ORIGINAL ARTICLE PERMANENT PACE MAKER IMPLANTATION THROUGH AXILLARY VEIN APPROACH

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Background: Device implantation is an integral part of interventional cardiology particularly electrophysiology. In this study, we are going to shear our experience of device implantation technique at electrophysiology department Hayatabad Medical Complex, Peshawar. Methods: The study was conducted from June 2011 to December 2015. Axillary vein was used to implant the devices but in some cases when this rout was not convenient due to any reason then subclavian vein was entered through the Seldinger technique. Fluoroscopy time was less than 10 minutes and total procedure time was not more than 45 minutes. Electric cautery was used only in two cases. Pressure dressing was used in a few cases. Results: Total numbers of permanent pacemakers (PPM) remain 800 during the study period. There were 450 single chamber pacemakers and 350 dual chambers pacemakers. No case of any major bleeding was documented and in very few cases there was mild ooze from the procedure site after the operation which was tackled with pressure dressing. Four cases of pneumothorax were noted during the study period and in three cases chest intubation were done and one patient was kept on conservative management. Patient were followed after one moth of discharge from the hospital and then yearly. Eight cases of lead dislodgment were documented during the study period. Conclusion: Axillary vein approach for implantation of permanent pacemakers is a safe and less time-consuming technique.

Keywords: Axillary vein; Permanent pacemakers (PPM); Seldinger technique; Subclavian vein

J Ayub Med Coll Abbottabad 2017;29(2):241-5

INTRODUCTION

Cardiology today became an invasive field in general and electrophysiology in particular. Permanent pacemakers are implanted by both general cardiologist and electrophysiologist.¹ Different operator are using different methods for the implantation of devices. Mostly the procedure is done under local anesthesia² and in some cases with mild conscious sedation. In very young patients and very irritable patients at time, general anaesthesia may be needed. Some operator uses the cephalic vein to implant the pacemakers lead.^{3,4} In this method after skin incision, the cephalic vein is exposed through blunt dissection and the vein cannulated under vision and lead inserted.

Though it is very safe because there is no chance of pneumothorax but there is much surgical skill involved and it is much time consuming and a bit troublesome in fully awake patients. In this method, the operator needs to expose the cephalic vein through blunt dissection with some risk of damaging the nearby neurovascular structure. The length of the vein is about 4.8 cm and in some cases the vein has a supra-clavicular course and putting the lead in the vein, exposes the hardware to mechanical stress and risk of fracture.⁵ The second choice is subclavian vein. This vein is entered by Seldinger technique. Mostly the insertion point is the medial two third and the lateral one third of the clavicle in the subclavian area while directing the needle the

needle to the supra-sternal notch keeping the needle at about 45 degrees to the horizontal line. But there is high risk of pneumothorax.^{6,7} The third possible way is to approach the axillary vein, which is an extra thoracic structure. The diameter of the vein is reasonable. The vein can be cannulated by Sildinger's technique. In this approach, there is less chance of complication⁸ and less surgical skill involved as cardiologist are not surgeons after all. This approach is less traumatic for the patient and much convenient for the operator.⁹ There is less chance of bleeding and better haemostasis can be achieved. The skin incision can be made with the direction of skin crease lines and so very cosmetic scar will be there after procedure. The healing process is fast and so the stay of the patient in the hospital is short. Since there is no cut down and the vein can be used for upgrading or re-implantation in cases there is lead facture, insulation break or lead dislodgment.

MATERIAL AND METHODS

All patients who presented to cardiology department Hayat Abad Medical Complex Peshawar with indication for pacemakers were included in this study. Patient base line characteristic recorded in table-1. Baseline investigation including full blood counts (FBC), renal function test (RFTs, i.e., serum creatinine, urea), random blood sugar (RBS), and virology analysed. Night before the procedure chest shaved in case patient was male and the whole chest was painted with pyodine in both genders. Informed consent was obtained from the patient and the patient was kept nil by mouth (NBM) in the morning. Patient was used to inject broad spectrum antibiotics about half an hour before shifting the operating room. Before starting the procedure, it is our common strategy to obtain cine film with contrast to document the anatomy of the axillary vein as shown in figure 1. Under local anaesthesia skin incision made at the selected site in the left subclavian area or the right subclavian area in case the left axillary vein is not available.

The subcutaneous tissue is separated under vision with mosquito forceps doing blunt dissection and then subcutaneous pocket constructed with two fingers. The left subclavian vein define earlier was enter by Seldinger's techniques in the position as shown in figure-2 and pacemakers sheath with dilator introduced over the guide wire. Guide wire pulled out with dilator and pacemaker lead passed to the right ventricle and position in the right ventricle apex most of the time or the right ventricle out flow tract if the apical position is not optimal. In case of dual chamber pacemakers, the second lead is passed in the same way and position in the right atrial appendage as shown in figure-3 and both leads screwed. Threshold and impedance was used to check and atrial sense also documented.

If reasonable intrinsic rhythm is there "R" wave amplitude was also checked. Pulse generator attached and secured in the pocket and wound stitched in layers. Aseptic dressing done and patient shifted to the bed. Patient kept for 5–7 days in the unit on I/V antibiotics. Patient's pacemaker's status re-examined on pacemaker's programmers next day of implantation and the after a month and then yearly or as there is any trouble shooting.

RESULTS

The study results are shown in the table-2. Total 800 procedures were done during the study period. Three hundred and seventy (46.25%) Male patients and 450 (53.75%) female patients were included in the study. 56.25% patient received Single chamber devices and 43.75% dual chamber devices were implanted during the period. 32.5% were diabetic patient. In 98% cases the devices were implanted from the left axillary vein and 2% from the right axillary vein. The average fluoroscopy time was 10 minutes and the average procedure time remain less than 45 minutes. No single case of major bleeding documented in the study population and in few cases those who were on anti-platelets, minor ooze was noted which was tackled with pressure dressing. Eight cases of lead dislodgment in the first week of implantation were noted for

whom repositioning was done. The average hospital stay was 5 days. All procedure was done on 2% lignocaine 20 ml except in 3 cases where the patients were very much irritable and so they were given I/V sedation. 4 cases of pneumothorax were documented, two patients needed chest intubation and one was aspirated with needle and the other was treated conservatively. All four recovered. All these four cases were having difficult puncture and they were very elderly and skinny. In two cases the puncture site changed to subclavian vein. There were eight cases of operation site hematoma: one was a case who was on low molecular weight heparin and also on dual anti-platelets. Pressure dressing was applied for a few days and the situation was controlled. The second case was a young lady with dilated cardiomyopathy and complete heart block. She was on comudine for left ventricle (LV clot). In her case the drug was hold for few days and the hematoma was surgically drained. Both remained well. No major complication was noted except mild pain or discomfort at the site of procedure in 30% of cases even on the 2^{nd} and 3^{rd} post operation day, however all patients were symptoms free at the time of discharge from the hospital.

Table-1: Basic characteristics of patients

Male	370	46.25%
Female	430	53.75%
Average age of patients	57±10 years	
Needs temporary pacemakers at	657	82.125%
presentation		
Symptomatic bradycardia	60	7.5%
Complete atrio-ventricular block	710	88.75%
Mobitz II 2 nd block	10	1.25%
Sick sinus syndrome	20	2.5%
Patients with Impaired renal function	6	0.75%
Diabetics	260	32.5%
Hypertensive	650	81.25%
Coronary artery disease	540	67.5%
Patients on dual anti platelets	15	1.75%
Patients with congenital heart diseases	2	0.25%
Patients for up gradation of devices	5	0.625%

Total implants	800	
Single chambers pacemakers	450	56.25%
Dual chambers (DDD) pacemakers	350	43.75%
Average time for implantation of DDD	<45 minutes	
Average fluoroscopy time	<10 minutes	
Tine leads	05	0.625%
Axillary vein approach	793	99.125%
Screwing leads	795	99.375%
Failure to puncture axillary vein	7	0.875%
Pressure dressing	45	5.625%
Pneumothorax	4	0.5%
Local hematoma	8	1%
Leads repositioning in the 1st week	8	1%

Table-2: Result

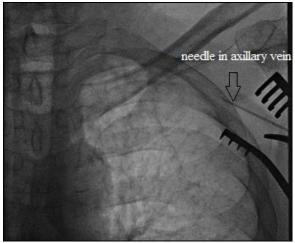


Figure-1: Axillary vein puncture

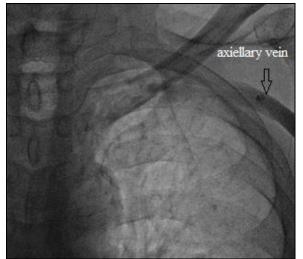


Figure-2: Venogram of axillary vein

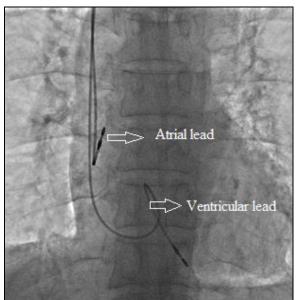


Figure-3: Cine View of Leads after Implantation

DISCUSSION

Since the first trans venous implantation permanent pacemaker in 1960,¹⁰ there is continuous improvement in the size and implantation techniques of pacemakers. The first ever device was 45 kg¹¹ and now the size is not only very small,¹² about oneounce, round about 28 grams but also the today pacemakers are much smart than the previous version. The initial version was just capable of pacing asynchronously but now they are able to sense not only the intrinsic rhythm but also to behave properly in bradycardia as well as in tachycardia.¹³ There is auto rate regulation and rate smoothing algorithm. Mode switching, hysteresis, data collection and data retaining capabilities and many more complex functions are integral parameters of today's pacemakers.^{14,15} It was not only the cumbersome size but also the implantation technique which improved many folds. The first device was used to be dragged in a patient's trolley,¹⁴ and then it was improved to a size to be implanted in the abdomen under general anaesthesia. The life of the first device was very short; it was active for one hour and the second device remain viable for two days.14 The patient who was implanted permanent pacemaker for the first time received twenty-six devices in his life time. Moreover, the facilities for programming were lacking. Now as the size improved to the size of an almond, even less than that if talk of leadless devices¹⁶ and there is telemetry to programme the device after implantation, at different occasion according to the need of the patient, so the implantation techniques improved a lot. Now the device is implanted with local anaesthesia under subcutaneous tissue giving minimal discomfort to the patient, but no single implantation technique is agreed upon. Different operators use different techniques for implantation of devices. All these techniques have advantages and disadvantages. All this depend on the operator convenience and expertise. Many people implant in the cephalic vein,^{17,18} and they are pretty much comfortable with the procedure. Though with this technique of implantation there is almost 0% chance of pneumothorax^{3,4} but it involves much surgical skill and is time consuming. Apart from pneumothorax other complication including local hematoma, vein thrombosis, chronic venostasis, and infection have been reported to be related to cephalic vein cut down and in some studies the complication rate reaches up to 11%.19 The subclavian vein approach is much easier but carries high risk of pneumothorax.^{3,4} We adopted axillary vein approach,²⁰ which is less traumatic and having negligible risk of pneumothorax^{21,22}. It has relatively bloodless field, if the incision is made vertically to the clavicle and we come across only two cases of hematoma. Both these cases resolved with conservative approach. The limb on the procedure side was immobilized and pressure dressing applied for a few days. There are few subcutaneous nerves in the field of procedure and no major vessel in the incision line so less chance of paraesthesia and bleeding. It is convenient both for the patient and operator. Very little surgical expertise is required and procedure time is very short in good hands. The rate of major complications in our experience was negligible. Since the puncture site is totally extra thoracic so there is no chance of pneumothorax. The major neuro vascular bundle is not in the incision line. The incision can be made parallel with the crease line "Langer lines"²³ for good cosmetics results and fast healing. In our study in very few cases we noted upper limb oedema, which resolved by keeping the limb above the body level at night and advise to actively move the limb on that side. Puncture of vein by Seldinger's techniques become very easy if a cine film²⁴ is recorded before embarking on puncture and the results are very encouraging if one tries to puncture under fluoroscopy while contrast still flowing in the yein. It not only improves the puncture but also decrease the rate of complication. The stay of the patient and the discomfort of opening the stiches can further be minimized by subcuticular sutures.

There is still a lot of room for improvement but in our experience, we found this technique very much comfortable both for the patient and operators. Our complication rate was very low and success of puncturing the vein via this approach reaches up to 100%.

CONCLUSION

Axillary vein is an extra-thoracic structure and targeting it by Sildinger's technique is safe, less traumatic and less time consuming. The rate of pneumothorax is almost negligible and the success very high. The success rate can further be increased by cine film and under fluoroscopic punctures

AUTHORS' CONTRIBUTION

BS: conceive the idea, perform the study and wrote the manuscript; CH: Proof reading; ZAA: supervision

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Received: 2 August, 2016	Revised: 30 November, 2016	Accepted: 24 February, 2017	
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