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Original Article

Study of Extrathoracic Subclavian/Axillary Vein Puncture with a Novel Technique using "Micro-Wire" as a Guide, for Device Lead Implantation

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ABSTRACT

Background: Cannulation of veins for Cardiovascular implantable electronic devices (CIED) therapy always involves some risk of complication. To prevent lead related complications, most operators now prefer large veins like proximal part of subclavian vein and axillary vein. A novel technique of subclavian/axillary vein puncture is described where a "micro-wire", a routine 0.014 PCI wire is used as a guide to obtain vascular access. **Aims and Objectives**: To study safety and efficacy of a novel technique of subclavian/axillary vein puncture using a microwire. **Materials and Methods**: 67 adult patients admitted for routine device therapy requiring 114 lead implantations were included. A 20 gauge IV cannula was introduced on medial side of anticubital area in ipsilateral arm. Through this cannula, PCI wire was advanced via axillary vein to right atrium under fluoroscopy. Same microwire was used to guide access of subclavian/ axillary vein over first rib. **Results**: One patient was excluded due to absence of any visible vein. In 66 patients, all 112 subclavian/axillary vein cannulations were successfully performed using microwire guidance technique. Success was achieved in first attempt for 86 (76.8%), in second attempt for 18 (16%) and in third attempt for 8 (7.2 %) punctures. No complications related to punctures were observed. **Conclusion:** This technique of extra-thoracic, subclavian/axillary vein cannulations using a 'micro-wire' introduced through ipsilateral arm vein is simple, safe and more predictable for device lead implantation. Puncture is virtually done under vision as radiopaque micro-wire serves as a real-time landmark of position and course of vein over first rib.

Key words: Pacing, Axillary vein, Microwire.

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INTRODUCTION

Device therapy is commonly performed through subclavian venous approach.[1-3] Every year the number of patients undergoing device implantations is increasing. Similarly the numbers of patients who are elderly, are associated with multiple co-morbid conditions or are on antiplatelet/anticoagulant agents and undergo such procedures are increasing proportionately. Cannulation of veins for device therapy always involves some risk of a complication, which can be occasionally dangerous. These complications increase the morbidity of the procedure and may be poorly tolerated by high risk patients.[4,5] These procedure related risks have always led to a constant search for safer techniques of obtaining vascular access. At present only few operators perform this puncture without any form of extra imaging. Various techniques for obtaining venous access are anatomical land marks, fluoroscopy, contrast venography, Doppler guidance and under vision like cephalic venous cut down.[3 6-9] Out of these, the safest technique till date is cephalic venous cut down, which unfortunately is not possible or feasible in every patient and also requires a good surgical skill.[7] In order to prevent lead related complications and for multiple lead insertions, most operators now prefer large veins like the proximal part of the subclavian vein and the axillary vein.[7,10] Extra thoracic subclavian/axillary vein puncture with or without a contrast agent is associated with minimal complications, but is difficult, time consuming and may not be always successful.[6,7,9,11,12] The safety of device lead implantation procedure in high risk patients undergoing multiple lead insertions and contrast associated complications remains a concern.

The authors describe a novel technique of axillary vein puncture where a "micro-wire", a routine 0.014 PCI wire is used as a guide to obtain vascular access without using any contrast agent. This "micro-wire" is passed through the vein on the medial side of the anticubital area to the basilic vein, axillary vein, subclavian vein, superior vena cava and to the right atrium under fluoroscopy, just before the implant procedure. Then the position of this micro-wire is used as a guide for obtaining the subclavian/ axillary venous access over the first rib during device lead implantation.

MATERIALS AND METHODS

Method

This was a prospective study done in the Department of Cardiology SKIMS, Soura, over a period of six months. The study was approved by the Institute Ethics Committee. Sixty seven adult patients admitted for routine device therapy requiring 114 device lead implantations were included, after taking a written informed consent. All procedures were performed by two cardiologists. The type of devices implanted were single chamber implantable cardioverter defibrillator (ICD), single chamber, dual chamber and biventricular pacemakers. For each lead to be implanted, one separate puncture was performed. All the implants were planned on the left side. The procedure is described as follows.

Under aseptic conditions a 20 gauge(G) intravenous (IV) cannula was introduced on the medial side of the anticubital area on the ipsilateral arm. After draping the area, the micro-wire was inserted through this cannula with the help of another 20 or 22 G cannula to insert the tip of this wire into the IV cannula (Figure 1a). A used 0.014 routine percutaneous coronary intervention (PCI) wire, reprocessed by H_2O_2 plasma

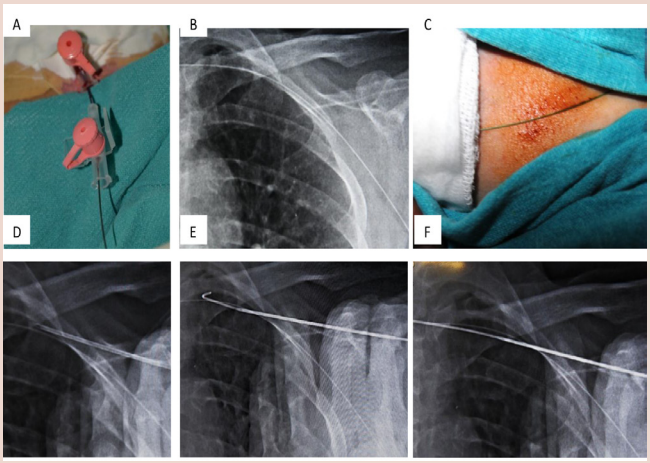

Figure 1: Steps (A to F) of "Micro-wire" assisted puncture technique

1A: The micro-wire was inserted through this cannula with the help of another 20 or 22 G cannula to insert the tip of this wire into the IV cannula. **1B** :Micro-wire was advanced through the basillic vein, axillary vein, subclavian vein, superior vena cava and to the right atrium under fluoroscopic guidance.**1C:** The IV cannula was removed to prevent bleeding through it and sterile gauze and adhesive tape was applied at the site of insertion.**1D:**Under fluoroscopy puncture needle aiming at microwire over the first rib to puncture the subclavian/axillary vein. **1E**: After successful puncture routine J wire being introduced into the axillary, subclavian vein.**1F.**Routine J wire being passed into subclavian vein , Superior vena cava and right atrium.
Note: Images BDE and F – (Negative Images to depict proper visualization of wire)

Video 1: Video showing Micro-wire being advanced through the basillic vein, axillary vein, subclavian vein, superior vena cava and to the right atrium under fluoroscopic guidance
To watch full video visit: https://youtu.be/w7m4kydWo7c

Video 2: Video showing Under fluoroscopy puncture needle aiming at microwire over the first rib to puncture the subclavian/axillary vein. After successful puncture routine J wire being introduced into the axillary, subclavian vein into subclavian vein , Superior vena cava and right atrium.
To watch full video visit: https://www.youtube.com/watch?v=Zr4W7DMAbKQ

sterilizations, was used so as not to increase the cost of the device implantation procedure. This micro-wire was advanced through the basillic vein, axillary vein, subclavian vein, superior vena cava and to the right atrium under fluoroscopic guidance. (Figure 1b and c, Video 1) The IV cannula was removed to prevent bleeding through it and sterile gauze and adhesive tape was applied at the site of insertion (Figure 1d). Patients were asked to keep their arm in neutral position as is routinely done for a device implantation. The other end of the wire was placed at the foot end of the patient so that it could be taken out at any time. If the insertion of the micro-wire would not take place in the first attempt or the desired subclavian/axillary vein was not crossed due to some reason, patients were excluded from the study. A contrast agent was instead injected through the cannula in the same arm to guide the subclavian/axillary venous puncture.

Procedure field was prepared maintaining absolute sterility and conventional reusable drapes were used in all the patients. Under local anesthesia subcutaneous pocket was prepared over the pectoralis muscle as is usually done for any device implantation. Under fluoroscopy the subclavian/axillary vein cannulation site was planned as per the location of the micro-wire over the first rib (Figure 1e). If the micro-wire detected the presence of a completely subclavicular subclavian/axillary vein over the first rib, cannulation was instead planned in the axillary vein over the second rib. The angle of the needle was kept steep, 60 degrees or more so as to keep the needle tip over the first rib, in the standard postero-anterior projection. The needle was advanced with an attached syringe as with any other indirect puncture technique aiming at the micro-wire below the clavicle and over the first rib until the rib was struck. (Figure 1f, Video 2) The needle was gently withdrawn by 1–2 cm while aspirating until there was a flashback of blood. If no flashback of blood was found, the caudocephalad angle of the needle was changed and aimed for either a slightly more cephalic or caudal position on the first rib guided by the same micro-wire. After obtaining the desired number of venous punctures for device lead implantations, the micro-wire was taken out. The number of attempts required per cannulation, any aspiration of air during the puncture, inadvertent arterial punctures, pain in the arm or failures to cannulate were recorded. Rest of the procedure for device implantation was carried out as usual. All patients were monitored during

Table 1: Showing indications of pacing and underlying co-morbidities of the studied patients.

Mean Age± SD	**59.6±10.42 (25-80)**	
Sex	**Males 42; Females 24**	
	Number	**Percentage (%)**
Indications for device		
Complete heart block	36	54.5
Type 2 II °AV block	7	10.6
Symptomatic bi-fascicular block	7	10.6
Sick sinus syndrome	6	9.1
Tri-fascicular disease	3	4.5
Dilated cardiomyopathy	6	9.1
ARVD	1	1.5
Co-morbidities		
Hypertension	18	27.3
Diabetes	7	10.6
COPD	5	7.5
Coronary artery disease	5	7.5

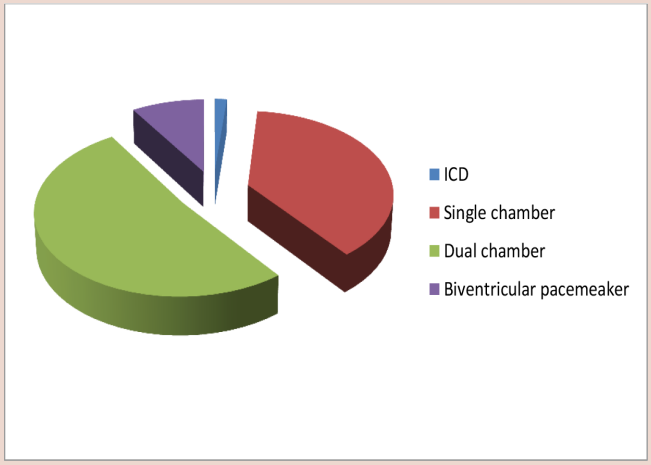

Figure 2: Types of devices used.

and after the procedure according to standard protocol and any puncture related complications like pneumothorax, hemothorax, brachial plexus injury, local hematoma or infection were recorded. Every patient underwent a routine pre-discharge x-Ray, device analysis and device site examinations to record any procedure related complication. Patients were followed at two weeks, six weeks and twelve weeks. At each visit, routine device analysis was carried out and the wound sites were examined to record any pocket hematoma or infection. Patients were telephonically enquired in case they were unable to follow due to any reason.

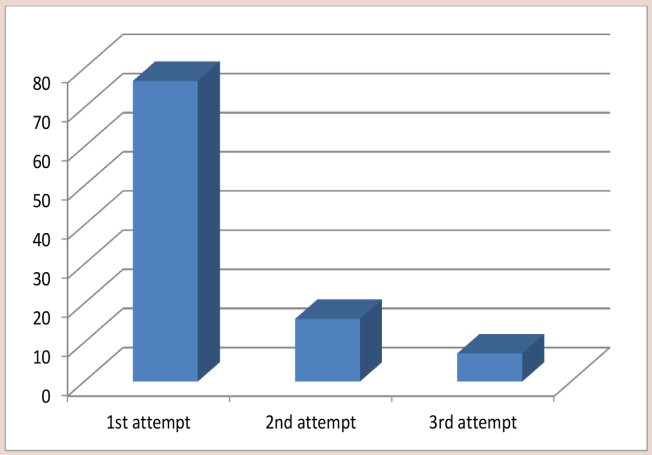

Figure 3: Bar diagram showing success rate with each puncture attempt.

Statistical analysis was done using descriptive statistics of Microsoft Windows Excel 2010.

RESULTS

We studied 67 patients requiring 114 lead implants over a period of 6 months. One patient was excluded due to the absence of a visible vein on the medial side of the anticubital area. The age of the patients ranged between 25-80 (mean 59.6 years) with 42 males (63.6) % and 24 females (36.4%). (Table 1). The devices used were 1 single chamber ICD (1.5%), 25 single chamber (38%), 34 dual chamber (51.5%) and 6 biventricular (9%) pacemakers. (Figure 2) All punctures were performed on the left side except for the two punctures in one patient in whom the micro-wire detected a venous anomaly, Left Side Superior Venecava (LSVC) to coronary sinus, which was afterwards confirmed by a contrast injection. On this patient the procedure was performed on the right side using the same technique. In all the 66 patients requiring 112 lead implants, cannulation was successfully performed with this micro-wire technique. All cannulations were performed over the first rib except for the one patient in whom the micro-wire detected a subclavicular subclavian/axillary vein and the cannulation of axillary vein was performed over the second rib using the same micro-wire technique. Two leads were successfully implanted in this patient. Out of the 112 cannulations, success was achieved in the first attempt for 86 (76.8%), in the second attempt for 18 (16%) and in the third attempt for 8 (7.2 %) punctures. (Figure 3) There was no arterial puncture, aspiration of air or arm pain recorded during the cannulation in any patient. There were no complications related to the puncture like pneumothorax, hemothorax, brachial plexus injury, wound hematoma or infection recorded in any patient during the procedure, the hospital stay or up to 3 months follow up.

DISCUSSION

At present, large vein cannulations like proximal subclavian/axillary vein are preferred for lead implantations to decrease the lead related complications and for multiple lead insertions.[7] In this prospective study a new technique of micro-wire assisted venous puncture was used to cannulate proximal subclavian/axillary vein in all the 66 patients requiring 112 lead implantations. All the cannulations were safely and successfully performed with this new micro-wire guidance technique. The safest method for cannulation of a vein for a device therapy is the venous cut

down technique usually performed on the cephalic vein. However this technique is time consuming and needs dissection and expertise. The presence and size of the vessel also cannot be predicted before the dissection.[7] Doppler assisted punctures are neither feasible for device lead implantations nor available at every hospital. Although the Ipsilateral contrast venography has increased the safety and success of punctures, yet this method is neither completely safe nor successful on every patient. Also, the contrast allergy or contrast related renal injury is a matter of concern.[6]

Burri H *et al*.[6] in a study of 142 patients, using contrast guidance for device lead implantations reported only 95% success rate. Also, the complication of pneumothorax related to the puncture was observed in 1% of patients. In the present study of the micro-wire guided cannulation, a success rate of 100% was achieved and no complications like pneumothorax. hemothorax, brachial plexus injury or pocket hematoma were observed. This present study of micro-wire technique also seems to be more predictable as a first attempt puncture was achieved in 76.8%, second attempt in 16% and third attempt in only 7.2 percent. Thus, a maximum of only three attempts were required to achieve the desired vein cannulation in this study. By using ultrasound guidance, A Sharma *et al*.[8] showed similar predictably with 76%, 16% and 6% success rate for the first, second and the third needle pass for obtaining infraclavicular axillary vein cannulation. However, the success rate in the study was only 96% with inadvertent arterial puncture rate of 1.5% and transient neuralgia in one percent.[3] Antonelli D, *et al*.[9] reported a success of 95.5% for axillary vein punctures using fluoroscopic landmarks, without contrast venography. Although no pneumothorax, hemothorax, or brachial plexus injury was reported yet this study had a failure rate of 5.5% even after 4-5 attempts.

Our study is relatively a small study to draw final conclusions about the safety and accuracy of this new technique. However, in this study of a new puncture technique, the absence of any aspiration of air or inadvertent arterial puncture and the need of only three attempts at maximum in all the 112 cannulations is encouraging and makes this technique less liable for such complications in the future also. Safety of the procedure is of utmost importance especially when it comes to high risk patients who already may be able to tolerate the procedure with difficulty. Such patients may not tolerate any procedure related complications. This micro-wire technique may help us to achieve that extra level of safety required in such patients, to gain the venous access for lead implantations or for even any other form of therapy. The safety and predictability observed in the current study of micro-wire technique is not unexpected considering the fact that the puncture is virtually done under vision. Under fluoroscopy, the radiopaque micro-wire constantly serves as a real-time landmark of the position and course of the desired vein. Change in the position of the vein related to the patient's position or respiratory movements do not affect this cannulation technique as the micro-wire also changes its position accordingly. Considering all these features, this technique can be of great help to the residents of cardiology on one hand who are beginners in this field and the most experienced operators on the other hand who deal with the high-risk patient population having multiple co-morbid conditions and/or receiving concomitant antiplatelet/anticoagulant therapy. In case of a complete subclavicular subclavian/axillary vein over the first rib, where the venous puncture is always difficult and lead related problems can be anticipated, this puncture technique can be safely performed over the second rib as was done in one patient in the current study. The micro-wire technique may also help us to prevent the formation of a redundant pocket as it can detect any venous anomaly before making the pocket. This was observed in one patient in this study where the site of the implant was changed from left to right side. An underlying renal impairment or a contrast allergy also makes it the preferable method in such patients. Use of a contrast agent can be reduced to only those patients in whom the desired vein on the medial side of the arm cannot be visualized for cannulation. However, this technique was used at a single center and only two operators performed the cannulations, it needs to be tried by many operators at different centers only then, a final word can be said about this new technique of obtaining venous access. Also, in this study we used a re-sterilized routine 0.014 PCI wire in order not to increase the cost of the procedure. The practice of reusing a PCI wire is common in this part of the world and no pacemaker infection was observed in the study patients at relatively a short follow up of 3 month. In centers where this practice might not be allowed, a new PCI wire may slightly increase the cost of the procedure. However, we believe that even then, considering the safety, reliability, feasibility and the ease with which the venous puncture can be performed with this new micro-wire technique, the benefits will always outweigh the additional cost incurred.

LIMITATIONS

Our study is relatively small to draw final conclusions about the safety and accuracy of this new technique and we need to have study where above mentioned technique can be compared with alternative method like injecting dye. In this small study with only three months of follow up it may not be possible to know whether the risk of the device infection increases, which may be related to this new micro-wire insertion technique in the peripheral vein and/or use of a re-sterilized PCI wire. Besides this flouro-time and total time taken for this new microwire technique should be compared with contrast injection so as to know whether this new technique takes more time than the usual methods for venous cannulation.

CONCLUSION

A new technique of extrathoracic subclavian/axillary vein puncture using "micro-wire", a PCI wire introduced through the Ipsilateral arm vein as a guide for device lead implantation, is described. In 66 patients all the 112 leads were successfully implanted without any complications. This new technique of micro-wire guidance under flouroscopy is simple, safe and more predictable as the puncture is virtually done under vision. The radiopaque micro-wire serves as a real-time landmark of the position and course of the desired vein over the first rib. This technique can be especially of great help to the operators who deal with the high risk patient population.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

ARVD: Arrythmogenic Right ventricular Dysplasia; **ICD:** Intracardiac Defibrillator.

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