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Original Research

A New Predictor for Patients with Cardiac Implantable Electronic Device in Iatrogenic Pneumothorax: The Clavicle Length Index

Abdullah Orhan Demirtaş[1], Yahya Kemal İçen[1], Esra Dönmez[2], İbrahim Ethem Özsoy[3], Hasan Koca[1], Fadime Karataş[1], Mevlüt Koç[1]

[1]Clinic of Cardiology, University of Health Sciences Adana Health Practice and Research Center, Adana, Turkey

[2]Clinic of Cardiology, Konya Numune Training and Research Hospital, Konya, Turkey

[3]Clinic of Chest Surgery, University of Health Sciences Kayseri Training and Research Hospital, Kayseri, Turkey

ABSTRACT

Objective: Pneumothorax (PTX) is a complication that occurs while placing cardiac implantable electronic devices (CIED) in the thorax. In the literature, no clear relationship has been identified between the patient's anatomic structure and the occurrence of PTX. We aim to investigate whether there is a relationship between PTX and anatomic structure in patients with CIED.

Methods: We retrospectively included 1602 patients in whom CIED had been placed for any reason between June 2008 and June 2018. The proximal clavicle tip, middle point, distal tip, and angulus mandible were marked and distances between these points were measured. The ratio between body mass index (BMI) and clavicle length was obtained (clavicle length index).

Results: We included 1568 (97.8%) patients without PTX and 34 (2.2%) patients with PTX in our study. The length of the clavicle and the distance between angulus mandible and clavicle middle point, angulus mandible, and clavicle distal tip significantly decreased, while the clavicle length index (CLI) significantly increased in PTX patients. The distance between angulus mandible and clavicle distal tip (OR: 0.811) and CLI (OR: 8.014) were determined to be independent predictors for pneumothorax. When the cut-off value for CLI was taken as 1.67, it was observed that PTX was predicted with 70% sensitivity and 62% specificity.

Conclusion: The operator can predict the PTX in the patient by measuring the length of the clavicle and the BMI.

Keywords: Cardiac device, clavicle, length index, pneumothorax

INTRODUCTION

Recently, cardiac implantable electronic devices (CIED) have been widely used in some cardiac arrhythmic diseases (1, 2). Although the positive effects of these devices on prolonging human life cannot be questioned, to a certain extent they do have some complications and risks (3). Some of these can threaten life unless a timely diagnosis is made. Pneumothorax (PTX) comes first among these complications (4, 5). A rate of 0.2–3.7% for PTX was reported following the placement of CEID in the literature (3-6). PTX can develop according to the patient, operator, or operational procedure (4). A patient being elderly and/or female and an operator having less experience are some risk factors. Besides, venous intervention (axillary, subclavian, or cut-down), ultrasound-guided intervention, or intervention with venography are also identified as risk factors (7).

In pneumothorax, the procedural and operator-related factors can be canceled out almost completely in experienced, high-volume, and full-capacity centers. Patient-related factors are inevitable and must be taken into consideration before the operation. When the related literature was reviewed, it was seen that data on the anatomy of the patient was very limited although the experience of the operator was mentioned as a risk factor for cardiac device implantation complication; pneumothorax (4-7). The clavicular and mandibular bones in the manubrium and neck region are apparent and easy to measure. We thought that clavicle might have an important role in iatrogenic PTX because of its proximity to both the subclavian vein and apex of the lung. Although BMI is defined as a risk factor in many diseases, there are conflicting data about the relationship between BMI and PTX (8, 9). In this study, we aimed to investigate if there was a relationship between the development of PTX in patients with CIED and clavicle and/or BMI.

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ORCID ID of the author: A.O.D. 0000-0003-4768-0536; Y.K.İ. 0000-0003-0070-5281; E.D. 0000-0003-4484-4259; İ.E.Ö. 0000-0003-2722-5309; H.K. 0000-0002-6232-4567; F.K. 0000-0002-3573-7593; M.K. 0000-0002-3000-4200

Corresponding Author: Abdullah Orhan Demirtaş **E-mail:** aorhandemirtas@gmail.com

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METHODS

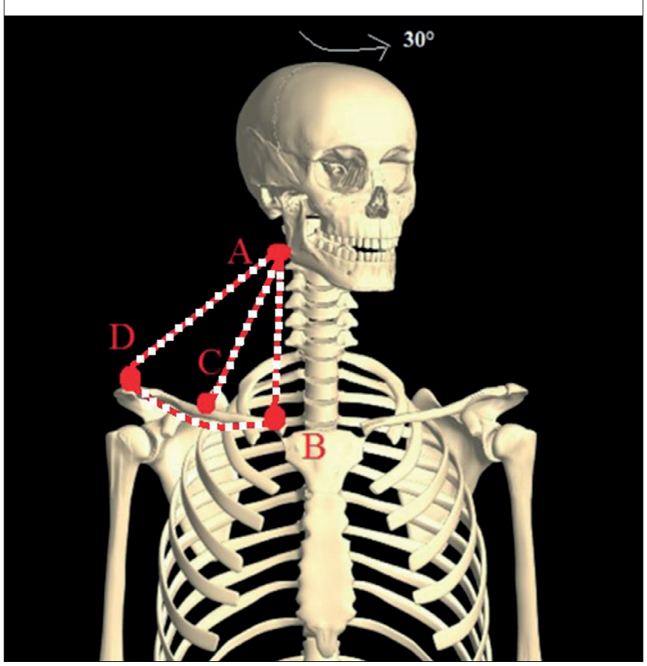
Study Population

We retrospectively included 1602 patients in whom CIED had been placed for any reason between June 2008 and June 2018. We excluded the patients who had chest deformities, had undergone radiotherapy on the chest region or an operation previously. We also excluded the patients in whom a CIED had been placed before or who had an upgraded or revised device due to the possibility of an anatomic change in the subclavian vein. We only included patients with a newly placed CIED. The devices of about 70–80 patients with CIED are controlled in our center every week. Apart from this, the other patients were called and invited to our center. Demographic data of all these patients were recorded. Ethics committee approval was received for this study from the ethics committee of Adana Numune Training and Research Hospital (date: 26.04.2017, no: 59).

Venous Puncture Method

A separate puncture was performed for each lead. Two venous puncture methods, subclavian and axillary, were used by 3 operators with high volume (>100 number/year). A previously described method was used in axillary vein puncture (10). Generally, before forming the device pocket, the skin and subcutaneous tissue were traversed by an 18-gauge needle with an angle of 45° (Cook Medical, Bloomington, IN, USA). The needle was taken forward without going beyond the medial border of the first rib. If the first rib could not be reached, the needle was pulled back close to the first entry point and was redirected with a steeper angle so as to prevent tissue laceration. This procedure was continued under fluoroscopy till it touched the first rib. When the rib was touched, the needle was pulled back slowly by maintaining negative pressure. The injector was pulled back until the venous blood flow was seen through it. If no blood flow was seen, the needle was pulled slightly back and was redirected to an area a few millimeters to the right or left, where upon the same procedure was repeated. When the venous blood flow was seen, the guide wire was advanced forward. The clavicle was divided into 3 imaginary pieces. It was advanced forward from the place where 2/3 of lateral region was intercepted by the first rib under the clavicle with a medial and cranial angle. The sheath was placed by the Seldinger technique. In subclavian venous puncture, the previously described method was used again (11).

Figure 1. Demonstration of anatomical measurement points (A-Angulus mandible, B-Proximal tip of the clavicle, C-Middle point of the clavicle, D-Distal tip of the clavicle)



The Measurement of Anatomical Distances and Pneumothorax Predictor Parameters

Clavicle proximal tip, middle point, and distal tip and angulus mandible were determined. The head was turned to the front with an angle of 90° and to the right with an angle of 30°. Clavicle length (the distance between distal and proximal tip), the distance between the angulus mandible and clavicle proximal tip, and the distances between middle point and distal tip were measured in centimeters (Figure 1). Then, the BMI we had measured before was divided by the clavicle length and a new index was obtained (CLI). All the measurements were recorded by two independent cardiologists.

Evaluation of Pneumothorax Diagnosis

Posterior-anterior (PA) chest radiography was taken routinely after the operation. If aeration deficiency was observed in PA chest radiography, a thorax computed tomography (CT) was performed on the patients. Final PTX diagnosis was established by CT scanning. Then, the patients were sent to the thoracic surgery department for consultation regarding the need for a chest tube. If the PTX area in CT was less than 20%, it was considered to be a small PTX and nasal oxygen therapy was given. Additionally, tube thoracostomy was applied to the symptomatic ones and to those who had more than 20% PTX area.

Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences for Windows 20.0 (SPSS IBM Corp.; Armonk, NY, USA). Variables were divided into categorical and continuous groups. Categorical variables were expressed as frequencies and percentages and were analyzed using the Chi-square test. The Kolmogorov–Smirnov test was used to determine whether continuous variables had a normal distribution or not. Continuous variables were expressed as mean ± standard deviation. Normally distributed variables were analyzed with independent samples t-test. Non-normal distributed variables were analyzed with the Mann–Whitney U-test. Independent predictors for PTX were determined by the binomial logistic regression analysis using $p<0.05$ variables. Receiver Operating Characteristic (ROC) analysis was used to calculate cut-off, sensitivity, and specificity values of the independent PTX predictors. As mentioned, the SPSS for Windows 20.0 Program was used for statistical analysis. A p-value <0.05 was considered to be statistically significant.

RESULTS

Cohen kappa values were expressed as a percentage that evaluated the inter-observer and intra-observer variability being higher than 95% for all anatomical distances. We included 1568 patients without PTX (average age: 74.4±10.4 years) and 34 patients with PTX (2.2%, average age: 74.4±10.4 years). Only 10 (2.9%) of 34 patients underwent tube thoracotomy. No significant difference was found between the two groups when demographic and procedural data were compared (Table 1). When anatomic distances were compared, it was observed that length of clavicle (p=0.003), distance between angulus mandible and clavicle middle point (p=0.012), and the distance between the angulus mandible and clavicle distal tip (p=0.047) significantly decreased in the patients with PTX, while the CLI of the same patients significantly increased (p<0.001) (Table 2). In the analysis of binomial logistic regression which was done only with the significant variables, it was determined that the distance between angulus mandible and clavicle distal tip (OR: 0.811, CI 95%: 0.692–0.950, p=0.009) and the CLI (OR: 8.014, CI 95%: 2.442–26.302, p<0.001) were the independent predictors for PTX (Table 3). In the analysis of ROC that was performed with the CLI, three cut-off values were defined and the values of sensitivity and specificity were calculated (Figure 2).

Figure 2. Receiver Operating Characteristic analyses to determine the predictive value of clavicle length index for iatrogenic pneumothorax

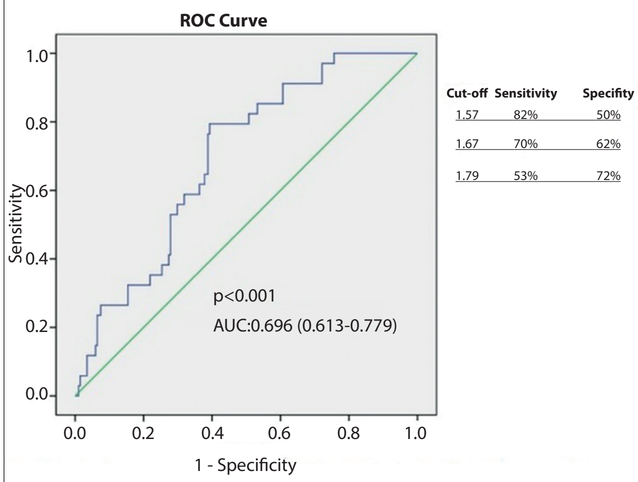


Table 1. Comparisons of demographic and procedural findings

	With pneumothorax n=34	Without pneumothorax n=1568	p
Age (years)	73.4±12.1	74.4±10.4	0.637
Male gender, n, %	18 (52.9)	889 (56.7)	0.662
SBP (mmHg)	127.0±11.0	126.2±11.1	0.712
DBP (mmhg)	81.4±6.2	81.5±5.8	0.906
Pulse (beat/minute)	74.2±13.2	75.5±13.1	0.634
BMI (kg/m^2)	25.2±3.2	26.2±2.2	0.078
Smoking, n (%)	6 (17.6)	186 (11.9)	0.304
DM, n (%)	14 (41.2)	658(42.0)	0.927
HT, n (%)	14 (41.2)	165 (38.6)	0.77
HPL, n (%)	2 (5.9)	114 (7.3)	0.757
COPD, n (%)	4 (11.8)	182 (11.6)	0.977
Single lead, n (%)	10 (29.4)	395 (25.2)	0.575
Two leads, n (%)	18 (52.9)	931 (59.4)	0.457
Three leads, n (%)	6 (17.6)	242 (15.4)	0.724
Axiller punction, n (%)	28 (82.4)	1344 (85.7)	0.58
Subclavian punction, n (%)	6 (17.6)	224 (14.3)	0.58
Venography, n (%)	6 (17.6)	180 (11.5)	0.267

COPD: chronic obstructive pulmonary disease, DM: diabetes mellitus, DBP: diastolic blood pressure, HT: hypertension, HPL: hyperlipidemia, SBP: systolic blood pressure

Table 2. Comparison of anatomical distances

	With pneumothorax n=34	Without pneumothorax n=1568	p
Clavicle length (cm)	15.4±1.5	16.4±2.9	0.003
Angulus mandible and clavicula proximal tip (cm)	10.7±1.5	11.2±1.6	0.075
Angulus mandible and clavicle middle point (cm)	5.6±1.0	5.4±0.7	0.012
Angulus mandible and clavicle distal tip (cm)	10.6±2.7	11.6±2.8	0.047
* Clavicle length index (n)	1.83±0.29	1.62±0.32	<0.001

*: body mass index/clavicle length

Table 3. Independent predictors for pneumothorax

	Odds ratio	95% Confidence interval	p
Clavicle length	1.123	0.850-1.484	0.413
Angulus mandible and clavicle middle point	1.457	0.791-2.654	0.227
Angulus mandible and clavicle distal tip	0.811	0.692-0.950	0.009
* Clavicle length index	8.014	2.442-26.302	0.001

*: body mass index/clavicle length

DISCUSSION

Our study is the first to investigate the anatomic quantitative data of patients with PTX. The ratio that is obtained by dividing the BMI by clavicle length is called the CLI (≥1.67), which predicted the occurrence of PTX with 70% sensitivity and 60% specificity. In addition to this, the PTX rate was found to be 2.1%.

The BMI that is accepted all over the world is a predictor for mortality in many diseases (cardiac and non-cardiac). Although the normal range has been defined as 18–25, a change of 1–2 points can be seen in these values across different populations (12).

The clavicle is one of the flat bones of the body. In the intrauterine period, ossification starts in the 5th and 6th weeks and might continue until almost 21 years (13). The subclavian vein which is frequently used for the puncture while placing the cardiac device extends between the first rib and clavicle. Because of its proximity to the subclavian vein and the apex of the lung, the clavicle has a unique role in directing the operator during the procedure. Therefore, it has been thought that a lengthier clavicle is a protector for PTX in patients. Even though the clavicle length is significantly shorter in the patients with PTX in the analysis with one variable, no difference was found in the multivariate analysis. The distance between angulus mandible and clavicle distal tip was determined as an independent predictor for PTX.

The ratio of BMI and clavicle length was also significant in multivariate analysis. We believe that there are two explanations for this relationship. The first one is that the possibility of PTX is lower if the clavicle is long, no matter how overweight the patient is. The second is that extra attention must be paid to the possibility of PTX if the patient's clavicle is short even if the patient's BMI is within the normal range. There are some conflicting results about the relationship between PTX and obesity in previous studies (8, 9). In our study, the BMIs of both groups were found to be similar. It is interesting that obesity, which is an important risk factor in many factors, was not determined as a distinct risk factor for PTX. We believe that clavicle length could be extended in obese patients, which might have protected the patient from PTX. Furthermore, we expected the PTX index that we found to be low in these patients.

In a study by Kotter et al. (14), a large number of patients with CIED were scanned retrospectively. The rate of PTX was reported as 1.7% and it was claimed that the most important predictor was subclavian vein puncture. It was mentioned that PTX was seen significantly less in the use of the axillary vein. In our study, no difference was found in axillary and subclavian punctures in terms of pneumothorax. However, the qualitative value which we described as CLI has a relationship with the clavicle, which is proximate to the subclavian vein. If the operator is experienced, we do not think the vein on which the puncture is made is a significant risk factor for PTX. In our center, no significant difference was found between the subclavian vein and axillary vein puncture by 3 experienced operators, who routinely treat >100 patients/year.

It was reported in two previous studies where a large number of patients were scanned, that there are many risk factors for PTX (4, 5). These are; the female gender, patient age of 80 years or above, chronic obstructive pulmonary disease, inexperienced center, extended operation time, and subclavian vein puncture. It was claimed that the experience of the operator was not a risk factor. Although many of these risk factors were checked in our study, no significant difference was revealed. In this study, multiple data were obtained about the patient, operation procedure, and the experience of the operator. It is important to scan a sufficiently large number of patients. We believe that significant difference in the rate of PTX would have been found if experienced and inexperienced operators had been compared separately as the effect of the experience of the operator on the development of PTX is unquestionable. It is interesting to have found that the experience of the operator is not a risk factor in the conclusion even though such a separation had not been made. We believe that many risk factors listed above can become unimportant in experienced centers.

In a meta-analysis of patients with cardiac implantable devices, it was reported that intervention technique and the place of puncture was not a risk factor for PTX in some selected studies and PTX was seen relatively more in the patients who underwent thoracotomy (6). It can be said that the results of this meta-analysis and our study match each other.

We also concluded in our study that the place of intervention is not a risk factor in experienced hands. It was presented in a studyon patients with CIED that PTX was seen less in the patients in whom a single chamber pacemaker had been placed (15). In our study, no significant relationship was found between the number of leads that were placed and PTX occurrence. Multiple punctures might increase the possibility of PTX but this might be reduced by experienced hands. In a study conducted on patients who received a revised and upgraded CIED, PTX was seen most in cardiac resynchronization therapy-defibrillators and pace upgrade patients. The general rate of occurrence was reported as 0.8% (3). Upgraded patients were not included in our study. A high rate is expected in upgraded patients due to disrupted anatomy. We think that the PTX rate was low as revised patients were also included in this study.

There are some limitations to our study. Since our rates and findings belong to a single high volume center, they might not be instructive in centers with low volume and in inexperienced centers. As the clavicle length is manually measured from the outside, it could be difficult to measure in obese patients. Further multi-center studies are needed to apply the CLI to all the patients in whom a CIED has been placed.

CONCLUSION

CLI is an easy and useful method to predict PTX. Before the CIED is placed, prior information about the risk of pneumothorax can be given to the operator, who can then be guided to be more careful.

Ethics Committee Approval: Ethics committee approval was received for this study from the Ethics Committee of Adana Numune Training and Research Hospital (date: 26.04.2017, no: 59).

Informed Consent: Due to the retrospective design of the study, informed consent was not taken.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.O.D., Y.K.İ., E.D., İ.E.Ö., H.K., F.K., M.K.; Design – A.O.D., Y.K.İ., E.D., İ.E.Ö., H.K., F.K., M.K.; Supervision - A.O.D., Y.K.İ., E.D., İ.E.Ö., H.K., F.K., M.K.; Resources – A.O.D.; Materials – Y.K.İ.; Data Collection and/or Processing – H.K., F.K.; Analysis and/or Interpretation – M.K.; Literature Search – M.K., A.O.D.; Writing Manuscript – A.O.D., Y.K.İ.; Critical Review – M.K.

Conflict of Interest: The authors have no conflicts of interest to declare.

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