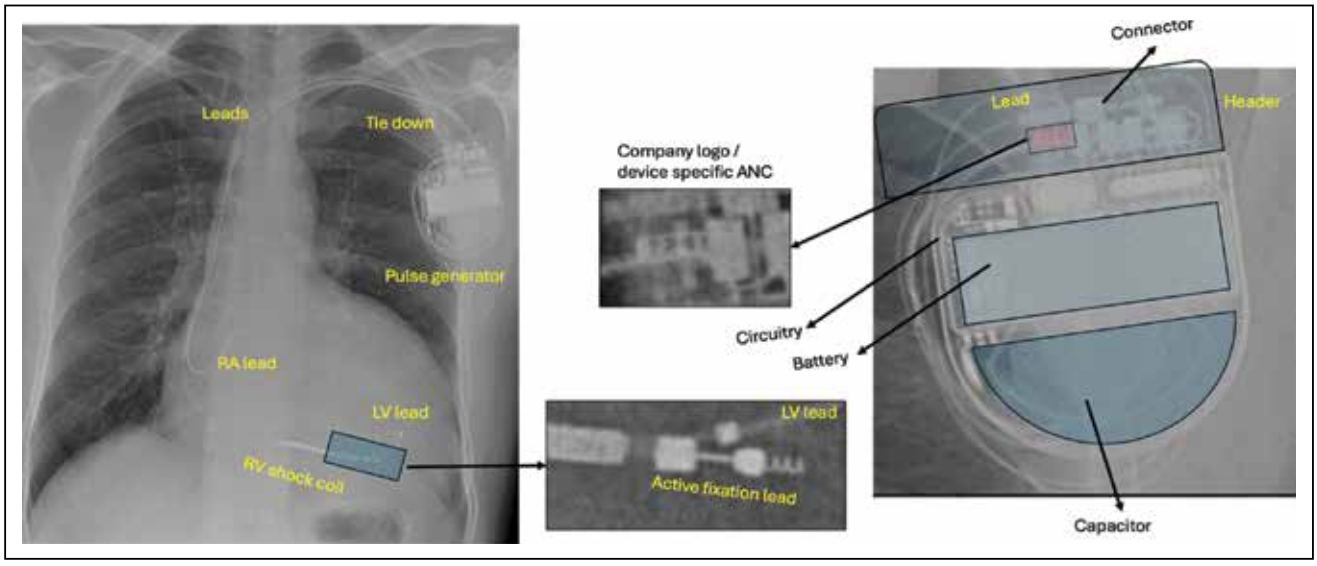


Fig. 3: different parts of a typical cardiac implantable electronic device (CIED). A typical CRT-D (cardiac resynchronisation therapy- defibrillator) was demonstrated. ANC: alphanumeric code

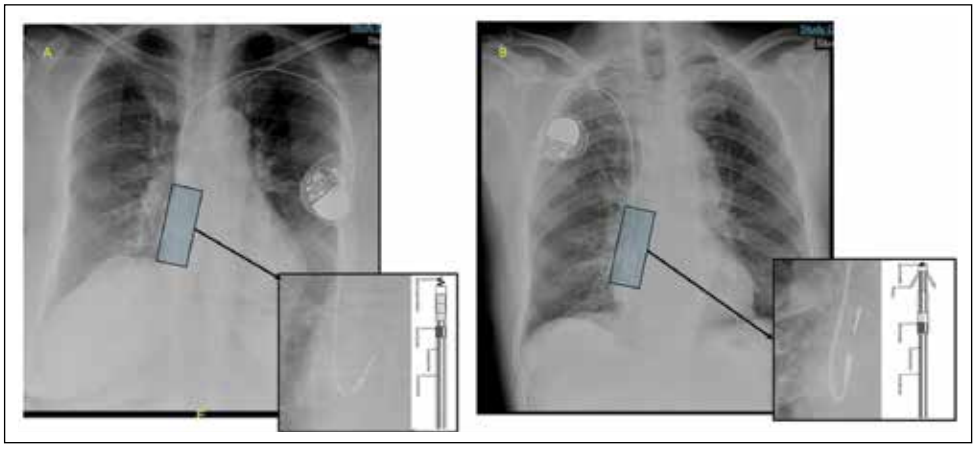


Fig. 4: Different types of screw fixation shown. An active fixation lead in the right atrium (A), a passively fixed lead in the right atrium (B). Inset showed a zoomed view and pictorial representation of both leads.

Multiple leads may be seen in the same chamber as old/damaged leads are often not removed due to high risks of complications associated with the removal procedure. Identifying the number of transvenous leads is vital as it can increase the patient's risk of superior vena cava obstruction and may complicate future attempts at endocardial access. In patients who have undergone removal of their pacing system, an X-ray can identify any lead remnants, which is imperative to be aware of when considering magnetic resonance imaging (MRI) (Fig. 5A, B, C).

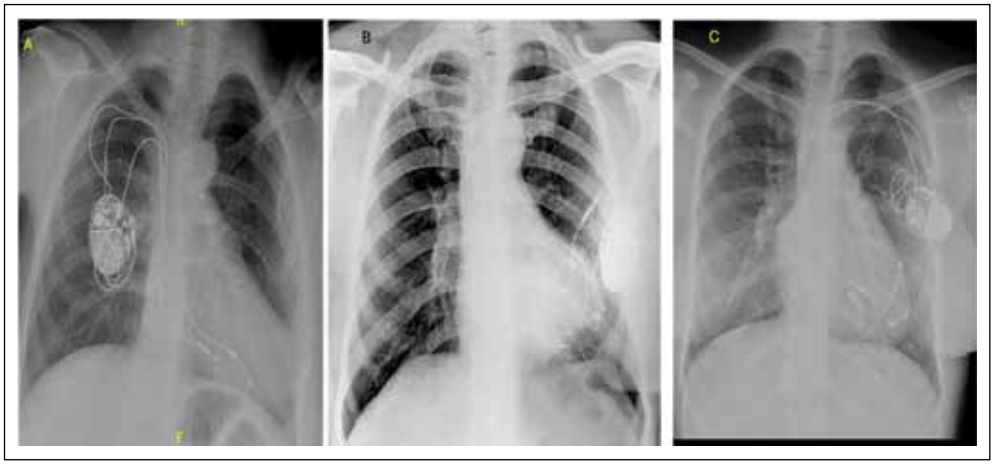


Fig. 5: Multiple redundant loops in right atrium in a patient with CHB who underwent dual chamber pacemaker 20 years ago, as the old tined ventricular lead was dysfunctional, new screwing lead was implanted (A), Single chamber endocardial VVI pacemaker along with old abandoned epicardial lead (B), A case of TGA, post sennings repair, endocardial pacing done into the morphological left ventricle for CHB with two endocardial leads because of pacemaker lead malfunction. Radio-opaque epicardial pacemaker lead fragment noted over the ventricle (C)

2. POSITIONING OF THE DEVICE AND LEADS

A single-chamber pacemaker has one lead, usually inserted into the right atrium (RA) or right ventricle (RV). In contrast, a dual-chamber pacemaker has leads in both RA and RV. When assessing the device, frontal chest X-ray is recommended, and lead position should be assessed ideally in both frontal (Fig.6) and lateral chest X-ray views (Fig.7).

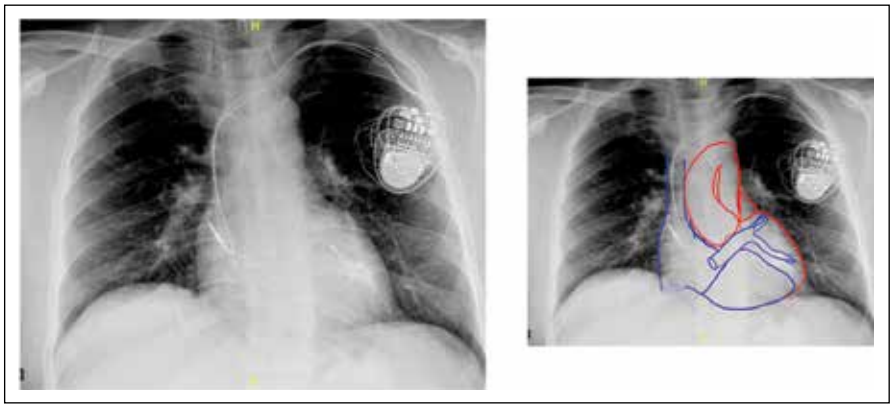


Fig. 6: Frontal chest radiograph of a patient who underwent CRT-P insertion showing various lead positions (RA, RV, LV). Annotated image of the same.

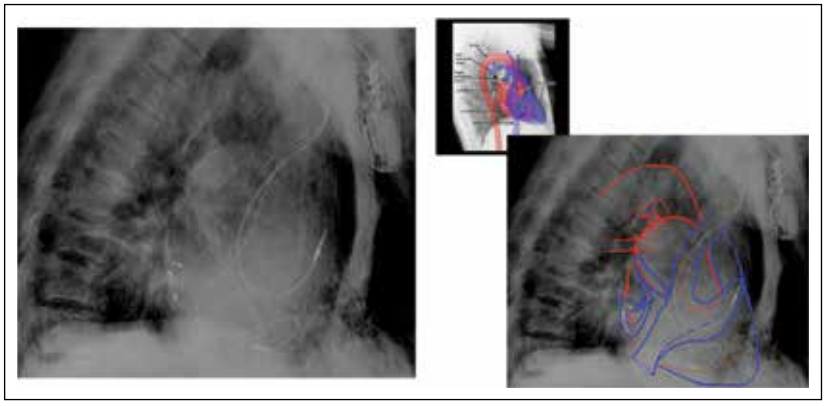


Fig. 7: Lateral chest radiograph showing different lead positions (RA, RV, LV leads) in relation to the cardiac chambers. Annotated image showing the same.

A. The RA lead(Fig.8)

The RA lead is usually inserted in the RA appendage but is rarely positioned in the atrial free wall, high, and lower atrial septum, particularly implanted in patients with fibrotic atrial appendage secondary to sick sinus syndrome. RA lead follows a slight medial course on a posterior-anterior (PA) radiograph whilst it is anterior, subtending an angle < 90 and forming a 'J' / "U" on a lateral view (Fig. 8).

B. The RV lead:

In the past, the RV lead was typically inserted in the apex, but to minimise the complications related to acute lead implantation, ideally, mid-septal insertion is the preferred location now. Moreover it may give a narrower paced QRS complex.

RV lead typically curves along the course of the right atrial lateral wall, passing to the left of the spine on frontal chest X-ray. Apical implantation of the lead can be recognised by its tip pointing towards the cardiac apex. It should be pointing anteriorly and slightly superiorly (or inferiorly) on lateral CXR (Fig. 9, 10, 11).

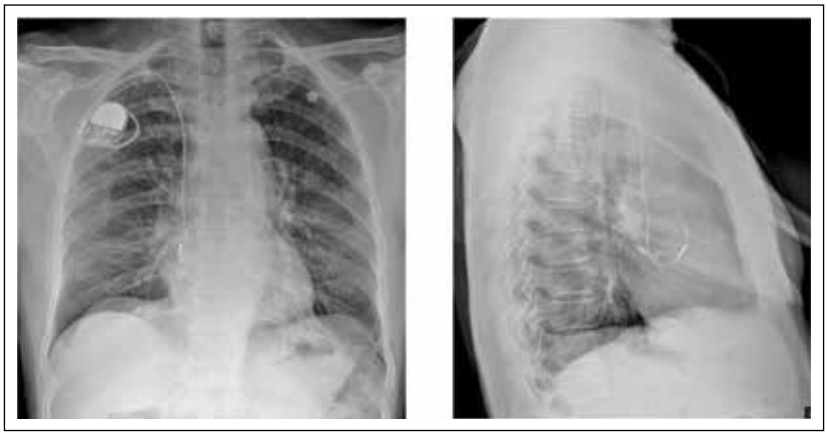


Fig. 8: Tined lead in the RA appendage seen in frontal chest radiograph and lateral film

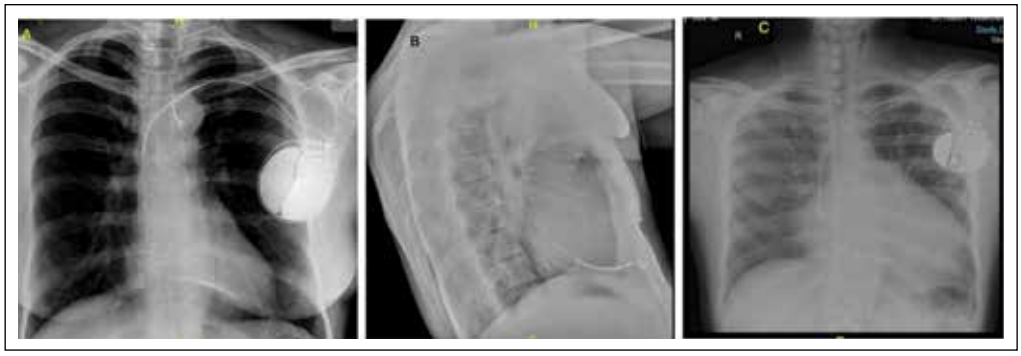


Fig. 9: RV apical pacing lead (Dual coil AICD lead) in frontal and lateral chest radiographs (A, B respectively), A dual chamber AICD insitu (C).

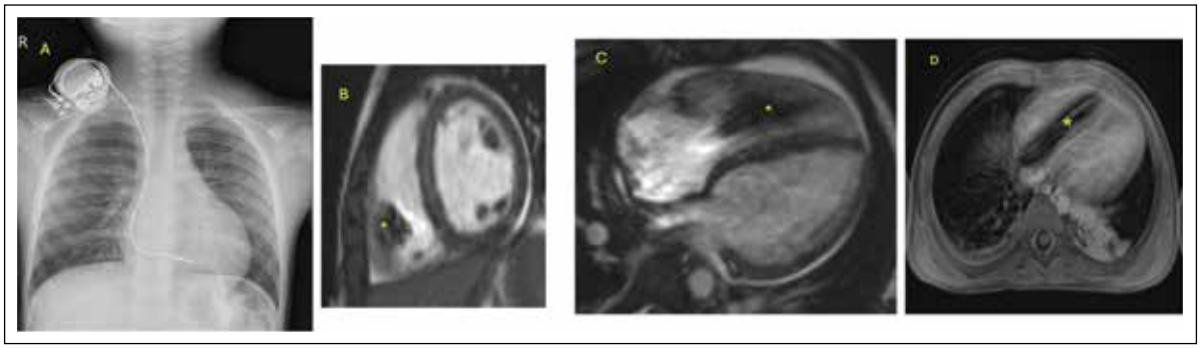


Fig.10: A case of myocarditis with CHB underwent semi permanent pacemaker insertion through Rt IJV on an emergency basis. Chest radiograph shows likely septal implantation of the lead (A), post pacemaker insertion, CMR (B, C, D) showing apical implantation of the lead. This illustrates how fallacious it is to implant pacemaker only in a single RAO/AP view. One should check the LAO view for septal implantation for better outcomes. As this was a semi permanent pacemaker, and this patient recovered from CHB after immunotherapy for myocarditis; the device was explanted later.

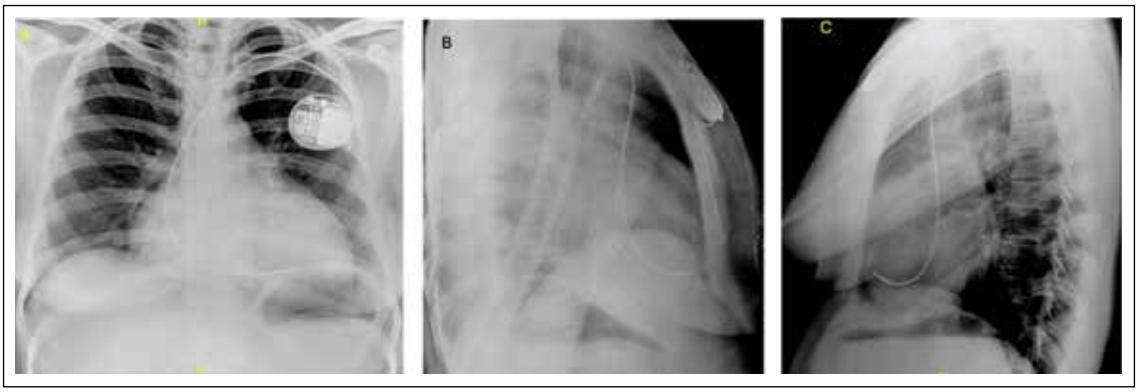


Fig.11: Another case of CHB with single chamber pacemaker insitu, lead position both in frontal (A), right (B) and left lateral (C) chest radiographs.

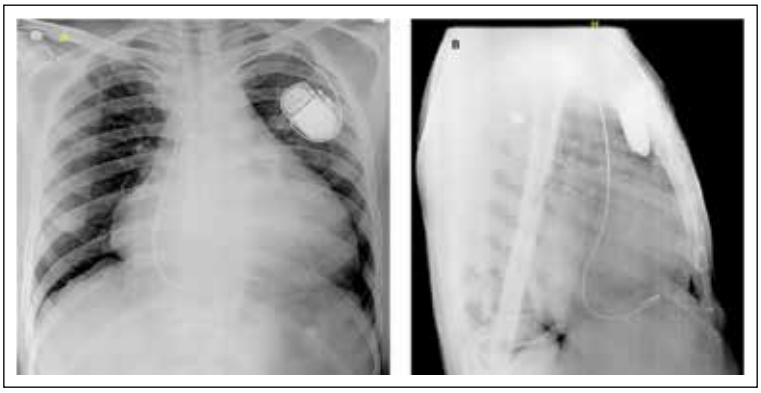


Fig. 12: This is a case of right ventricular endomyocardial fibrosis (RVEMF) in view of AF with a slow ventricular rate who underwent endocardial VVI pacemaker insertion. RV basal septal / inflow septal pacing was done as the body and apex of the right ventricle were obliterated. Frontal (A) and lateral chest radiographs(B) show the lead positions.

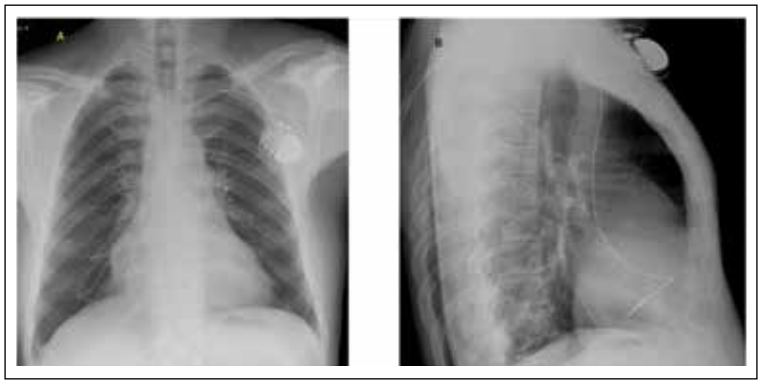


Figure.13: Another case of right ventricular endomyocardial fibrosis (RVEMF) who underwent endocardial VVI pacemaker insertion. RV basal septal / inflow septal pacing was done as the body and apex of the right ventricle were obliterated. Frontal (A) and lateral chest radiographs(B) showing the lead positions.

In the lateral film, septal placement points away from the anterior side. The other placement sites of RV lead may be in the RV outflow tract and inflow, which are particularly useful in individuals with severe degrees of tricuspid regurgitation and RV endomyocardial fibrosis, respectively (Fig.12,13).

C. The LV lead

CRT devices can be identified on chest X-ray by an additional left ventricular(LV) lead. This lead is placed via the coronary sinus and fed into an epicardial venous system. The LV lead is commonly placed at the lateral or posterolateral wall of the LV (Figure14). LV lead is usually implanted as a part of the CRT / left bundle optimised CRT(LOT-CRT) / His bundle optimised CRT (HOT-CRT) (see below).

In rare clinical scenarios, LV lead alone can be a pacing lead. E.g. In a tropical disease like right ventricular endomyocardial fibrosis, the RV body and apex will be obliterated, and only the outflow tract exists. In such cases, pacing may be possible only by the LV lead. LV lead threshold is often normal unless LV endomyocardial fibrosis co-exists. Another situation is a tricuspid mechanical valve, which hinders the pacing lead entry into RV. (Fig. 15C, D &16).

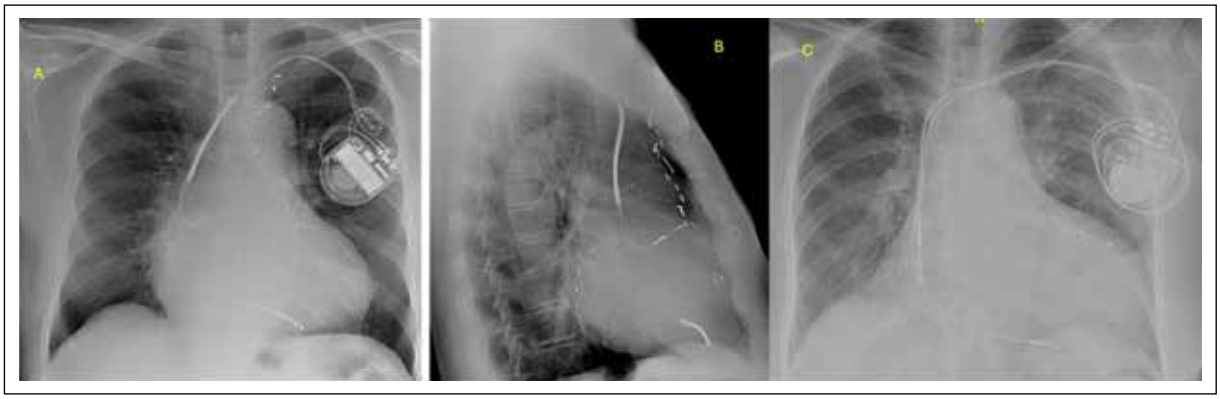


Figure.14: Images show lead positions in a patient with dual chamber dual coil CRT-D in frontal (A) and lateral chest radiographs(B). Note the defibrillator lead is positioned in the apical RV septum. The RA lead in the lateral film shows an L / open "V" configuration, indicating the lead is pulled up due to less loop while fixing the lead. An optimal loop of RA lead should look like the letter "U". Another patient (C) with bipolar CRT-P device insitu.

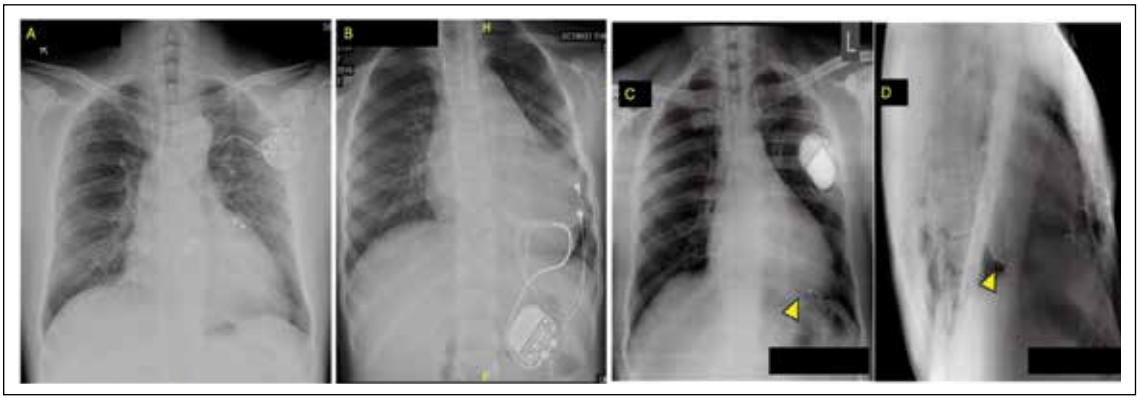


Fig. 15: Figure shows different modalities of LV pacing. Patient A is a case of severe AS with mild LV dysfunction and LBBB, perioperatively developed transient CHB. Hence, an epicardial LV lead was inserted to convert to CRT-P later. But the patient improved after a few weeks of discharge and currently Vp<1% with incomplete LBBB. Hence, CRT-P was not contemplated. LV dysfunction improved after AVR. Epicardial LV pacing with a pulse generator in the left infraclavicular subcutaneous plane can be seen (A). Patient B is a newborn who was diagnosed with severe coarctation of the aorta, and CHB underwent surgical repair and epicardial pacing for CHB with a pulse generator over the abdominal wall. Patient C is a case of severe RV endomyocardial fibrosis and AF with CHB. As there is no RV body and apex, pacing was done with a bipolar LV lead inserted into one of the epicardial coronary venous tributaries and connected to a single-chamber VVI pulse generator. Frontal chest radiograph (C) and lateral film (D) show the position of the LV lead (arrowhead).

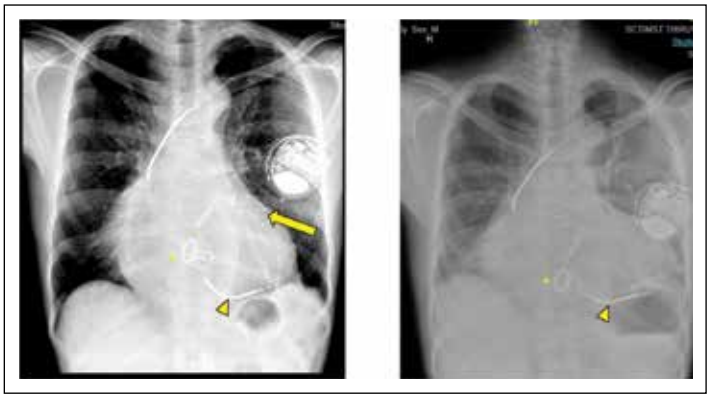


Fig. 16: This is a case of post-operative DVR (AVR + TVR with mechanical prosthesis) with multiple hemodynamically unstable VTs requiring resuscitation and Resuscitated cardiac arrest. The tricuspid valve is a mechanical ball-in-cage prosthesis (*), so a dual coil AICD lead was implanted in the middle cardiac vein (arrowhead). For pacing and sensing, another bipolar LV lead (arrow) was implanted in one of the posterolateral venous tributaries and connected to the DF-1 pulse generator. A frontal radiograph of the same is shown for the lead positions.

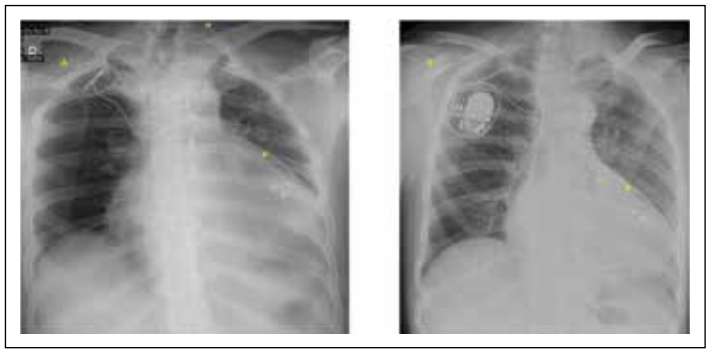


Fig. 17: Frontal chest radiographs showing bipolar epicardial leads implanted for a CRT super-responder. This patient developed a device site infection during a pulse generator replacement. During surgical extraction of the leads, epicardial LV bipolar pacing electrodes (yellow *) were implanted, and later endocardial pacemaker leads were implanted, completing the hybrid CRT (B)

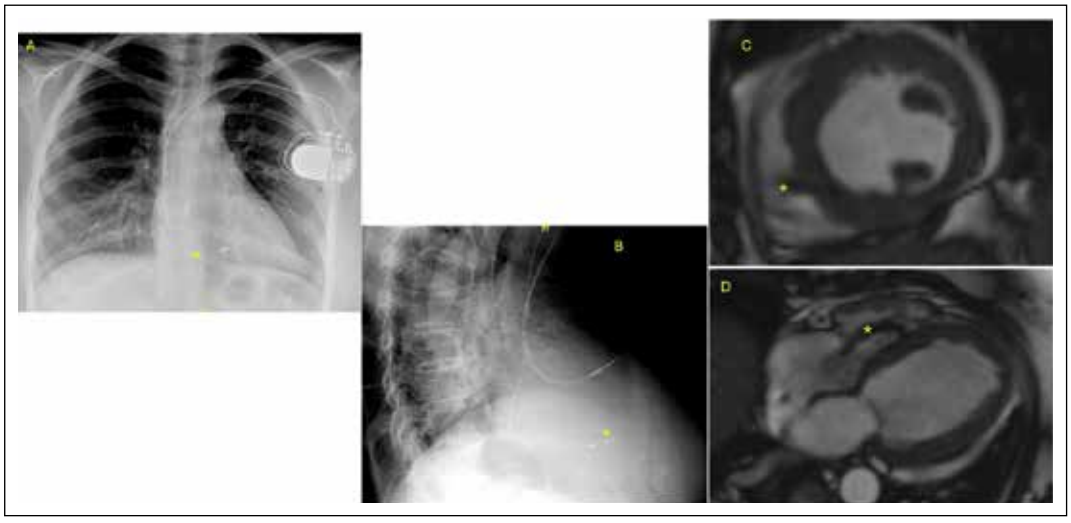


Fig. 18: Images showed lead positions in a case of dual chamber left bundle pacing in frontal and lateral radiographs (A, B). Note that the ventricular lead appears thinner than the atrial lead, which suggests a Medtronic 3830 lead (denoted by an asterisk*). CMR of the same person after pacing shows the position of the 3830 lead (denoted by asterisk*) in the basal interventricular septum (C, D).

Needless to say, epicardial lead placement is an alternative option in these cases. Rarely, surgically implanted lead can be seen at similar locations of LV lead of CRT devices, particularly in patients with no good coronary venous tributaries (Fig.15 A, B & 17). Surgically implanted leads are always bipolar. In contrast, endocardial leads can be quadripolar or bipolar.

D. Physiological pacing lead (Fig.18,19,20)

In left bundle branch area pacing (LBBaP), the lead position is like a conventional lead placed over the mid-septum but with a more basal location in both frontal and lateral projections. Medtronic 3830 lead can be identified by its thinner size, which is 4.1 Fr compared to 6 or 7 Fr conventional leads.

E. Left sided superior venacava (SVC)

All endocardial leads are normally inserted via left or right subclavian veins and then into the superior vena cava (SVC) to enter the cardiac chambers. In case of absent right-sided SVC and prominent left-sided SVC, leads are often inserted through LSVC into the cardiac chambers. (Fig. 21)

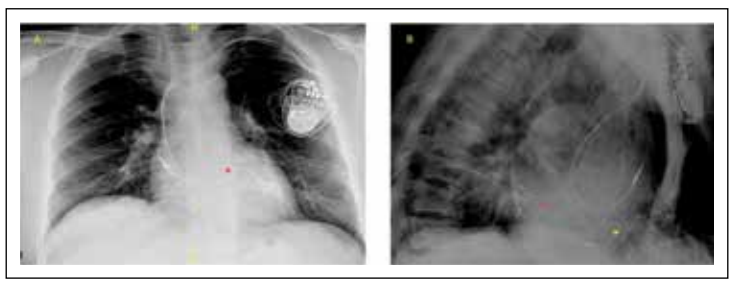


Fig. 19: The images show lead positions in a patient with LOT CRT-P in frontal (A) and lateral chest radiographs(B). Note that the thinner 3830 Medtronic lead is positioned in the basal RV septum(yellow*) and LV lead (red*). The RA lead in the lateral film shows an "U" configuration, which indicates an adequate loop in the lateral film. The reader can compare with Figure 14 to get a visual impression of the optimal atrial lead loop.

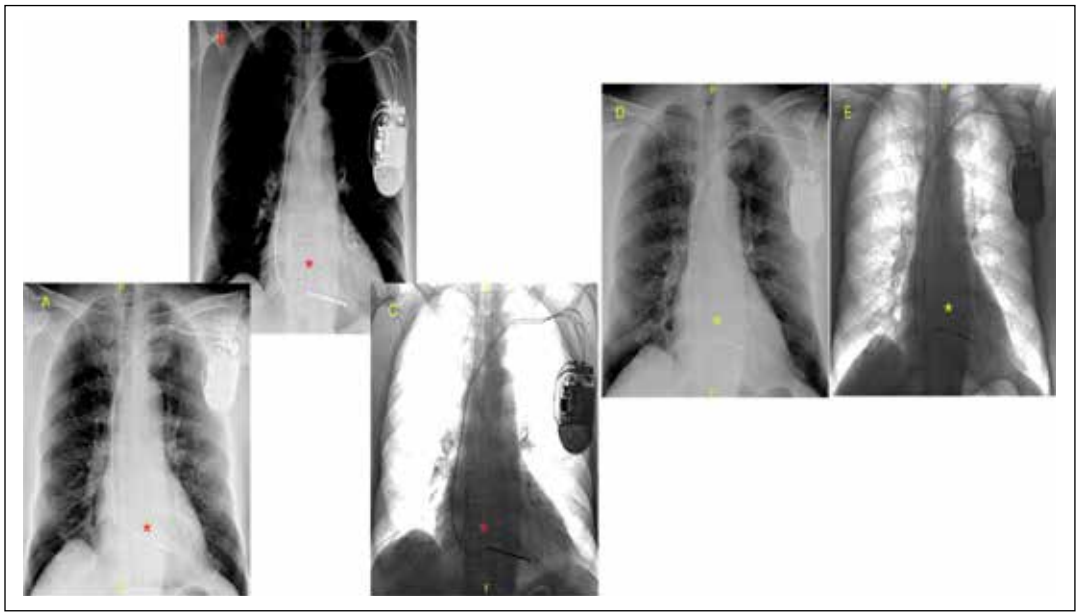


Fig. 20: Images show a case of non-ischemic dilated cardiomyopathy who underwent bipolar SJM CRT-P (A) who presented for routine device interrogation on follow-up after six months of implantation, which showed high LV capture threshold, frontal chest radiograph showed likely displaced LV lead (red *) (B), which was not very clear in routine exposure. When the exposure is decreased, the lead position can be confirmed to be in the proximal coronary sinus. For better visualisation, inversion of the x-ray film can clearly show the lead position. Subsequently he underwent lead revision with left bundle branch pacing as there were no coronary sinus venous tributaries. Frontal chest radiograph (D) and inversion of the same film to visualise the 3830 lead (yellow *).

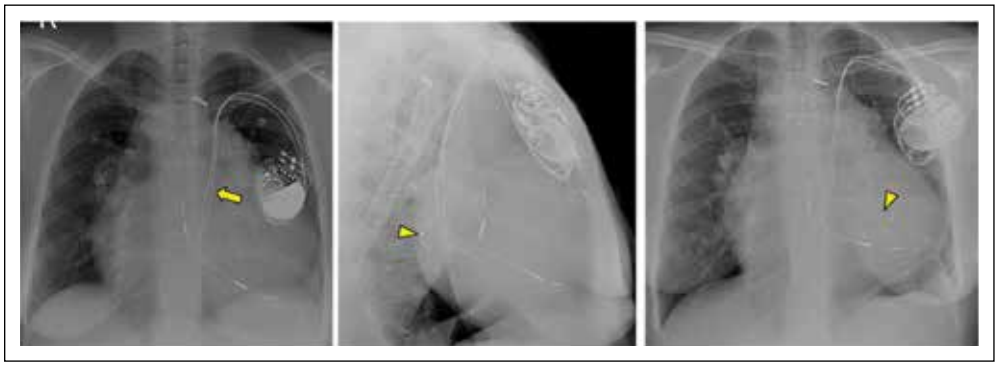


Fig 21: This frontal and lateral chest radiographs of a patient who underwent pacemaker insertion for complete heart block, the course of leads through left SVC seen (this can be recognised by the the presence and course of leads to the left of spine) (arrow) (A), as the patient developed pacing-induced cardiomyopathy and worsening of LV dysfunction later device was upgraded to CRT-P with an additional LV lead (arrow-head) implanted through LSVC.

3. TYPES OF DEVICES

A. Pacemakers

Endocardial pacemakers are inserted via the venous system, typically by subclavian or cephalic approach.

Epicardial systems are inserted via a supradiaphragmatic abdominal incision or by thoracotomy. The generator for a pacemaker can be inserted subcutaneously or below the pectoralis muscle (Figure15 A, B & 22).

Semi permanent pacing is often used as reliable bridging therapy for permanent pacemaker implantation, like reversible complete atrioventricular blocks (CAVB) viz. fulminant myocarditis with CAVB, IWMI with CAVB, dyselectrolytaemia resulting in severe bradycardia. (see Figure.10). They are also useful in pacemaker infections in pacing dependent patients until the infection clears off.

Recently, leadless pacemakers have emerged that can provide backup ventricular pacing. The pacemaker is about the size of a large multivitamin capsule, and it avoids the need for wires to be inserted. It is inserted

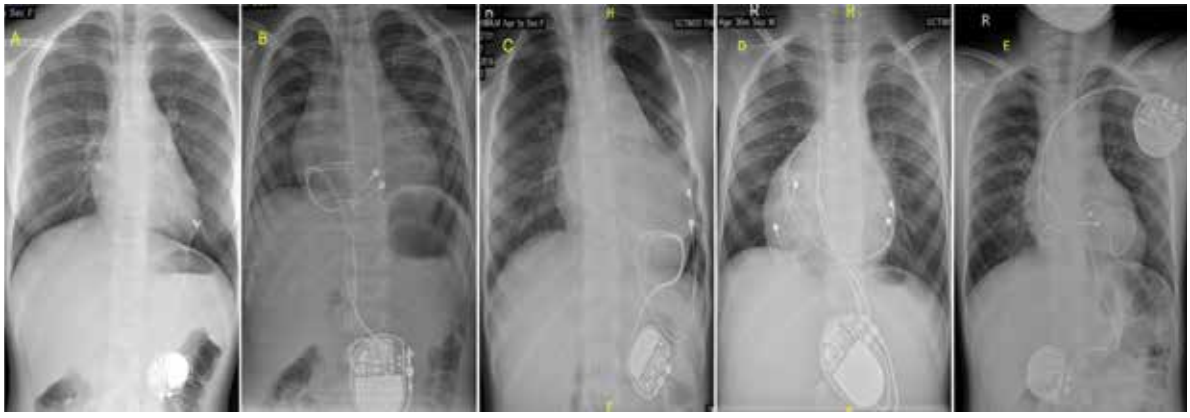


Fig. 22: This image series shows different locations and types of epicardial pacemakers. A Unipolar epicardial lead over the left ventricular tip with single chamber VVI pacemaker (A), A bipolar epicardial single chamber pacemaker, the electrodes of bipolar leads placed over typical location i.e., anterior right ventricular wall (B), Bipolar epicardial lead over the left ventricular tip with single chamber VVI pacemaker (C), A case of situs solitus, dextrocardia, congenitally corrected transposition, post Sennings procedure with CHB, with bipolar dual chamber epicardial pacemaker system and the image shows bipolar atrial lead and bipolar ventricular lead with pulse generator in the epigastrium (D), A case of congenital CHB who underwent bipolar single chamber ventricular epicardial pacemaker insertion in infancy, being upgraded to the endocardial dual chamber system. Note that the endocardial ventricular lead shows an alpha loop that allows sufficient length to accommodate the child's growth of the subclavian vein. After wound healing, the epicardial PG was explanted (E).

into the RV via the femoral venous system. A lateral radiograph is still essential when assessing this system, as leadless pacemakers can be mistaken for implantable loop recorders. (Figure 23)

B. CRT Devices

These devices are typically inserted for patients with significant heart failure on maximal medical therapy. They deliver electrical energy to both ventricles to augment synchrony between the ventricles. They are identified by the presence of leads in both the RV and LV. They may have a pacing electrode in the case of CRT-pacing or a shock coil in CRT-D (see Figures 14, 19, 20,21).

Newer devices, such as wireless cardiac stimulation (WiCS) devices, are being inserted in specialist centres. The LV lead is replacedby a wireless endocardial LV electrode, which communicates with a pulse generator that delivers ultrasound energy to coordinate pacing. The electrode is placed subcutaneously in the left fourth to sixthintercostal space to achieve an optimal acoustic window. The LV endocardialdevice is inserted retrogradely via the aortic valve. These devices are considered when traditional CRT lead placement is not possible ordoes not provide adequate resynchronisation. (Fig.24)

C. Physiological pacing devices

His bundle pacing paved the way for physiological activation of the right ventricle. His bundle pacing leads directly activate the bundle of His, thus correcting the underlying bundle branch block. (Figure 25). Subsequently left bundle branch area pacing has revolutionised the pacing field since its inception. Currently, evidence is accumulating for its non-inferiority over CRT in various aspects. Left bundle-optimized

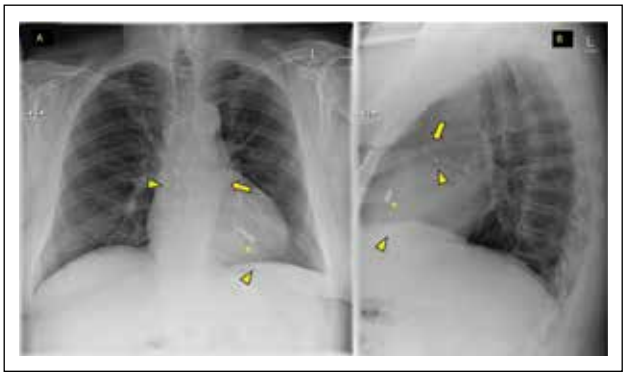


Fig. 23: Frontal (A) and lateral (B) chest radiographs showing lead-less pacemaker insitu (asterisk). Note the presence of the LAA appendage closure device (arrow) and retained RA and RV pacemaker lead tips (arrowhead) as well. (Image courtesy: Marianne Cossens: Radiopedia)

CRT is considered an alternative to conventional CRT in selected patients. The pulse generator is similar to conventional pacemakers and CRT devices. It can be identified by its typical lead position in the proximal or basal septum with or without an epicardial LV lead (Figures18,19). Similarly, isolated LBB area pacing is being done instead of conventional pacing in selected CAVB patients without infrahisian conduction system disease (Fig.18).

D. Implantable cardiac defibrillators

These high-energy devices encompass both ICD and CRT-D. They are designed to deliver a large amount of electrical energy to the heart in response to a life-threatening tachyarrhythmia. Coiled electrodes can identify high-energy devices on chest radiographs (see Figure 9, 14, 20). There may be single or dual shocking coils, i.e., superior vena cava (SVC) and RV coils. The ideal position of the RV screwing lead is at the RV apical septum. (fig.14, 26)

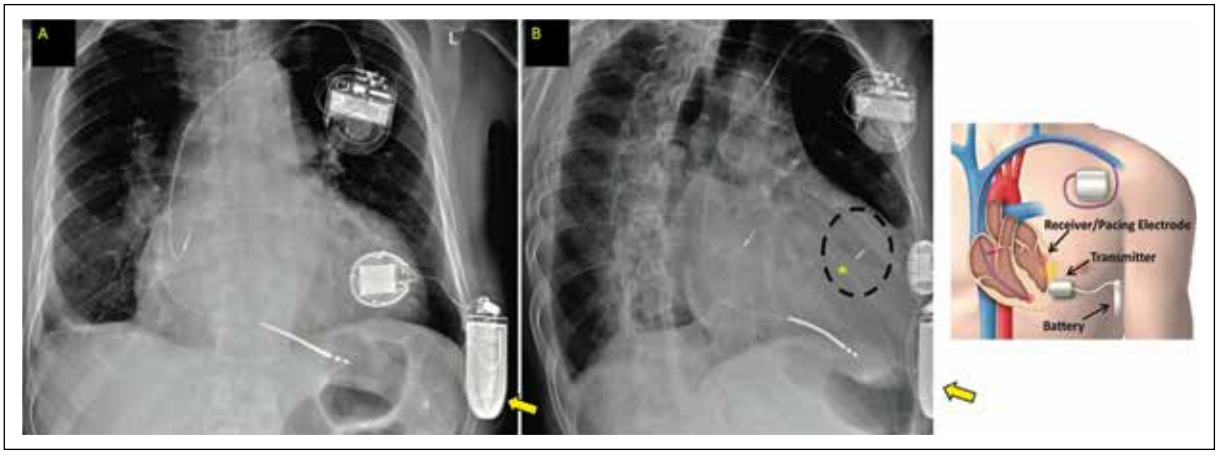


Fig. 24: WiSE CRT system: Wireless left ventricular endocardial pacing: Typical frontal and lateral chest radiographs with wise-CRT system which includes an electrode implanted within the LV endocardium (*), Ultrasound energy pulse emitter and a battery similar to a pulse generator implanted subcutaneously (arrow) and the dual chamber implanted device (in this image dual chamber AICD). A schema is also represented in the inset. (Image courtesy: Reddy et.al From SELECT- LV investigators[2])

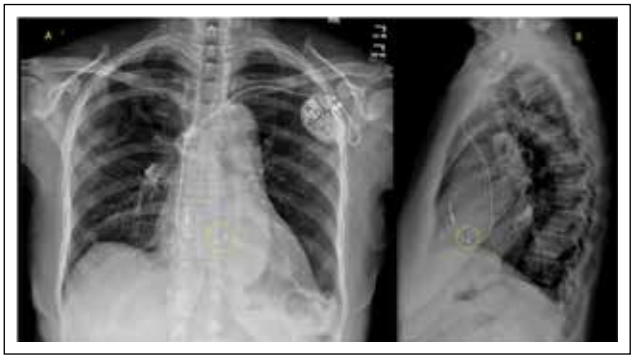


Fig. 25: Chest radiographs in frontal and lateral show the typical location of the His bundle lead (dotted circle) (Image courtesy: Chen et.al).[3]

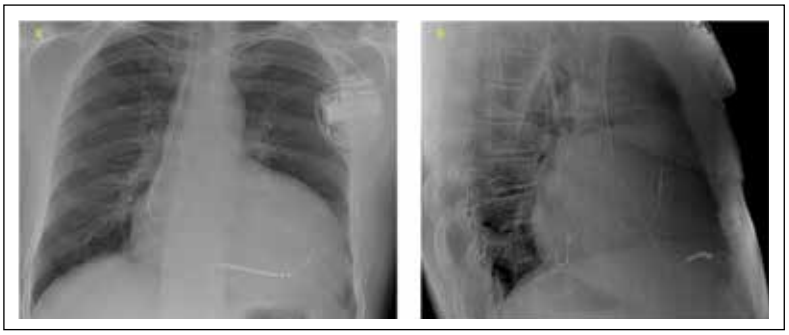


Fig. 26: Frontal and lateral chest radiographs of a patient with a Medtronic CRT-D device. Note the ICD lead was inserted in the typical location of the apical septum. There is a good spatial separation between the LV and RV leads, which favours the CRT response.

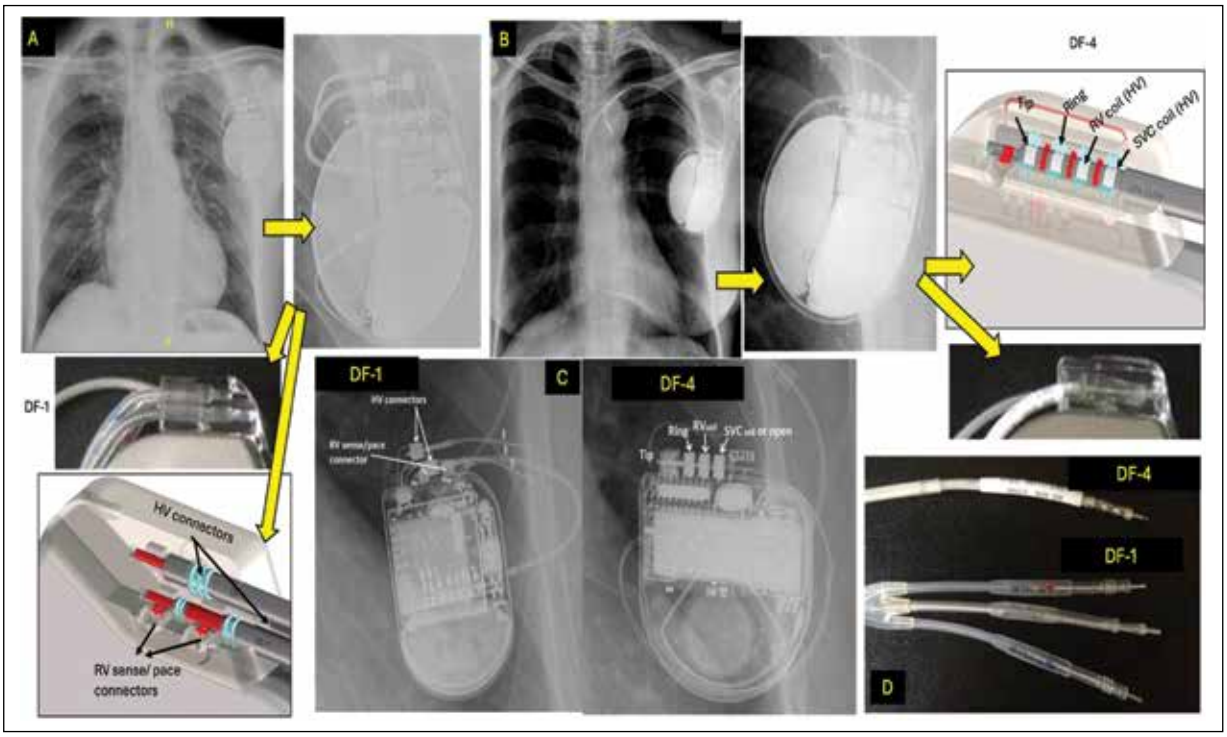


Fig. 27: These frontal radiographs show the different defibrillator pulse generator models: a typical Boston Scientific DF-1 pulse generator with separate ports for pacing, sensing, and high energy (A) and another Boston Scientific DF-4 pulse generator with a single common connector for pacing, sensing, and defibrillation (B). Respective insets show a zoomed view and the pulse generator's typical physical appearance and connections. Annotated typical DF-1 SJM system and Medtronic DF-4 system seen(C). Typical DF-1 and DF-4 leads are shown (D).

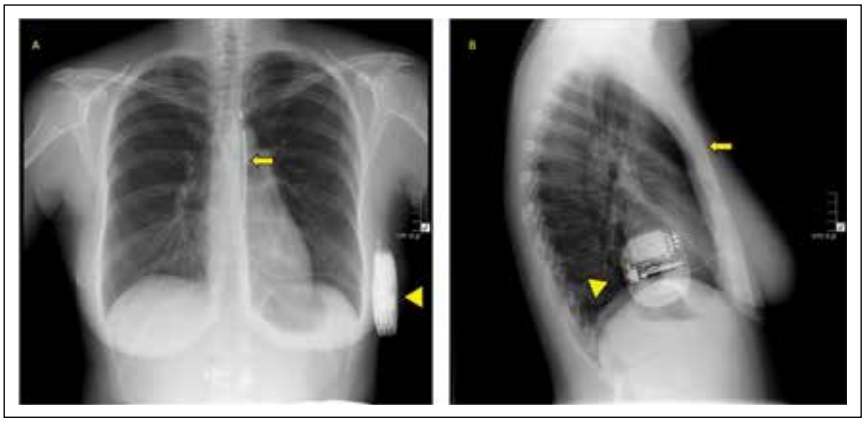


Fig. 28: Typical lead (arrow) and pulse generator (arrowhead) position in a patient with sub cutaneous AICD. (Image Courtesy: Sigmund Stuppner, Radiopedia)

Older generation devices have a DF-1 type of arrangement, with separate connector ports for pacing/ sensing function and defibrillator function. In contrast, current generation devices adopted an integrated port integrating all the functions into a single DF-4 connector. These can be easily differentiated by their appearance on the chest radiograph (figure 27). The generator is activated based on pre-determined algorithms to deliver energy via a certain vector involving the coil on the lead. The leads can be implanted into the endocardium, epicardium, or subcutaneously; however, subcutaneous ICDs are not capable of pacing (Figure 28).

E. ILR and other diagnostic devices

These are the diagnostic devices that are usually implanted for long-term rhythm monitoring. These loop recorders are often implanted in the subcutaneous plane, usually along the lead II axis, preferably near the left parasternal area, and interrogated during the episodes of syncope/index events. Later, after obtaining the necessary information, they can be explanted, and respective disease-specific treatments can be offered if necessary (see Figure 29).

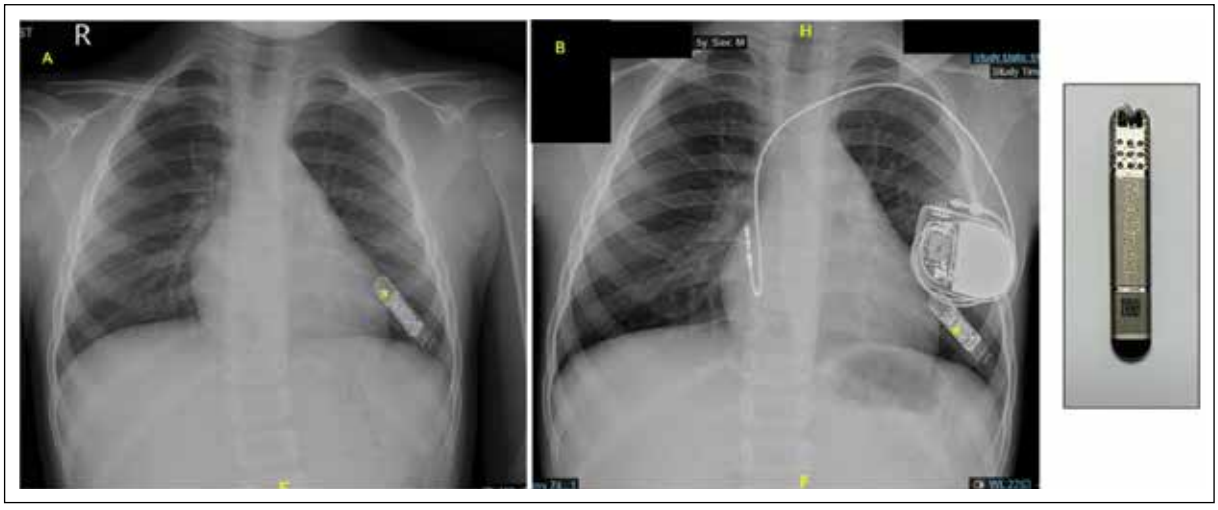


Fig. 29: These frontal chest radiographs of a child with long QT syndrome presented with recurrent episodes of loss of consciousness; for the diagnosis of the event, an implantable loop recorder was inserted (yellow *). As the event recorder showed the bradycardia-induced torsades, this child received a single chamber atrial-based pacemaker. Later on, the recorder was explanted. The explanted device showed in the inset.

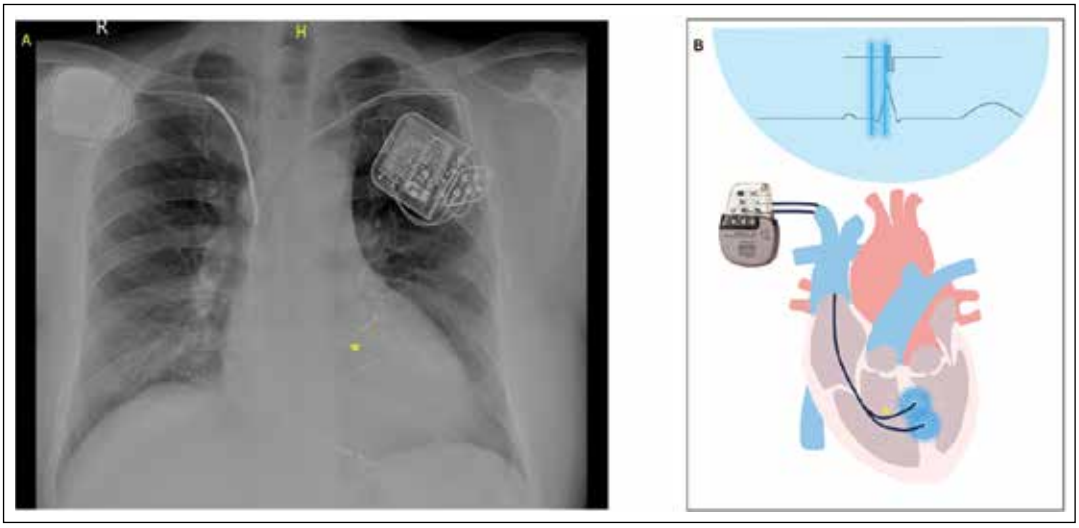


Fig. 30: Frontal radiograph of a patient which showed cardiac contractility modulating device in the left infraclavicular position, which can be recognised by the typical leads, their size and position in the RVOT septum. As this CCM doesn't have a defibrillator within the system, an additional dual coil cardioverter–defibrillator device is implanted on the right infraclavicular position (A). Inset shows the classical ECG and device with leads in the ventricular septum (B).

F. Cardiac contractility modulators

Cardiac contractility modulation (CCM) is a newer and unique device-based therapy for patients with refractory heart failure with severe LV dysfunction. This device delivers high-frequency biphasic electrical stimulation to the ventricular myocardium in an absolute refractory period to augment ventricular contractility. The device can be identified by two RV leads placed in a typical position, i.e., inferior RV outflow septum at least 2 cm apart. Current generation devices don't have defibrillators. Hence, patients often need a defibrillator and a CCM placed via contralateral subclavian access (see Figure 30).

IDENTIFICATION OF THE DEVICES

Every pacemakers manufacturer produces an exclusive device interrogator for proper testing. Though the patients usually have company identification cards, we do encounter patients with unknown devices. Chest radiographs, in such cases, help to identify the manufacturer and can aid the clinician in choosing the interrogator.

To identify, most manufacturers place easily identifiable company logos or an alphanumeric code (ANC) on their generators, in addition to device-specific identifiers (Fig. 31). Examples include St. Jude Medical (SJM), Boston

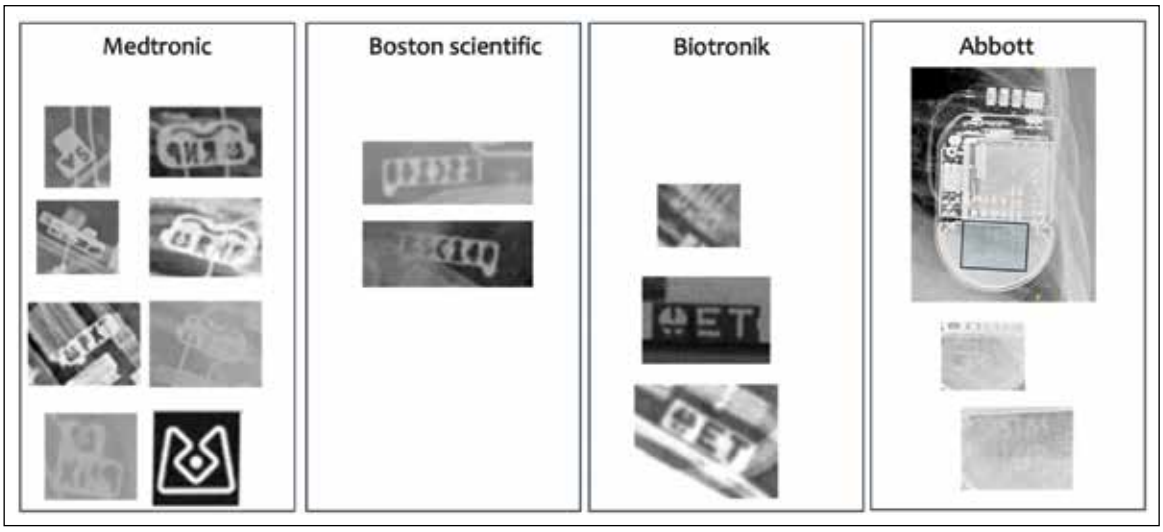


Fig. 31: This figure shows four common manufacturers available in India by their ANC (alphanumeric code), which can be used to differentiate them. Current generation Medtronic devices use "M/V/RNP", Boston Scientific devices use "BSc...no...", Biotronik uses "ET", and Abbott uses "SJM" on their devices.

Scientific (BSc), Medtronic (M); Biotronik ("ET/NT"). Additionally, several algorithms based on the shape of the can, orientation of the header and connector PINs to the can, etc., have been devised to identify the devices on chest radiograph details are beyond the scope of this review. Readers can refer to the widely quoted article using the CaRDIA-X algorithm from Jacob et al. published in Heart Rhythm.[4]

Additionally, a few web-based applications like Pacemaker-ID,a simple application that identifies four common pacemakers and defibrillators, can assist in identifying devices in an urgent scenario in a medical setting with limited EP resources. The development of these applications assists healthcare facilities not only by providing a point-of-care tool but also by assessing MRI compatibility. Few studies validated this application with high accuracy using a machine-learning approach (Fig.32).

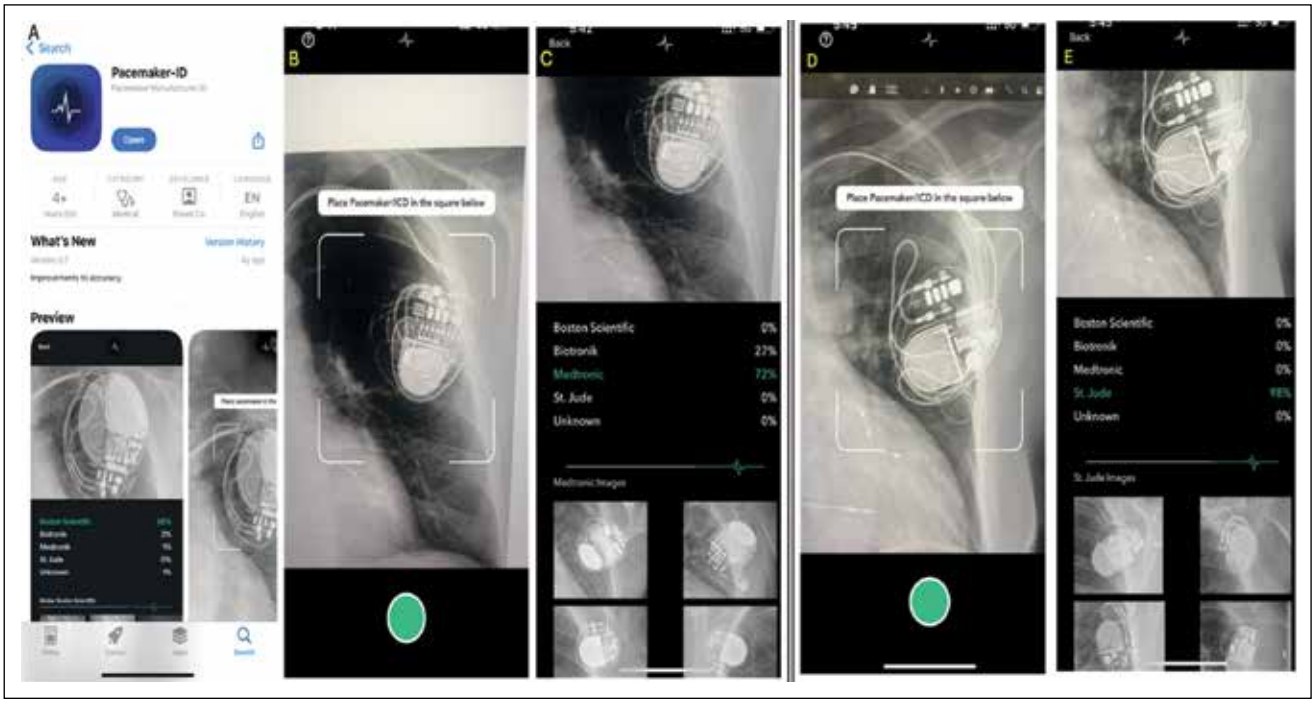


Fig. 32: This image series demonstrates an AI-based application called pacemaker-ID (A) and its utility. Scanning the pacemaker pulse generators on a radiograph will give the likely possible manufacturer of that device in terms of percentage probability (B, C, and D, E show an example of pulse generators and their probability) and is noted to be appropriate.

4. COMPLICATIONS

Complications of the implantation of CCDs can be generally dividedinto acute complications, which occur at the time of device implantation, and chronic complications, which occur on follow-up. Lead-related complications appear to be more prevalent than those associated with generators.

A. Pneumothorax

Pneumothorax usually happens during the subclavian puncture phase of the procedure. The occurrence of pneumothorax is commonest with intrathoracic puncture followed by extra-thoracic puncture, and almost none with cephalic cut-down. This is usually detected on chest X-ray after CIED insertion (see Figure 33). It can

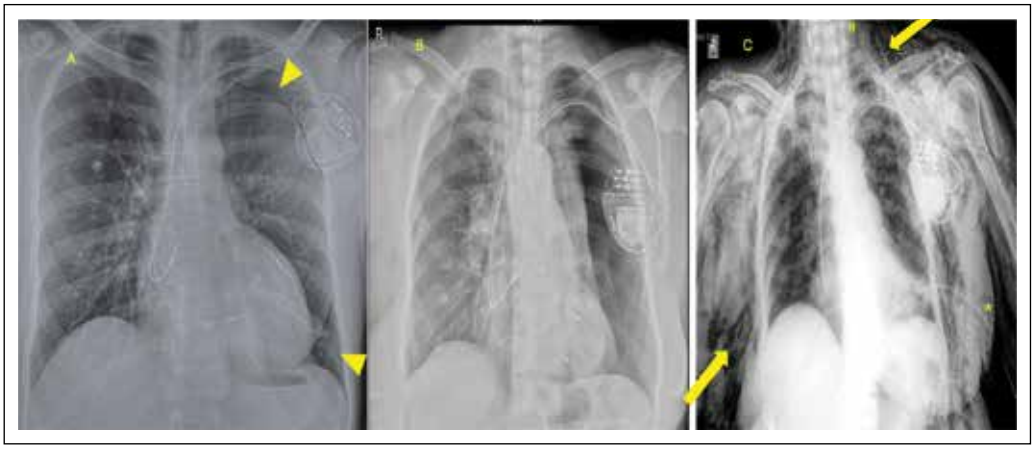


Fig. 33: Frontal chest radiograph of three patients who underwent CRT showing the severity of pneumothorax. It can be as minimal as in the case of patient A, where pneumothorax was confined to the apex of the left lung and base without any mediastinal shift (arrowhead). This patient received conservative therapy, and the pneumothorax spontaneously cleared. Patient B, who underwent LOT-CRT, which showed massive left pneumothorax and was later intercostal tube drainage, was inserted and later stabilised and discharged (A); another patient who underwent CRT-P, post-procedure frontal chest radiograph showing extensive subcutaneous emphysema (arrow) and pneumothorax, note an intercostal tube drain insitu (*) for draining left tension pneumothorax. The pneumothorax may be asymptomatic in most cases as the compensatory hyperexpansion of other lungs ensures ventilation.

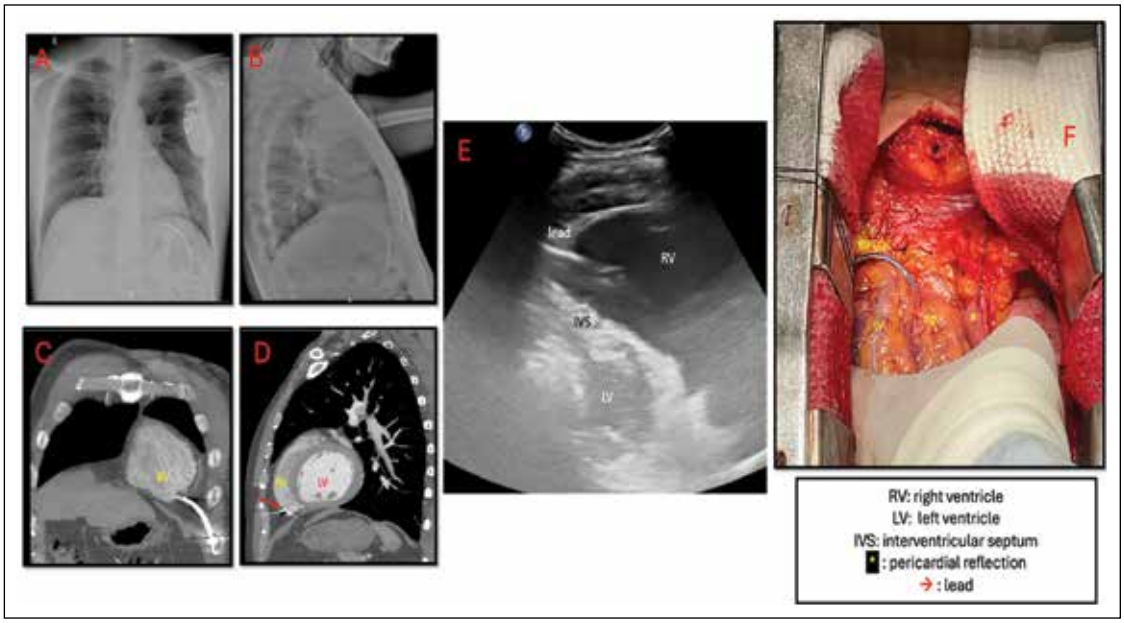


Fig. 34: Chest radiographs of a patient with single coil AICD lead inserted for primary prevention in AP and lateral views, respectively (Panels A, B), Cardiac computer tomography in coronal and sagittal views, respectively (Panels C, D), Echocardiography modified four-chamber view showing lead perforation and exiting beyond the right ventricle lying above the diaphragm and within the pericardial sac. Panel F: An intraoperative image of the same case showed perforated lead with an even coil portion seen migrated beyond the RV within the pericardial reflection.

rarely occur with pneumomediastinum and extensive surgical emphysema. Most of the pneumothoraxes, which are minimal without mediastinal shift, can often be manageable with observation. Those with severe mediastinal shift and/or hemodynamic compromise warrant urgent intercostal tube drainage.

B. Perforation

Myocardial perforation occurs more commonly after ICD placement than pacemaker insertion. The commonest site is the RV apex. A lateral and frontal radiograph offers a useful screening tool for myocardial perforation (see Figure 34), but cardiac CT remains a sensitive and specific modality for diagnosis and management. Septal placement of the lead by visualising in LAO during implantation is the most crucial step to avoid perforation and other associated complications.

C. Lead dislodgement

Atrial lead dislodgement is more prevalent than ventricular lead dislodgement. Lead displacement/ dislodgement immediately after implantation is usually seen secondary to improper loop creation, most commonly lesser loop. Improper fixation either at the distal end of the lead or at the proximal end, i.e., at tie-down/ sleeve level, is the most common reason for the displacement. Optimal loop creation is the key to avoid this complication (see Figure 35, 36).

D. Loose set screw/lead misplacement

Another less common complication usually seen immediately after implantation is loss of capture with high lead impedance. Likely related to the loose set screw or improper screwing of the lead at the connector end (Figure 37). Rarely, inadvertent exchange between the

Fig. 35: Frontal radiographs of three different patients show different loops for the ventricular lead. Panel A shows a lesser loop for the ventricular lead (a Dashed line indicates an optimal position for the lead). Panel B shows an optimally placed lead with an adequate SVC loop (arrowhead). Panel C shows the optimal position of the lead despite the dilated right atrium.

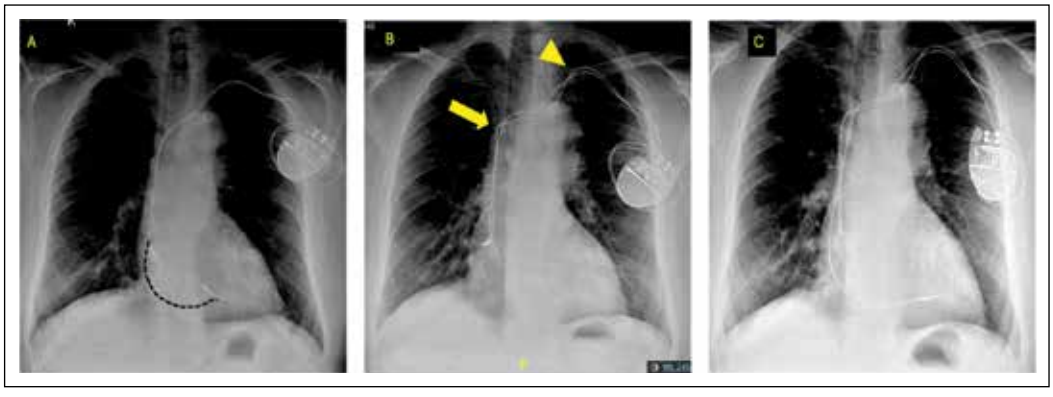


Fig. 36: A series of frontal radiographs of a single patient with sick sinus syndrome who underwent dual chamber pacemaker insertion- depicts the importance of loop creation. Panel A shows the final position of the leads with clearly less loop for the ventricular and atrial leads. The dashed line indicates the ideal position for the ventricular lead. After one week of discharge, during 1st visit, a repeat frontal radiograph shows grossly displaced loops and the formation of SVC (arrow) and subclavian loops (arrowhead). Interrogation revealed loss of R wave and high capture threshold of ventricular lead with normal atrial lead parameters (B). Panel C shows the final position of the ventricular lead after repositioning, showing adequately formed RA (*), SVC and subclavian loops. The atrial lead was densely adhered to and could not be repositioned. Given normal acceptable parameters, the lead position was accepted.

leads during screwing to connectors can often results on dangerous consequences related to lead noise which is particularly fatal in DF-1 defibrillator connectors, and it may result in inappropriate ICD shocks.

E. Twiddler syndrome

Twiddler syndrome is a rare complication caused by conscious or unconscious manipulation at the implantation site by the patient, resulting in lead dislodgement. Usually, it is associated with displacement of both the leads. (Figures 38, 39)

F. Pericardial effusion

Rare complications like pericardial effusion (Figure 40)/ air embolism/ hemothorax/ AV fistula at the implantation site may be seen.

To rule out all these complications, post-implantation, at least before discharge, a formal device interrogation, 12 lead ECG with magnet, and chest radiograph in frontal and lateral views are mandatory.

G. Lead fracture/insulation breach

Lead fracture is one of the most common chronic pacemaker complications.

The lead fracture may lead to a defibrillator delivering inappropriate shocks or a pacemaker failing to sense. This is likely related to the mechanical stress that pacemaker leads undergo in their lifetime. Common sites of lead stress are at stationary points of the lead, such as the subclavian vein–first rib junction (clavicular crush) and at the site of excessively tight fixation sutures. Another important risk factor is the creation of acute bends during the procedure, which can also predispose to fracture in the long run. (Figure. 41, 42, 43). Lead fractures are associated with high impedance, whereas insulation breaches are associated with extremely low impedance values.

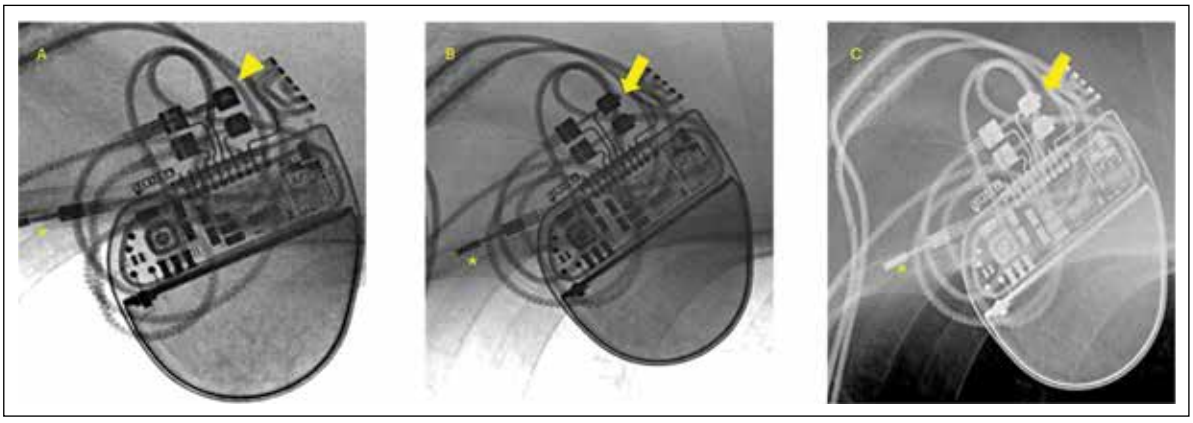


Fig. 37: This image series was that of the patient whose device interrogation, showed high atrial lead impedance (>1500 Ω) with loss of capture. On interrogation, chest radiograph showed atrial lead was not properly screwed in. This can be identified as no projection of the proximal part of the lead beyond the screw (arrowhead) which can be compared with the ventricular lead counterpart (A). The proximal portion of the lead seen projecting out of the screw after repositioning (arrow) (B). Note another abandoned, capped and buried lead (C) underneath the pulse generator (*).

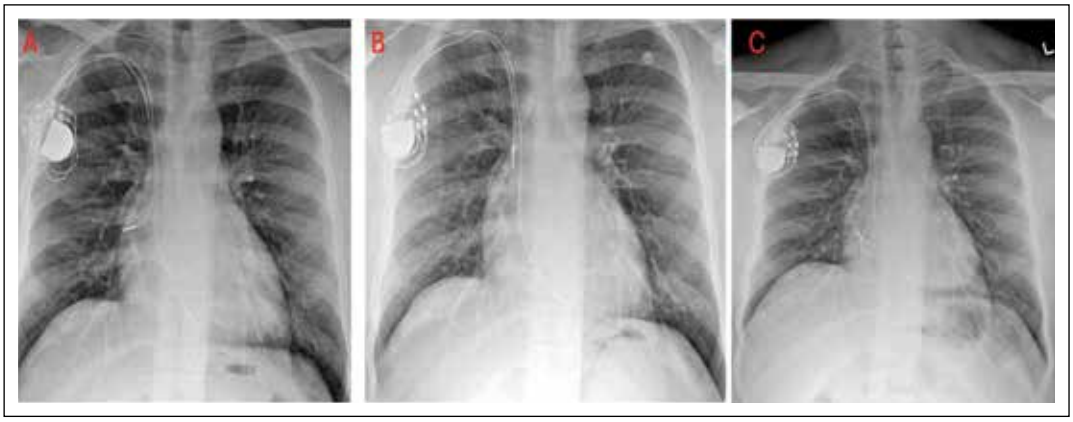


Fig. 38: These are the series of frontal chest radiographs of the patient who received dual chamber implantation for symptomatic sick sinus syndrome; during initial implantation, as one can note, the loop of both leads was less seen in the pre-discharge radiograph (A). The device interrogations during follow-up revealed elevated capture thresholds with displacement of the leads along with rotation of the pulse generator. Later, it was successfully repositioned with optimum loops of both leads (C)

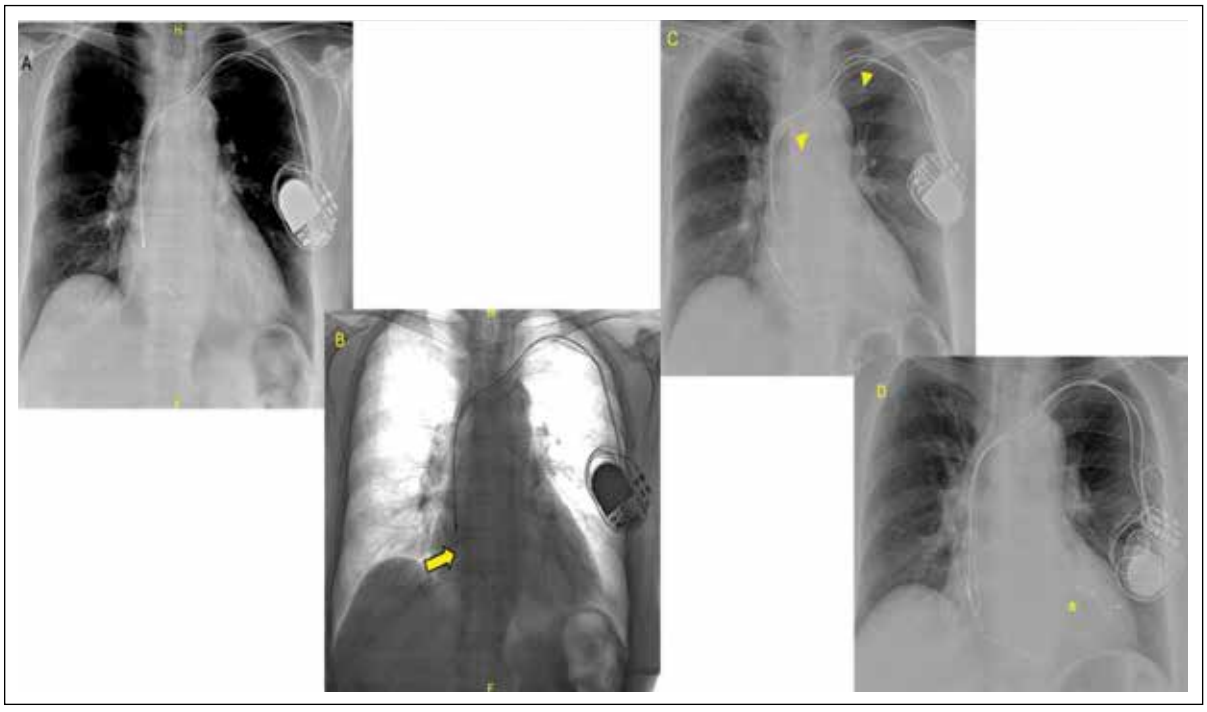


Fig. 39: Another case of Twiddler syndrome in a patient who underwent dual chamber left bundle pacing with Medtronic system presented with recurrent episodes of syncope. Both leads showed lead displacement with Twiddler syndrome (A) and the inverted image also shows confirms same (B). leads were repositioned with an adequate subclavian and SVC loops (arrowheads) (C). At a later stage, due to pacemaker-induced cardiomyopathy, this patient received CRT-P upgradation (*: LV lead) (D).

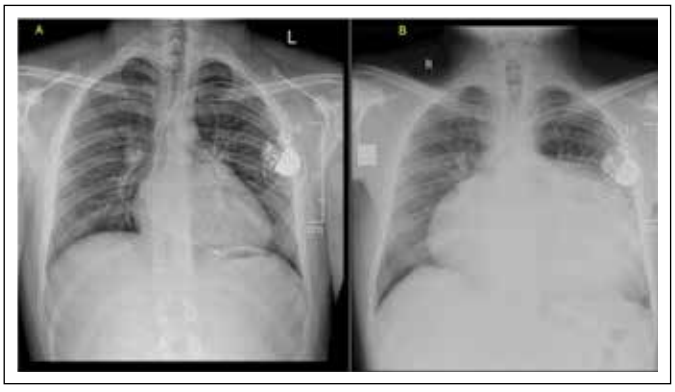


Fig. 40: A case of RCMP with AF and CHB with single chamber VVI pacemaker in situ frontal chest radiographs before and after massive pericardial effusion (A, B respectively).

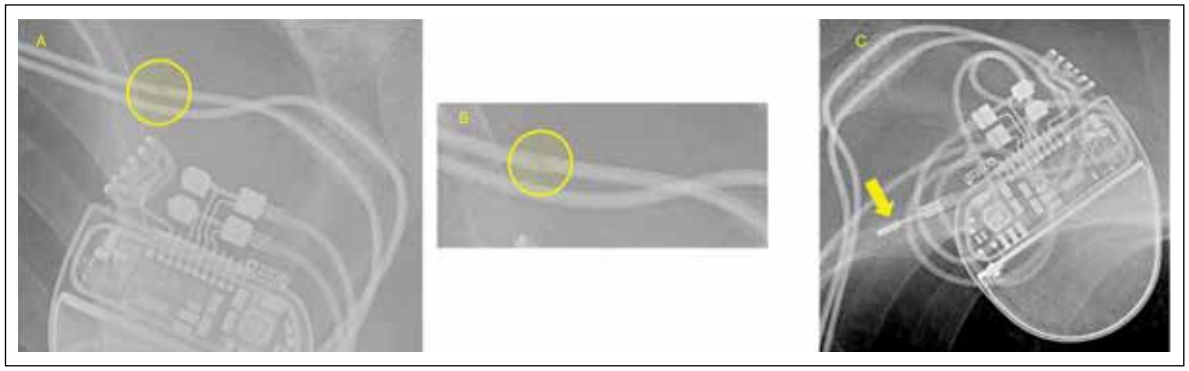


Fig. 41: Zoomed frontal chest radiograph of the pulse generator and leads of a patient who had CHB underwent dual chamber pacemaker implantation in the past now presented with recurrent syncope. On evaluation, high capture threshold with acutely elevated lead impedance detected. A chest radiograph showed discontinuity with the dense part of the lead, suggesting lead fracture, shown in the inset (A, B). The fractured lead was capped and buried within the pocket (arrow), and a new ventricular lead was inserted (C).

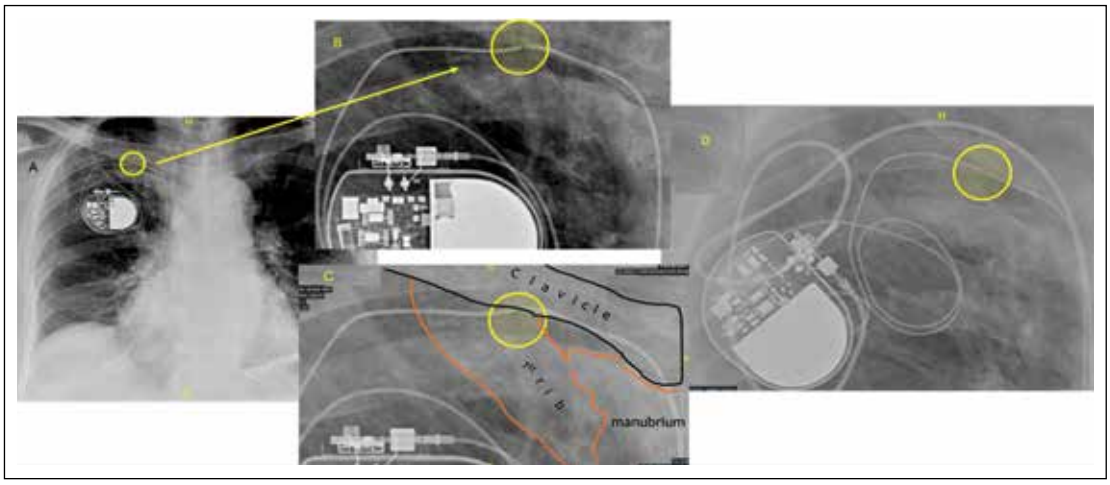


Fig. 42: This frontal chest radiograph (A) of an elderly patient who had CHB and underwent single chamber lead in the past and presented with an episode of syncope and fall. On interrogation, the patient had a loss of capture with high impedance with a ventricular escape rhythm. Chest radiograph showed discontinuity in the ventricular lead at the position of the clavicle and 1st rib interface, likely due to the chronic crush insult (B, C, D). The lead was capped and buried within the pocket, and new ventricular lead was inserted.

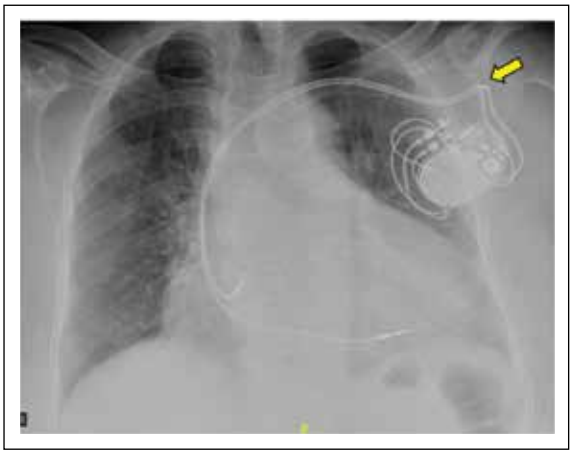


Fig. 43: Frontal chest radiograph of a patient with sick sinus syndrome, who underwent double chamber pacemaker implantation. Note the acute bend (arrow), which should be avoided during implantation as it might lead to long-term stress over the lead conductors and may result in fracture of the conductor/ lead.

H. Lead dislodgement

Chronic lead dislodgement is relatively uncommon as the leads at proximal and distal ends undergo fibrotic reaction, often fixing the lead. But leads like passive LV leads don't have any active fixation mechanism and those leads are particularly predisposed to lead dislodgement. Close monitoring of lead thresholds, QRS duration, and clinical symptoms during each device interrogation visit should be done. (Figure 44)

5. HOW TO EVALUATE A RADIOGRAPH WITH A CIED?

• Gross complications

Look for immediate gross post-procedural access-related complications, such as pneumothorax, hemothorax, and fluid in the pericardium (Figure 40).

• Pulse generator

Ensure the proximal end of the lead that attaches the lead to the generator andis beyond the pins in the pulse generator.

• Lead integrity

» Trace the entire course of the lead in two views, the PA view and the lateral view. Check for lead integrity—normally, the lead should follow a linear pathway with uniform density and an optimal loop. If lead positions are unclear, decrease the exposure or invert the film contrast.

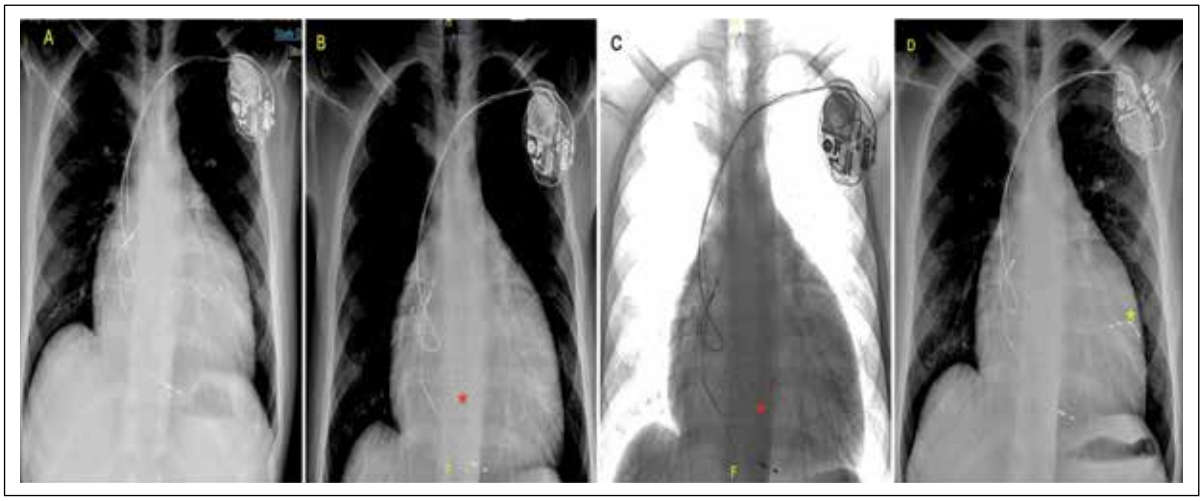


Fig. 44: CRT-P (A) presented with heart failure, noted to have LV lead non-capture on follow-up. X-ray showed likely displaced LV lead (red *) (B), which was unclear in routine exposure. When the exposure was decreased, the lead position could be confirmed to be in the proximal coronary sinus. For better visualisation, inversion of the x-ray film can clearly show the lead position(C). Subsequently, he underwent LV lead repositioning. The Frontal chest radiograph showed the final position of the LV lead (yellow *) (D).

- Develop a mental template for the normal position and normal loop of the common leads (Figures 35,36,45) and any lead appearing as in abnormal location suspect myocardial perforation/ misplacement of the lead after ruling out the underlying corrected congenital heart diseases (Figure.46).
- In case of doubt, compare with the periprocedural final fluoro images and perform a device interrogation for lead parameters.
- Overall, Clinical correlation with any radiological findings is key.
- If there is even the slightest doubt, perform a fluoroscopy to check the lead positions and confirm before discharge.

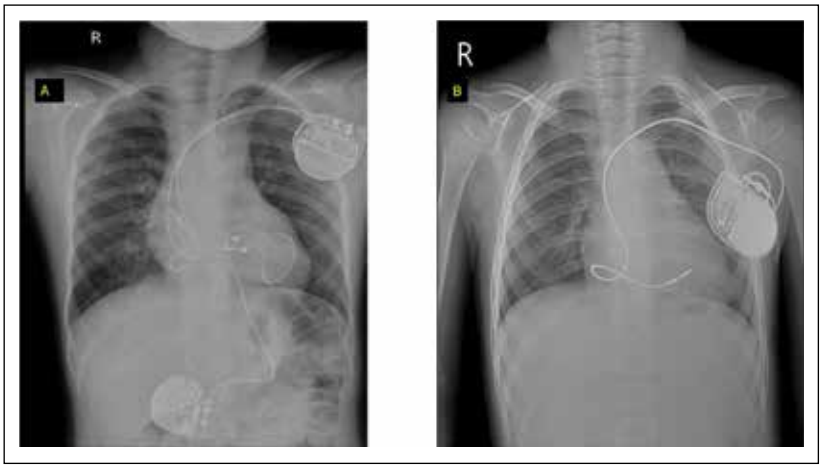


Fig. 45: A case of congenital CHB who underwent bipolar single chamber ventricular epicardial pacemaker insertion in infancy, being upgraded to the endocardial dual chamber system. Note the endocardial leads; the ventricular lead shows an alpha loop that allows sufficient length to accommodate the growth of the subclavian vein in the child. After wound healing, the epicardial PG was explanted (A). Similar case of a 5-year child with fulminant myocarditis and CHB, after optimal immunotherapy, CHB failed to recover, and single chamber VVIR pacemaker implantation was done (B). Note that a sufficient alpha loop is maintained.

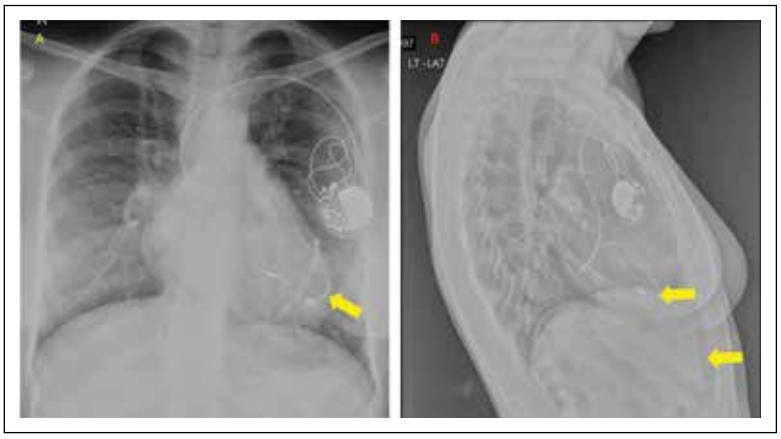


Fig. 46: A post-operative TGA (transposition of great arteries) underwent Sennings repair with epicardial pacemaker insertion during the procedure. Later, endocardial conversion was done with a single-chamber endocardial pacemaker inserted into the morphological left ventricle, seen in both frontal and lateral radiographs. A lead was inserted into the free wall of the morphological LV. Note the presence of an abandoned epicardial lead (arrow).

Step-by-step guide on how to assess chest radiograph for a new cardiac symptom/device malfunction/ unknown device:

- If available, always compare with the previous radiographs to confirm the type of device inserted and any change in lead positions.
- PA and lateral chest X-rays are required to evaluate the lead position.
- Compare the serial ECGs and identify any changes. Immediate post-procedural magnet ECG and current office ECG with and without magnet tracings

1. Pulse generator

» **Location**

» **Try to identify the manufacturer.**

» **Device type – Identify the type of device.**

» **Lead proximal connection: appropriate / rule out loose connector screw / inadvertent exchange between the leads.**

2. Leads

» **Location** (Epicardial Vs endocardial location vs multiple (figure 47) /unusual sites (Figure.46, 48)

» **Nature of lead** (pacemaker / ICD lead / VDD lead (Figure 49)) (Active vs Passive lead)

» **Lead integrity** (trace the entire lead length carefully) and possible long-term complications should be searched for. These include lead dislodgement, lead fracture (at the tip of the electrode or the point of access to the axillary/subclavian due to clavicular crush), and insulation break.

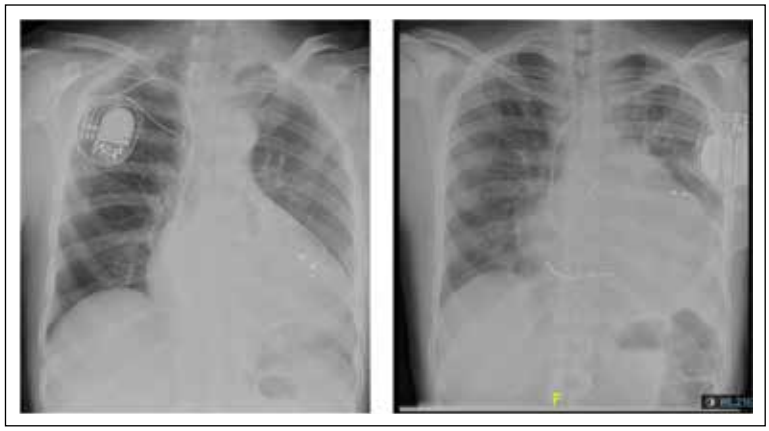


Fig. 47: Frontal chest radiographs showing Hybrid CRT, endocardial leads in RA, RV with an epicardial LV bipolar lead to complete CRT; Patient A had infected CRT-P device during pulse generator replacement who underwent surgical extraction of lead during that surgery, epicardial LV lead was implanted and later completed by endocardial RA, RV lead placement from right side. Another patient, B, who was diagnosed to have anterior wall MI with ischemic dilated cardiomyopathy, attempted CRT-D insertion and had coronary sinus dissection during the procedure. Endocardial LV lead placement was abandoned, and he received endocardial leads for RA and RV, which was completed to CRT-D with an epicardial LV lead surgically placed in.

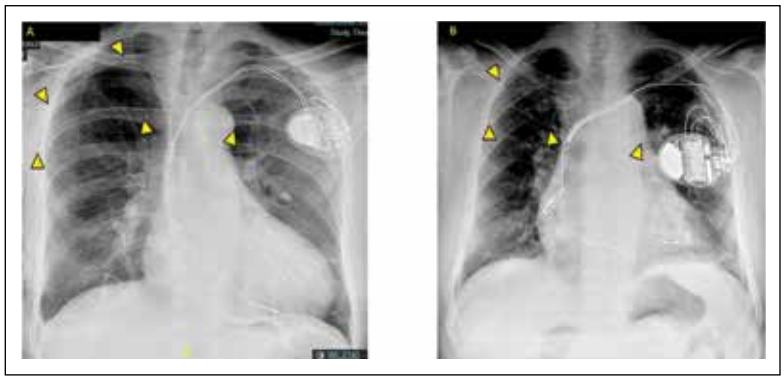


Fig. 48: Two patients' Frontal radiographs show tunnelled LV lead from the right side to the left infraclavicular site. Patient A is a case of CHB who underwent a dual chamber pacemaker in past and now presented with severe LV dysfunction as the left subclavian venogram showed a completely occluded vein, a right-sided quadripolar LV lead (arrowheads) was inserted and then tunnelled sub-sternally towards the left infraclavicular subcutaneous pocket and connected to a Medtronic CRT-P pulse generator. Patient B is a case of Anterior wall STEMI with CHB and VT and underwent dual chamber AICD and currently has worsening LV dysfunction and heart failure. As the left subclavian venogram showed a completely occluded vein, a quadripolar LV lead (arrowhead) was implanted from the right subclavian access, tunnelled to the left infraclavicular fossa, and upgraded to the CRT-D system.

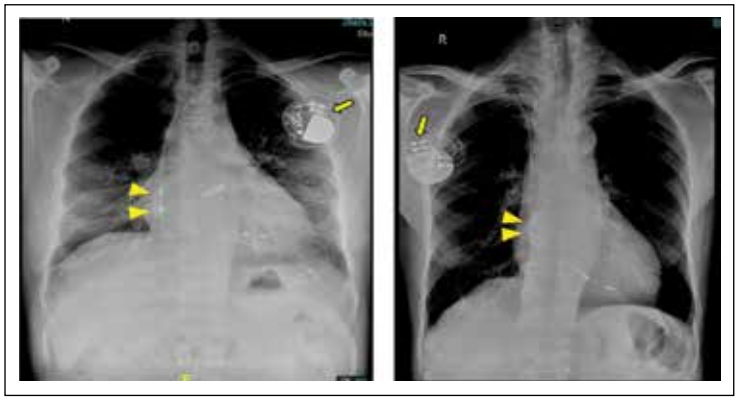


Fig. 49: Frontal radiographs showing the VDD lead, i.e., a lead that can sense events in two chambers but with a pacing function confined to the ventricle. Currently, these leads are not being used. Two extra electrodes can identify these leads with contact over the lateral RA wall (arrowheads) and two connector ports in the pulse generator header (arrow).

» **Any abandoned leads / other lead fragments** (figure 23) /**displacement** (inversion of the image/ reducing the exposure often helps in the identification of the leads and their exact location)

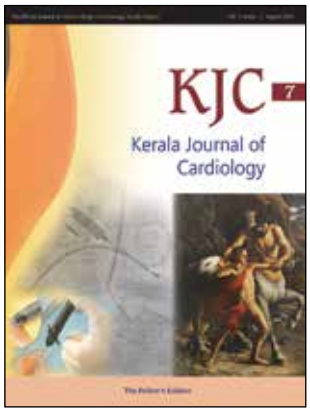
3. Correlation with patient history, ECG, and device interrogation is important.

6. CONCLUSION

Chest radiographs provide a straightforward, cost-effective method to evaluate the proper placement and potential complications following CIED insertion. This resource aims to assist young cardiologists in recognising the typical appearances of CIEDs and their associated complications on chest radiographs, enabling early detection of potential issues.

REFERENCES/ FURTHER READING

1. Shu Zhang. APHRS white book: tenth edition [Internet]. 2022. Available from: https://www.aphrs.org/attachments/article/42/APHRS%20White%20Book%202022.pdf
2. Reddy VY, Miller MA, Neuzil P, Søgaard P, Butter C, Seifert M, et al. Cardiac Resynchronization Therapy With Wireless Left Ventricular Endocardial Pacing. Journal of the American College of Cardiology. 2017 May;69(17):2119–29.
3. Chen AY, Upadhyay GA. Current Treatment Options in Cardiovascular Medicine Arrhythmia Section From the His Bundle to the Left Bundle: Clinical Applications of Conduction System Pacing. Curr Treat Options Cardio Med. 2021 Jan;23(1):7.
4. Jacob S, Shahzad MA, Maheshwari R, Panaich SS, Aravindhakshan R. Cardiac Rhythm Device Identification Algorithm using X-Rays: CaRDIA-X. Heart Rhythm. 2011 Jun;8(6):915–22.



Syncope in A Young Male - A Case Report

Teena Mary Varghese
Department of Cardiology, KIMS HEALTH, Thiruvananthapuram, Kerala.
Divya Saikumar
Department of Radiodiagnosis, KIMS HEALTH, Thiruvananthapuram Kerala.
Ramesh Natarajan
Senior Consultant Cardiologist, Department of Cardiology, KIMS HEALTH, Thiruvananthapuram, Kerala.

ABSTRACT

Sarcoidosis has been a diagnostic dilemma for physicians because of its varied manifestations. Of patients with pulmonary sarcoidosis, 30% have extrapulmonary sarcoidosis. The heart is one of the organs that can be affected. Although not as common as pulmonary sarcoidosis, around 25% of patients with systemic sarcoidosis have subclinical involvement of the heart, detected only on autopsy. Only around 5% of patients with cardiac sarcoidosis are symptomatic.

We report the case of a 29-year-old male, who presented to us with recurrent episodes of presyncope for the past 2 months. ECG at presentation showed Complete AV block and CT scan of chest and abdomen revealed granulomatous lesions in multiple sites, including the lungs, liver, spleen, kidneys and the retroperitoneum. Biopsy taken from the liver and finally Cardiac MRI helped to clinch the diagnosis in this young man.

INTRODUCTION

Sarcoidosis is a multisystem inflammatory disease of unknown etiology that predominantly affects the lungs and intrathoracic lymph nodes. Sarcoidosis is manifested by the presence of noncaseating granulomas (NCGs) in affected organ tissues. It is characterized by a seemingly exaggerated immune response against a difficult–to-discern antigen.[1] Although its incidence is low, the disease is often misdiagnosed as tuberculosis, due to its primarily pulmonary presentation. Incidence peaks in people aged 25-35 yrs. Evidence of extra pulmonary disease, predominantly cardiac and neurologic are considered as markers of poor prognosis. Cardiac involvement presents predominantly as heart blocks, ventricular arrythmias, heart failure or even sudden cardiac death.

We hereby, report the case of a 29-year-old male, who presented to us with recurrent episodes of giddiness and syncope and had complete heart block on ECG.

Key words: *Sarcoidosis; AV block; non caseating granuloma; Asteroid bodies.*

Address for correspondence: Teena Mary Varghese, Department of Cardiology, KIMS HEALTH, Thiruvananthapuram, Kerala. Email: tmvebenezer@gmail.com

CASE REPORT

A 29-year-old male, with no prior comorbidities, presented to our Emergency Department with c/o giddiness and episodes of presyncope for the past 2 months. The episodes had become more frequent in the past 2 weeks with a couple of fainting spells. There was no history of syncope or sudden cardiac death in the family. No other cardiac complaints were present at the time of presentation.

His pulse rate was 24/min and blood pressure 130 / 70 mmHg. Heart sounds were normal and auscultation of the lung fields revealed normal vesicular breath sounds. ECG taken in the Emergency room showed Complete Heart Block (CHB) with a ventricular escape rate of 25/min with RBBB morphology. Emergency temporary pacing was instituted. Coronary angiogram was done and obstructive CAD was ruled out.

He had deranged renal function (serum Creatinine -3.2 mg/dl) with hypercalcemia (Serum Calcium 13.2mg/dl) and low parathormone levels suggestive of PTH independent hypercalcemia.

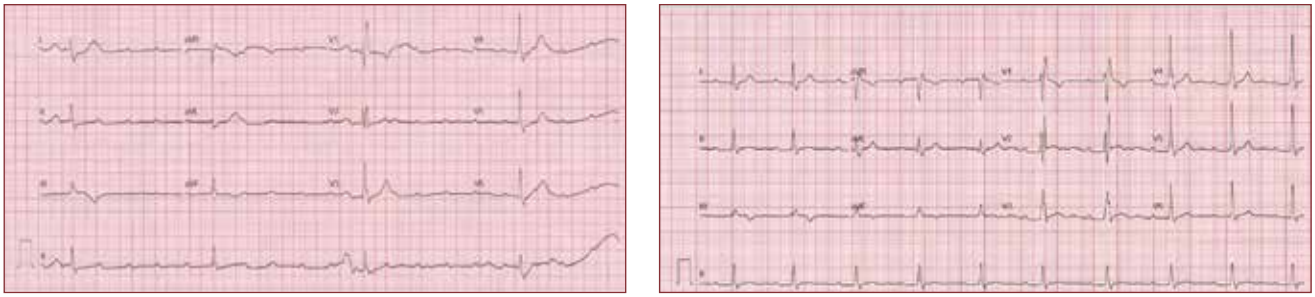
In view of the high calcium levels and the presentation with CHB on ECG, the possibility of cardiac sarcoidosis was suspected and S. Angiotensin Converting Enzyme (ACE) levels were sent, which was high (106.4). CT scan of chest and abdomen done showed sharply defined nodules with a predominantly peri lymphatic distribution in both lungs with bilateral mild pleural effusion. Liver was dysmorphic with hepatomegaly and tiny nodules with band like hypodense areas in the parenchyma. Nodules were also seen in the spleen, retroperitoneum and both kidneys. The differential diagnosis suggested were sarcoidosis, disseminated tuberculosis and lymphoma.

In view of the high possibility of sarcoidosis, he was initiated on Inj. Solumedrol 500 mg IV od for 5 days. Within 24 hours of starting steroids, his AV block improved and he was in Mobitz Type 1 and Type 2 AV block intermittently. Temporary pacing was however, continued. Investigations to rule out tuberculosis, including Gene Xpert was done, which came out negative.

For a tissue diagnosis, the feasibility of biopsy from any of the lymph nodes was considered and with the help of interventional radiologist, ultrasound guided biopsy from the liver nodules was obtained. It showed portal and parenchymal discrete granulomas composed of epithelioid histiocytes and prominent multinucleate giant cells. Some of the giant cells showed "Asteroid bodies". Ziehl Neelsen stain was negative for acid fast bacilli. Histomorphological features favored a diagnosis of sarcoidosis.

CARDIAC MRI also was done subsequently which showed focal thickening of anteroseptal and anterior segments of the basal left ventricle, inferolateral segment of mid left ventricle and inferior and lateral segments of apical left ventricle with heterogeneous mid myocardial to subepicardial enhancement and tiny peripherally myocardial enhancing lesions. Features were suggestive of granulomatous myocarditis.

After a total of 5 days of intravenous steroids, he was started on oral steroids and his complete AV block reverted to first degree heart block. He remained asymptomatic and temporary pacing was discontinued after six days. He was continued on oral steroids in tapering doses. He was discharged on oral prednisolone. He continues to be asymptomatic with his ECG showing first degree heart block and RBBB. He has been advised close follow up and monitoring. The possible need for permanent pacemaker implantation in future has been discussed with patient and relatives.



(a) (b)

Fig:1 (a)– ECG at presentation showed Complete AV block with atrial rate of 100/min and ventricular rate of 25/min in RBBB pattern. **(b) ECG at discharge** showed sinus rhythm with first degree AV block and RBBB.

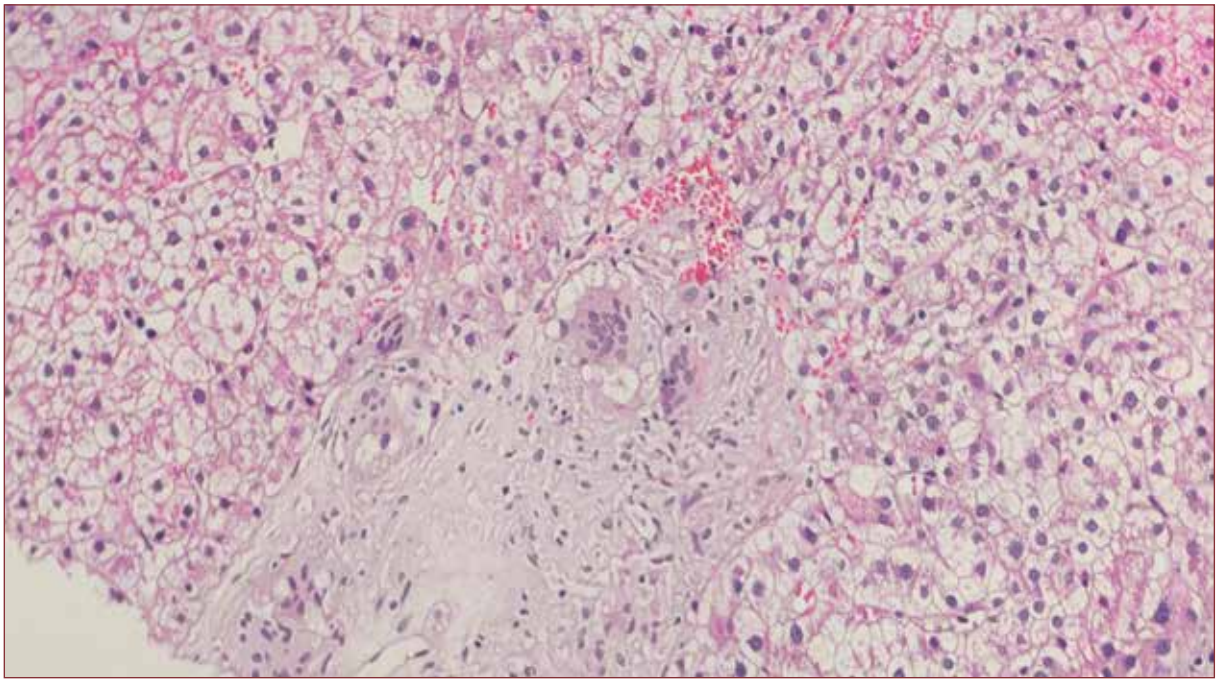


Fig :2 – Liver biopsy - Non caseating granuloma with Asteroid bodies in multinucleate giant cells.

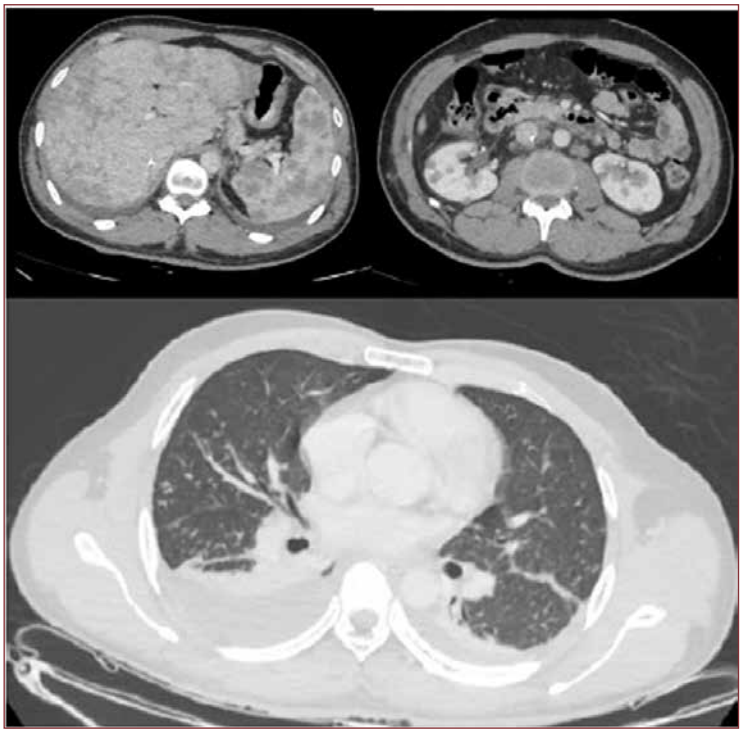


Fig:3 – CT Chest and abdomen- Sharply defined nodules with a predominantly peri lymphatic distribution in both lungs with mild pleural effusion. Tiny nodules and band like hypodense areas in the liver parenchyma. Splenomegaly with multiple parenchymal nodules and cortical nodules in both kidneys.

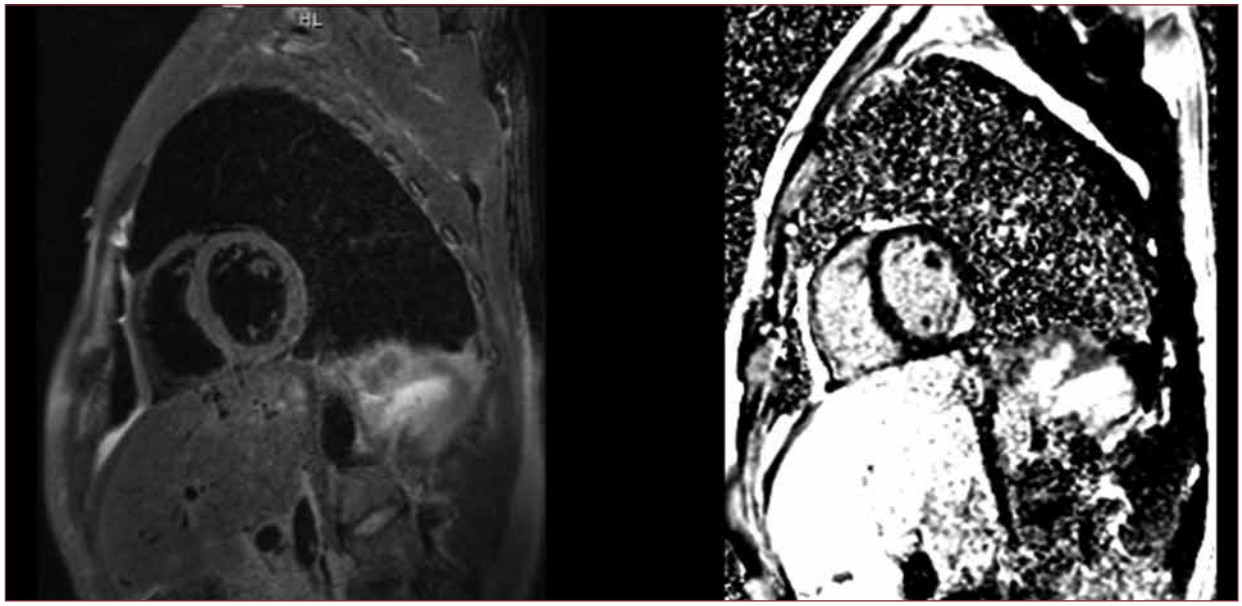


Fig: 4 – Cardiac MRI (Mid segment) - Mild focal thickening of the inferolateral segment of mid left ventricle with heterogeneous mid myocardial to subepicardial late gadolinium enhancement in the post contrast image.

DISCUSSION

Sarcoidosis has the worst prognosis when it involves the heart muscle (although it can involve any part of the heart), accounting for more than two-thirds of global deaths in sarcoid patients.[2] Only 5% of patients with sarcoidosis show symptomatic cardiac involvement. Clinical presentation of cardiac sarcoidosis (CS) is variable – symptomatic, benign, or life-threatening with symptoms of heart failure, cardiac arrhythmias, or sudden cardiac death (SCD). The latter is the most common cause of death from CS and could be the first and only manifestation of CS in some cases.

The Heart Rhythm Society (HRS) has two pathways for the diagnosis of cardiac sarcoidosis: (1) histological evidence of noncaseating granulomas in myocardium in endomyocardial biopsy specimen and (2) clinical and imaging based diagnosis (histological evidence of extracardiac sarcoidosis plus one or more of the following: steroid± immunosuppressant responsive cardiomyopathy or heart block, unexplained LV EF <40%, unexplained VT, second/third-degree AVB, patchy uptake of FDG-PET, LGE on MRI and positive gallium uptake consistent with CS).[3]

Cardiac MRI provides a noninvasive means of detecting morphological and functional abnormalities consistent with CS. Corticosteroids form the mainstay of treatment with or without the need for additional immunosuppressants. Heart block in sarcoidosis often requires permanent pacemaker implantation and the same was considered in our patient. However, the dramatic improvement in conduction after initiation of steroids and the young age of the patient prompted us to take a more conservative approach with close follow up. Patients presenting with ventricular arrythmias often require implantation of ICD.

Guidelines for the diagnosis of cardiac sarcoidosis are evolving, with less emphasis on the need for a tissue diagnosis. The sensitivity of endomyocardial biopsy is very low considering the patchy nature of myocardial involvement. Increasing emphasis on imaging modalities such as CT scan, MRI and PET scan is seen in recent published literature.

REFERENCES

1. Ten Berge B, Kleinjan A, Muskens F, Hammad H, Hoogsteden HC, Hendriks RW, et al. Evidence for local dendritic cell activation in pulmonary sarcoidosis. Respir Res. 2012 Apr 18. 13:33.
2. Perry A, Vuitch F. Causes of death in patients with sarcoidosis: A morphologic study of 38 autopsies with clinicopathologic correlations. Arch Pathol Lab Med. 1995;119(2):167-172.
3. Birnie DH, Sauer WH, Bogun F, et al. HRS expert consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis. Hear Rhythm. 2014;11(7):1304-1323. 10.1016/j.hrthm.2014

KJC Focus Issues

(Available online at www.icckeralachapter.org)

KJC 1 - Congenital Heart Diseases
KJC 2 - Valvular Heart Diseases
KJC 3 - Interventions of Inter Atrial Septum
KJC 4 - Pulmonary Hypertension
KJC 5 - Hypertrophic Cardiomyopathy
KJC 6 - Imaging in Cardiology
KJC 7 - The Fellow's Edition

KJC 8

Team KJC invites articles

(Original research, Review articles, Case reports, Images, Perspective)

Please mail to: abhispin@gmail.com

In Dyslipidemia/CAD/ACS/PCI/Post PCI Patients

Rosuvas®

Rosuvastatin 40/20/10/5mg

The Most Efficient Statin

TO BRING
SMILE ON FACE
PEACE IN HEART

YOUR TRUST MADE US A

TEXTBOOK BRAND

NOW AVAILABLE IN

Drugs and Cosmetics Act Compliant Pack

- **ANTI-COUNTERFEIT**
  - *3D Hologram*
- **DYNAMIC QR CODE**
  - *Product Journey*
  - *Product Information*
  - *Patient Engagement*

COMMITTED TO

Making India HeartSTRONG!

cprcube PRO
The smallest smart CPR class in the world

- **DETECTION**
  - *Diagnostic service to >2.5 lac Patients*
- **AWARENESS**
  - *Patient education support to >10mn Patients Annually*

Rise above the risks of HF,

Sacurise™

Sacubitril / Valsartan(50mg/100mg/200mg Tablets)

Able Heart.Enabled Life

> Rs. 20,000/- Savings*
Vs. Other Brands

50 mg	100 mg	200 mg
₹15/- per tab	₹25/- per tab	₹40/- per tab

SUN PHARMA | your CardioCompanion

Ref: 1mg.com as on 4th January,2019

The Official Journal of Indian College of Cardiology, Kerala Chapter