

A Safe and Rapid Technique for Pacemaker Implantation: Roadmap-Guided Subclavian Vein Puncture

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Abstract

Objective: Widely used method is blinded puncture of subclavian vein, but the complication rate is high in this method. In this study, we aimed to demonstrate the effect of roadmap use during implantation of permanent pacemaker on the success rate, speed of puncture and complications. **Methods:** The study was designed as a prospective randomized controlled study. Totally, 125 devices were implanted to the patients included in the study, and 518 punctures were performed for implantation of these devices. 186 punctures were performed in roadmap group and 332 punctures were performed in conventional group. Two groups were compared with regard to clinical and demographic features, speed and success of puncture and complications. **Results:** Baseline characteristics were similar between groups. Median duration of intervention for each puncture was 27 (15/46) s in roadmap group and 56 (30/100) s in conventional group. The number of attempts for a successful puncture was detected as 1 (1/2) in roadmap group and 2 (2/4) in conventional group. Arterial puncture incidence was 10.3% in roadmap group and 37% in conventional group ($P < 0.001$ for all). Considering complications, the incidence of pneumothorax and intramuscular puncture was seen lower significantly ($P = 0.046$ and $P = 0.006$, respectively). **Conclusion:** Number of attempts for successful puncture, time needed for successful puncture, number of arterial puncture and complication rate was significantly lower in patients undergoing pacemaker implantation by roadmap technique. Based on these data, roadmap technique may take the place of conventional method of puncture.

Keywords: Defibrillator, pacemaker, roadmap, subclavian puncture

INTRODUCTION

Subclavian venous access is preferred frequently for implantation of permanent pacemakers since it allows the implantation of multiple leads in a reasonable period.^[1,2] Procedural success and complication rate is closely related with the operator experience and the anatomy of the operation area. Blinded punctures performed with conventional method can cause various complications. In the case of failed punctures, repeated attempts increase the risk of complications such as pneumothorax,

hemothorax, lung laceration, arteriovenous fistula, and injury to brachial plexus.^[3,4] Contrast venography-guided puncture of the subclavian vein has been used to increase the success rate of the procedure and to avoid the complications. In this method, venous anatomy has been visualized by 15–20 cc of contrast agent

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Submission: 01-Feb-19 Revision: 20-Mar-19 Accepted: 15-Apr-19

Access this article online

Quick Response Code:



Website:
<http://www.ijcv.com>

DOI:
10.4103/IJCA.IJCA_10_19

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How to cite this article: Gunes H, Katircibas MT, Balcioğlu AS, Aksu E, Sokmen A, Sokmen G, *et al.* A safe and rapid technique for pacemaker implantation: Roadmap-guided subclavian vein puncture. *Int J Cardiovasc Acad* 2019;5:86-91.

injection made from the ipsilateral peripheral venous access and subclavian puncture has been performed under fluoroscopy.^[5,6] Punctures performed between costoclavicular ligament and subclavian muscle can cause lead fractures later on.^[7] It is difficult to avoid this complication in punctures achieved by conventional method in which extrathoracic and intrathoracic subclavian vein discrimination cannot be done. Similarly, the complication rate including lead fractures decreased in studies determining extrathoracic subclavian vein anatomy to avoid lead fractures.^[8,9] In addition, ultrasonography-guided intervention of axillary vein also reduced lead fractures and other complications related with the subclavian venous puncture.^[10]

Roadmap is an imaging technique that is created by converting the first image taken during injection to digital information and holding it in the device memory. It is important to visualize the vascular bed simultaneously that allows the positioning of the guide wires and catheters without need for repetitive contrast injections. The usage of roadmap increases the success rate and speed of the cannulation.^[11]

In this study, we aimed to investigate the effect of roadmap use during the implantation of permanent pacemaker on the success rate and speed of venous puncture, and number of attempts for successful puncture as well as to various complications such as arterial puncture, intramuscular puncture, pneumothorax, and pocket hematoma.

METHODS

Patient selection

The study was designed as a prospective randomized controlled study. Patients over 18 years old who were taken to catheterization laboratory for permanent pacemaker implantation through the subclavian vein were included in the study. Patients were divided into two groups: those who underwent roadmap-guided subclavian venous puncture and those who performed conventional subclavian venous puncture. Both puncture techniques performed separate puncture for each lead implantation. In both groups, demographic characteristics, the total number of punctures performed, number and type of inserted devices, time for successful punctures, time for single successful intervention, number of arterial punctures, clinical and laboratory data before and after the procedure, and complications after the procedure were recorded. Diabetes mellitus was defined as fasting blood glucose ≥ 126 mg/dl or taking antidiabetic medication. Hypertension was defined as systolic arterial blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg measured on three separate office visit or taking antihypertensive treatment. The pacemaker implantation decision was made by our heart team including electrophysiologists and heart failure experts in accordance with related guidelines of the European Society of Cardiology and pacemaker implantation was performed by the same electrophysiologist in both groups.

Pacemaker implantation procedure

All patients were questioned whether receiving antiaggregant and anticoagulant therapy before the procedure and if

necessary, they were managed properly, and the treatments were recorded. The implantation area was cleared off skin hairs 24 h before the procedure. Nasal oxygen was given to the patients when needed. All patients were sedated by intravenous midazolam (1–2.5 mg) to perform a smooth implantation. Flumazenil was kept for use when required. Appropriate antibiotic prophylaxis was given to the patients before the procedure. Two venous vascular accesses were established in all patients. One of them was placed on ipsilateral antecubital region with the proper venous catheter for delivering contrast material to generate a roadmap in the roadmap group.

Following skin preparation and local anesthesia, the skin incision was made 2 cm below and parallel to the clavicle, as the medial edge of incision ending in 1/3 middle part of the clavicle. The length of incision was 4–6 cm for implantable cardioverter defibrillators (ICDs) and 3–4 cm for pacemakers. After progressing toward pectoralis muscle fascia by blunt and sharp dissection, a pocket proper for device size was created under the muscle to decrease the erosion and to get a favorable appearance cosmetically based on the operator's choice. Then, in conventional subclavian venous puncture group, 2–3 ml saline was taken by conventional 18-gauge needle mounted to 10 cc injector and the puncture was performed from the point combining middle and inner third of clavicle by progressing the needle under the clavicle with the needle tip pointing the upper notch of the sternum. The duration of the intervention was defined as the time between the beginning of the puncture and cannulation of the subclavian vein. The repeated intervention was defined as the removal of the needle from the puncture area completely and beginning the puncture from a different region. Arterial puncture was defined as the puncture of the subclavian artery accidentally. An independent observer calculated the duration of each successful venous puncture. Number of attempts for venous cannulation and number of arterial puncture was also recorded. In the roadmap group, after stabilization of the arm, a roadmap was formed by injecting 15 ml of contrast agent through antecubital venous line [Figure 1]. The puncture was performed in the

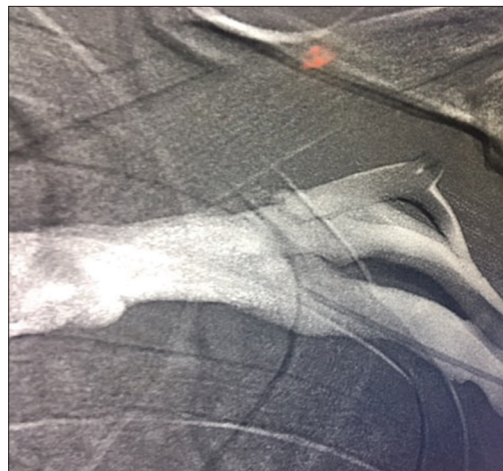


Figure 1: Roadmap-guided subclavian vein puncture

same way as described above and time to puncture, number of attempts for venous cannulation and number of arterial puncture was also recorded. Fluoroscopy duration required for creating roadmap was recorded by an angiography technician. The total fluoroscopy time was also noted if fluoroscopy was needed in the conventional procedure group. After the implantation and fixation of the leads, the pocket irrigated with antibiotic (rifocine) and pacemaker generator was inserted into the pocket enabling that the portion of leads outside the vein are placed under the generator which was fixed by a single suture. Then, the incision was sutured and the pacemaker was programmed. Pressure was applied on to the incision area by 1000 cc physiological saline solution pack for 2 h. Patients were followed up for 24–48 h. Any complication such as pneumothorax and pocket hematoma was recorded. Ten days later, incision area was reevaluated during the removal of the sutures, and any complication such as wound infection was recorded.

This study was approved by the Ethics Committee of the Kahramanmaraş Sutcu Imam University under protocol number 52. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

Statistical analysis

Statistical analyses were conducted through SPSS 17.0 (for Windows SPSS 17.0, Chicago, Illinois, USA). Continuous variables were presented as mean \pm standard deviation (for parameters with normal distribution) and median (25%/75% interquartile range) for parameters without normal distribution, and categorical variables were presented as percentages. Normality analysis was performed using the Kolmogorov–Smirnov test. Comparison of categorical variables between the groups was performed using the Chi-square test. The Student's *t*-test was used for the comparison of normally distributed variables, and the Mann–

Whitney U-test was used for the comparison of normally distributed multiple variables. A two-tailed $P < 0.05$ was determined to be statistically significant within a confidence interval of 95%.

RESULTS

Randomization phase

In study, 126 patients were enrolled consecutively and randomized (1:1) either to conventional group or roadmap group. One of the patients who received a single-chamber pacemaker with the roadmap method was excluded from the study because of withdrawing consent. Two patients in the conventional group were switched to roadmap group due to failure of subclavian vein puncture with conventional method. Accordingly, roadmap group composed of 64 patients and conventional group consisted of 61 patients. For a total of 125 devices, 245 leads were implanted. Operators received a deadline of 5 min or 8 subclavian vein puncture to complete the conventional method subclavian vein puncture.

Baseline characteristics of study population are presented in Table 1. Of these patients, 45 (36%) underwent single chamber (SC) ICD/pacemaker, 40 (32%) underwent dual chamber (DC) ICD/pacemaker, and 40 (32%) underwent CRT implantations. Roadmap-guided implantation was performed in 64 patients (22 [35%] SC ICD/pacemaker, 22 [34%] DC ICD/pacemaker, and 20 [31%] CRT) while the implantation was performed by conventional method in 61 patients (23 [37%] SC ICD/pacemaker, 18 [30%] DC ICD/pacemaker, and 20 [33%] CRT). There was no significant difference between groups considering SC ICD/pacemaker, DC ICD/pacemaker, and CRT implantation ratios ($P = 0.881$, $P = 0.645$, and $P = 0.759$, respectively). Demographic data of the patients were given in Table 1. Groups were similar for basal characteristic features. There was no statistically significant difference between groups considering hematological and biochemical parameters [Table 1].

Table 1: Baseline characteristics of study population

Baseline characteristics	All patients (n=125)	Roadmap group (n=64)	Conventional group (n=61)	P
Age, years*	67 (58/75)	65 (57/72)	68 (58.5/76)	0.149
Weight, kg	73.4 \pm 12.3	72 \pm 11.1	74.8 \pm 13.7	0.198
Height, cm*	161 (155/168)	158 (154.25/163.75)	164.5 (159.25/170.75)	<0.001
Gender, male/female, n (%)	90/35 (72/28)	45/20 (69.2/30.8)	45/15 (75/25)	0.473
Hypertension, n (%)	81 (64.8)	41 (63.1)	40 (66.7)	0.761
Diabetes mellitus, n (%)	56 (44.8)	29 (44.6)	27 (45)	0.972
Current smoking, n (%)	79 (63.2)	42 (64.6)	37 (61.7)	0.647
Hyperlipidemia, n (%)	82 (65.6)	46 (70.8)	36 (60)	0.163
COPD, n (%)	30 (24)	15 (23.1)	15 (25)	0.839
CAD, n (%)	95 (76)	49 (75.4)	46 (76.7)	0.989
SC pace or ICD, n (%)	45 (36)	23 (35.4)	22 (36.7)	0.881
DC pace or ICD, n (%)	40 (32)	22 (33.8)	18 (30)	0.645
CRT, n (%)	40 (32)	20 (30.8)	20 (33.3)	0.759

*Data presented as median (25/75% IQR). CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, CRT: Cardiac resynchronization therapy, DC: Dual chamber, ICD: Implantable cardioverter defibrillator, SC: Single chamber, IQR: Interquartile range

On the comparison of outcomes, it was seen that 186 punctures were performed in roadmap group and 332 punctures were done in conventional group. The median duration of intervention for each puncture was 27 s (15/46) in roadmap group and 56 s (30/100) in conventional group. The number of attempts for a successful puncture was detected as 1 (1/2) in roadmap group and 2 (2/4) in conventional group. Arterial puncture incidence was 10.3% in roadmap group and 37% in conventional group. Time to puncture, number of attempts for successful puncture and arterial puncture ratio was seen significantly lower in roadmap group ($P < 0.001$, $P < 0.001$, and $P < 0.001$, respectively). When peri- or post-procedural complications were compared, incidence of pneumothorax and intramuscular puncture was seen lower significantly ($P = 0.046$ and $P = 0.006$, respectively). Although pocket hematoma was seen less frequently in roadmap group, the difference between groups was not statistically significant ($P = 0.075$). The groups were found similar as the success of the procedure ($P = 0.113$) [Table 2].

When mean duration of puncture, number of attempts for successful puncture and ratio of arterial puncture were

compared according to device type, it was found that usage of roadmap method for device implantation reduced the time needed for successful puncture, number of attempts for successful puncture and incidence of arterial puncture significantly in all types of devices. In patients undergoing VR and DR pacemaker/ICD implantation, total procedure time was less in road map group whereas in patients performed CRT implantation, total procedure times were same in both groups. Considering fluoroscopy durations, images were taken from all patients by the way of fluoroscopy for 5 s in road map group. Then, puncture was performed and no additional fluoroscopy was performed. In conventional group, fluoroscopy was not performed in successful blinded punctures, but fluoroscopy times required for venography and anatomic localization were recorded. These durations were found as 20 s (0/40) for VR and 20 s (0/43) for DR and were significantly higher as compared to those of road map group ($P = 0.001$ for both). In CRT implantations, fluoroscopy times used for cannulation of coronary sinus were longer and were found similar between two groups (28.3 ± 6.0 vs. 30.7 ± 8 , $P = 0.286$) [Table 3].

Table 2: Procedural characteristics and complication frequencies of both groups

	Roadmap group (n=64)	Conventional group (n=61)	P
Total/successful punctures, n	186/126	332/119	<0.001
Failed attempts, n (%)	60 (32.3)	213 (64.2)	<0.001
Time to puncture, s*	27 (15/46)	56 (30/100)	<0.001
Attempts for successful puncture, n*	1 (1/2)	2 (2/4)	<0.001
Incidence of arterial puncture, %	10.3	37	<0.001
Incidence of pneumothorax, %	0.8	5	0.046
Incidence of intramuscular punctures, %	0	5.9	0.006
Incidence of pocket hematoma, %	1.6	5.9	0.075

*Data presented as median (25/75% IQR). IQR: Interquartile range

Table 3: Procedural characteristics of both groups according to device types

	Roadmap group (n=64)	Conventional group (n=61)	P
SC ICD/pace, n	22	23	-
Attempts for successful puncture, n*	1 (1/2)	3 (1/4)	0.004
Time to puncture, s*	30 (23/70)	145 (18/180)	0.014
Incidence of arterial puncture, %	9.1	30.4	0.063
Fluoroscopy times, s*	5 (5/5)	20 (0/40)	0.001
Total procedure time, min*	26±5.1	30.6±7.2	0.017
DC ICD/pace, n	22	18	-
Attempts for successful puncture, n*	1 (1/2)	2 (1.25/4)	<0.001
Time to puncture, s*	25 (10/37.25)	63.5 (22.25/86.25)	<0.001
Incidence of arterial puncture, %	9.1	33.3	0.006
Fluoroscopy times, s*	5 (5/5)	20 (0-43)	0.001
Total procedure time, min*	33.7±5.2	39.9±5.9	0.001
CRT, n	20	20	-
Attempts for successful puncture, n*	1 (1/2)	2 (2/4)	<0.001
Time to puncture, s*	26 (15/46)	47 (30/97)	<0.001
Incidence of arterial puncture, %	11.7	40.3	<0.001
Fluoroscopy times, min*	28.3±6.0	30.7±8	0.286
Total procedure time, min*	65 (40/100)	65 (45/120)	0.242

*Data presented as median (25/75% IQR). IQR: Interquartile range, DC: Dual chamber, SC: Single chamber, CRT: Cardiac resynchronization therapy, ICD: Implantable cardioverter defibrillator

DISCUSSION

This is the first study evaluating the effect of roadmap use on the success and the complication rate of the implantation of permanent pacemakers. The study revealed that complication rate was lower; success rate of puncture was higher; fluoroscopy time, total procedure time, and time to puncture were lower in patients undergoing permanent pacemaker implantation using roadmap technique. Since roadmap technique allows the anatomic imagination of subclavian vein, cannulation of extrathoracic portion of subclavian vein may prevent punctures through the muscle and decrease the probability of lead fractures.

Nowadays, the subclavian vein is preferred for permanent pacemaker implantation because of rapid and easy applicability. The number of attempts and time for successful puncture of subclavian vein depends on both anatomical factors and operator experience. A technique that can minimize the unfavorable effect of these two factors is supposed to decrease both the rate of puncture failure and duration of successful puncture. Accordingly, this will reduce the complications related with puncture and increase patient comfort because of less number of trials for successful puncture and shorter procedure duration. Previously, Higano *et al.* and Chan *et al.* performed subclavian puncture by the guidance of fluoroscopic venography in their studies and reported that puncture guided by venography was safer.^[6,7] Similar to these studies, we planned to compare subclavian puncture performed after anatomic imagination of subclavian vein with conventional blinded puncture. But differently, we used roadmap technique to visualize subclavian vein. There are several advantages of roadmap technique to venography. One of them is shortened fluoroscopy duration and accordingly decreased exposure of both patient and operator to radiation. The other one is that single roadmap image enables opportunity to multiple attempts of puncture; so recurrent use of contrast agent during the implantation of pacemakers with multiple leads is avoided. However, in the group of patients performed conventional method, there is no need for fluoroscopy and contrast injection during successful venous puncture. In case of contrast agent allergy or renal impairment, blinded puncture is superior to roadmap or fluoroscopy-guided techniques. On the other hand, when the intervention is considered under fluoroscopic venography due to anatomical difficulties or unsuccessful attempts, then the use of roadmap method may be more reasonable unless there is no contraindication to contrast agents.

Although various studies comparing different techniques used for intervention are present in the literature, our study is the first one using roadmap technique for subclavian puncture.^[8,9,12,13] In this study, blinded subclavian venous puncture was compared with the puncture guided by roadmap with regard to success of the procedure, time needed for a successful venous puncture and unintended puncture of subclavian artery, and roadmap technique was found superior to blinded puncture in all these

parameters. Main complications of subclavian venous puncture are pneumothorax and hemothorax, and their incidence is 1%–3%.^[14] In order to decrease these complications venography has been used frequently and shown to be effective in various studies.^[6,15,16] In our study, pneumothorax was reported only in the blinded puncture group. Higher number of attempts for successful puncture in this group may be a causative factor for these complications.

Pocket hematoma is a widely seen complication of pacemaker implantation.^[17] It increases the duration of hospitalization and the risk of device infection. Many factors may contribute to development of pocket hematoma. Procedure type (first implantation or reimplantation), operator experience, device size, number of leads, venous route (subclavian or cephalic vein), body mass index and anticoagulant and/or antiaggregant use are regarded among them.^[18-22] In our study, pocket hematoma was shown to be more frequent in the group of blinded puncture. Detailed analysis revealed that unintended puncture of subclavian artery was performed in most of the patients having pocket hematoma. This finding made us to think that subclavian arterial puncture could be a contributing factor for pocket hematoma. However, further studies are needed to support this hypothesis considering the factors predisposing to pocket hematoma such as device size, number of leads implanted, and patient's medication.

Another problem that can be encountered during subclavian puncture is puncture of intrathoracic subclavian vein that can result in lead fracture. Intrathoracic subclavian puncture causes trapping of leads between costoclavicular ligament and/or subclavian muscles which results in lead fractures.^[5] Based on these data, we intended to puncture extrathoracic subclavian vein in the patients of roadmap group. In blinded puncture, since we could not do this discrimination, there were some intramuscular punctures, which were identified by the factors based on the operator experience such as resistance to the insertion of sheath and resistance and difficulty during manipulation of leads after removal of sheath. Puncture site was changed in these patients to decrease the risk of lead fracture. Roadmap-guided puncture may provide to avoid intramuscular puncture and/or intrathoracic puncture of subclavian vein, which is the most important cause of lead fractures, independently of operator experience. As a result, lead fractures can be prevented by this technique.

Study limitations

Our study has some limitations. Of these, number of study population was relatively small and all pacemakers were implanted by electrophysiologists. The roadmap technique has also some limitations such as keeping the patient immobile and use of contrast agents for visualization of the vein. Although we thought that lead fractures might be prevented by puncture of extrathoracic subclavian vein, we could not document the rate of lead fracture since long-term follow-up was not done. Finally, the team conducting the study will also report the results. This is an important limitation for bias.

CONCLUSION

Our study revealed that number of attempts for venous puncture was lower and time needed for successful puncture was shorter in patients undergoing pacemaker implantation by roadmap technique. Moreover, complications of pacemaker implantation such as pneumothorax, hemothorax, and pocket hematoma were seen less frequently in roadmap group. These data indicate that procedure of pacemaker implantation can be managed more successfully and safely using roadmap technique.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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