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ORIGINAL ARTICLE

Safety of Venography-Guided Extrathoracic Vein Puncture to Prevent Pneumothorax in Pacemaker Implantation

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Abstract

Introduction: Pacemaker implantation is routinely and widely used around the world for a variety of heart conditions. The use of venography guidance is very important for the operator at the puncture site and prevent complications such as pneumothorax. The aim of this study is to determine the effect of venography in preventing complications and to compare the rate of pneumothorax between patients operated with and without venography guidance.

Methods: A total of 539 consecutive patients who had a pacemaker implanted in our clinic between 2012 and 2022 were included in this study. Pacemaker type according to the number of leads used, diagnosis for pacemaker implantation, patient age, gender, concomitant chronic obstructive pulmonary disease (COPD), presence of defibrillator battery and lead, venography guidance were evaluated and their contribution to the complication of pneumothorax was analyzed.

Results: The incidence of pneumothorax development was found to be 1.3% in our study. Venography guidance was found to be significantly protective against pneumothorax, as the patient group that developed pneumothorax consisted of patients who did not undergo venography at a high rate. It was determined that in the patient group that developed pneumothorax, there was a high percentage of patients between the ages of 18-65, of female gender, without concomitant COPD, with 2 leads inserted and with implantable cardioverter defibrillator (ICD) implantation (single/double leads). Our study revealed that routine venography in pacemaker implantation is an effective method to protect patients from pneumothorax as well as lead fracture.

Discussion and Conclusion: Our study revealed that routine venography during pacemaker implantation is an effective method to protect patients from pneumothorax. Since blind puncture of venous structures increases the risk of complications, venography guidance can be used routinely in pacemaker implantation.

Keywords: Axillary vein puncture; pacemaker; subclavian vein puncture; venography.

Although pacemaker implantation is a safe procedure, it has potential complications that increase the risk of mortality and morbidity, such as pocket or systemic infection, pacemaker hematoma, pocket erosion, lead disposition, pneumothorax, and cardiac tamponade[1]. Pneumothorax is of iatrogenic causes of these complications and requires attention. Pneumothorax development occurs in 1-2% of pacemaker implantations and is mostly due to needle injury to the pleura during puncture of the extrathoracic (subclavian or axillary) vein[2,3]. In addition, it is stated in the literature that pneumothorax may develop very rarely (at approximately 0.0001% rate) due to pleura puncture with leads in pacemaker implantation[4].

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Known risk factors for the development of pneumothorax are female gender, advanced age (>80), body mass index <20, concomitant chronic obstructive pulmonary disease (COPD), bullous emphysema, steroid treatment, emergency procedures, inexperienced operator and uncooperative patient[2,5]. It is recommended to use ultrasonography or venography for extrathoracic vein puncture for pacemaker implantation, especially if there are risk factors. In particular, venography provides convenience and confidence to the operator, since it can also show vein patency and venous anatomical variations[6].

The aim of this study is to investigate the importance of venography in pacemaker implantation and to compare the rate of pneumothorax development in patients with and without venography guidance in extrathoracic vein puncture.

Materials and Methods

All consecutive patients who applied to the Department of Cardiology at Izmir University of Economics Medical Point Hospital and were implanted a cardiac device between 2012 and 2022 were retrospectively scanned for the study. The demographic characteristics and laboratory parameters of the patients were recorded at the time of admission. The patients were divided into two groups: those who underwent venography under scopy and those who did not, and the patient groups were compared in terms of the frequency of pneumothorax development.

Patients and Study Design

A total of 551 patients with cardiac devices were scanned for the study. Twelve patients whose patient records and data could not be accessed were excluded from the study. A total of 539 remaining patients were included in the study. Clinical characteristics and accompanying comorbidities of the patients were recorded. All patients underwent echocardiography to evaluate left ventricular functions in detail. A 12-lead electrocardiogram (ECG) recording was taken for each patient before and after the procedure. The type of cardiac device was determined by the cardiologist who would perform the procedure by evaluating the patient's clinical presentation, the presence of bundle branch block and QRS duration on ECG, the accompanying left ventricular ejection fraction, and the patient's risk of arrhythmia. After cardiac device implantation, all patients were clinically screened for complications and a chest radiograph was taken to look for pneumothorax.

Hypertension was defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg and/or being on antihypertensive therapy. Diabetes was defined as having at least two fasting blood glucose levels ≥126 mg/dL, HBA1C value ≥6.5%, and/or blood glucose measured at any time ≥200 mg/dL and/or being under antidiabetic treatment. The presence of COPD was accepted by the pulmonologist for patients diagnosed with COPD based on anamnesis, physical examination, radiological findings and pulmonary function tests. The study was conducted in accordance with the Declaration of Helsinki and the necessary permission was obtained from the local ethics committee for the study.

Statistical Analysis

Data analysis was done using SPSS 25.0 (IBM Corporation, Armonk, New York, United States) statistical package program. Descriptive data were expressed as mean, standard deviation and percentage. Normality distribution of continuous variables was tested with Kolmogorov-Smirnov or Shapiro-Wilk tests. Continuous variables were expressed as mean±standard deviation, and categorical variables were expressed as percentages. Continuous variables were compared between groups using Student's t test, and categorical data were compared using chi-square test or Fisher's exact test.

Results

A total of 539 patients were included in our study and pneumothorax was determined to develop at a rate of 1.3% (n=7). The average age of the patients was 69.77±12.86 years. When the patients were evaluated according to their age ranges, the highest percentage of patients who developed pneumothorax was between the ages of 18-65 (57.1%). Additionally, it was determined that no patient between the ages of 66 and 75 developed pneumothorax (Table 1). When patients were evaluated according to gender, the number of female patients in the patient group who developed pneumothorax was 4, while the number of male patients was 3. It was determined that pneumothorax developed at a higher rate in female patients in patients who developed pneumothorax, as well as among the total patients (57.1% vs 42.9% and 0.7% vs 0.6%, respectively) (Table 2).

In our study, 39 patients had concomitant COPD and the rate of pneumothorax development in these patients was 5.1% (n=2). The rate of pneumothorax development in the non-COPD patient group (n=500) was 1% (n=5). When all patients were evaluated, it was found that the rate of

Table 1. The relationship between age and patients who developed pneumothorax

		Pneumothorax present	Pneumothorax absent	Total
Age				
18-65 years	Number	4	179	183
	Percentage among patients aged 18-65	2.2%	97.8%	100%
	Percentage among total patients who developed pneumothorax	57.1%	0%	57.1%
	Percentage among total number of patients	0.7%	33.2%	34.0%
66-75 years	Number	0	137	137
	Percentage among patients aged 66-75	0%	100%	100%
	Percentage among total patients who developed pneumothorax	0%	0%	0%
	Percentage among total number of patients	0%	25.4%	25.4%
76-84 years	Number	2	148	150
	Percentage among patients aged 76-84	1.3%	98.7%	100%
	Percentage among total patients who developed pneumothorax	28.6%	0%	28.6%
	Percentage among total number of patients	0.4%	27.5%	27.9%
85 years and above	Number	1	68	69
	Percentage among patients aged 85 and above	1.4%	98.6%	100%
	Percentage among total patients who developed pneumothorax	14.3%	0%	14.3%
	Percentage among total number of patients	0.2%	12.6%	12.8%
Total Patients	Number	7 (1.3%)	532 (98.7%)	539 (100%)

Table 2. Relationship between gender and patients developing pneumothorax

		Pneumothorax present	Pneumothorax absent	Total
Gender				
Female	Number	4	192	196
	Percentage among total female patients	2%	98%	100%
	Percentage among total patients who developed pneumothorax	57.1%	0%	57.1%
	Percentage among total number of patients	0.7%	35.6%	36.4%
Male	Number	3	340	343
	Percentage among total male patients	0.9%	99.1%	100%
	Percentage among total patients who developed pneumothorax	42.9%	0%	42.9%
	Percentage among total number of patients	0.6%	63.1%	63.6%
Total Patients	Number	7 (1.3%)	532 (98.7%)	539 (100%)

patients with COPD who developed pneumothorax was lower than the group of patients without COPD who developed pneumothorax (0.4% vs 0.9%, respectively) (Table 3).

When the indications for pacemaker implantation of the patients were evaluated, diagnoses were bradyarrhythmia in 237 patients (44%), tachyarrhythmia in 45 patients (8.4%), congestive heart failure in 254 patients (47.1%) and other reasons (hypersensitive carotid sinus syncope and neurocardiogenic syncope) in 3 patients (0.6%). When the patients were evaluated according to the number of pacemaker leads, it was determined that pneumothorax developed at a higher rate in patients with 2 leads than in those with 1 lead (n=4 vs n=3, 0.7% vs 0.6%, respectively). It was noteworthy that no pneumothorax developed in patients implanted with a 3-lead pacemaker (Table 4). The relationship between implantable cardioverter defibrillator (ICD) implantation and the development of pneumothorax was also examined. It was determined that pneumothorax developed at a higher rate in patients with single or double lead ICD implantation than in those without ICD implantation (0.7% vs 0.6%, respectively) (Table 5).

Table 3. The relationship between the presence of COPD and patients who develop pneumothorax

		Pneumothorax present	Pneumothorax absent	Total
COPD				
Present	Number	2	37	39
	Percentage among patients with COPD	5.1%	94.9%	100%
	Percentage among total patients who developed pneumothorax	28.6%	0%	28.6%
	Percentage among total number of patients	0.4%	6.9%	7.2%
Absent	Number	5	495	500
	Percentage among patients with no COPD	1%	99%	100%
	Percentage among total patients who developed pneumothorax	71.4%	0%	71.4%
	Percentage among total number of patients	0.9%	91.8%	92.8%
Total Patients	Number	7 (1.3%)	532 (98.7%)	539 (100%)

COPD: Chronic obstructive pulmonary disease.

Table 4. The relationship between the number of pacemaker leads and patients who developed pneumothorax

		Pneumothorax present	Pneumothorax absent	Total
Number of Battery Leads				
1 lead	Number	3	227	230
	Percentage among patients with 1 lead implantation	1.3%	98.7%	100%
	Percentage among total patients who developed pneumothorax	42.9%	0%	42.9%
	Percentage among total number of patients	0.6%	42.1%	42.7%
2 leads	Number	4	243	247
	Percentage among patients with 2 leads implantation	1.6%	98.4%	100%
	Percentage among total patients who developed pneumothorax	57.1%	0%	57.1%
	Percentage among total number of patients	0.7%	45.1%	45.8%
3 leads (CRT-P)	Number	0	62	62
	Percentage among patients with 3 leads implantation	0%	100%	100%
	Percentage among total patients who developed pneumothorax	0%	0%	0%
	Percentage among total number of patients	0%	11.5%	11.5%
Total Patients	Number	7 (1.3%)	532 (98.7%)	539 (100%)

CRT-P: Cardiac resynchronization therapy (CRT) pacemaker.

The relationship between venography and pneumothorax development is presented in Table 6. While the rate of pneumothorax development was 0.9% in patients who underwent venography, it was 1.9% in patients who did not receive venography. When evaluated according to all patients, the rate of patients who underwent venography and subsequently developed pneumothorax was lower compared to patients who did not undergo venography and subsequently developed pneumothorax (0.6% vs 0.7%).

Discussion

In this retrospectively designed study, we compared the rate of pneumothorax development between patients in whom extrathoracic vein puncture was performed under venography guidance and those without venography guidance in the pacemaker implantation procedure. It was noteworthy that the group of patients who developed pneumothorax consisted of a higher proportion of patients who did not undergo venography. In addition, it was determined that the patient group that developed pneu-

Table 5. Relationship between single or double lead ICD implantation and patients developing pneumothorax

		Pneumothorax present	Pneumothorax absent	Total
ICD presence (Single/double Lead)				
ICD present	Number	4	298	302
	Percentage among patients implanted with ICD	1.3%	98.7%	100%
	Percentage among total patients who developed pneumothorax	57.1%	0%	57.1%
	Percentage among total number of patients	0.7%	55.3%	56%
ICD absent	Number	3	234	237
	Percentage among patients not implanted with an ICD	1.3%	98.7%	100%
	Percentage among total patients who developed pneumothorax	42.9%	0%	42.9%
	Percentage among total number of patients	0.6%	43.4%	44%
Total Patients	Number	7 (1.3%)	532 (98.7%)	539 (100%)

ICD: Implantable cardioverter defibrillator.

Table 6. The relationship between venography and patients developing pneumothorax

		Pneumothorax present	Pneumothorax absent	Total
Venografi cekimi				
Present	Number	3	322	325
	Percentage among patients who underwent venography	0.9%	99.1%	100%
	Percentage among total patients who developed pneumothorax	42.9%	0%	42.9%
	Percentage among total number of patients	0.6%	59.7%	60.3%
Absent	Number	4	210	214
	Percentage among patients who did not undergo venography	1.9%	98.1%	100%
	Percentage among total patients who developed pneumothorax	57.1%	0%	57.1%
	Percentage among total number of patients	0.7%	39.0%	39.7%
Total Patients	Number	7 (1.3%)	532 (98.7%)	539 (100%)

mothorax included a high percentage of patients between the ages of 18-65, of female gender, without concomitant COPD, with 2 leads inserted and with ICD implantation (single/double leads).

Many techniques are used in the pacemaker implantation procedure for extrathoracic vein puncture, such as ultrasonography guidance technique, blind fluoroscopy guided puncture, caudal fluoroscopic technique and venography guided puncture[6-8]. Venography-guided puncture is a technique considered the 'gold standard' that is easy to learn, has a low rate of side effects, and is used safely and widely by many operators. Its ability to show the patency of the venous system and abnormal venous structures such as persistent left superior vena cava guides the operator in many cases. The important disadvantages of this technique are the risk of contrast allergy and limitations in its use in patients with renal failure[7,8]. Additionally, another complication of venography use that should be considered is venous spasm, which has been reported by Duan et al.[9] to occur in 8-30% of their patients, which is thought to be due to the chemical effect of the contrast and may lead to puncture failure. Once venous spasm is diagnosed, venous puncture attempts should be avoided. Intravenous fluid and nitroglycerin may relieve spasm. In axillary venous spasm, puncture from the medial part of the subclavian vein or axillary vein should be attempted[10]. It is known that ultrasound-guided puncture reduces complications and is a fast and reliable technique in patients who cannot undergo venography[11]. It has been reported that axillary vein puncture without venography can prevent complications of conventional subclavian vein puncture[12-14]. Liu et al.[15] showed that the risk of developing pneumothorax and subclavian crush syndrome complications is more common in subclavian vein puncture.

An important complication that increases the risk of mortality and morbidity in pacemaker implantation and requires attention is the development of pneumothorax. Pneumothorax is the presence of air in the pleural space, which leads to limitation of lung functions. Pneumothorax develops during or within the first 2 days after the pacemaker implantation[2]. Pneumothorax often develops on the ipsilateral side with extrathoracic vein puncture. In the literature, the incidence of pneumothorax development in pacemaker implantation has been reported as 1-2%[2,3]; and in line with the literature, the incidence of pneumothorax development was found to be 1.3% in our study.

The most important risk factor for the development of pneumothorax is the venous access technique. Blind extrathoracic venous puncture has the highest risk in particular. Venography guidance is important at this point. Beig et al.[6] reported in their study that in the patient group (n=105) in which they performed extrathoracic vein puncture under venography guidance, 1 patient (0.95%) developed pneumothorax requiring chest tube drainage. Burri et al.,[7] in their prospective study evaluating patients with and without venography guidance for pacemaker implantation, reported that pneumothorax did not develop in the group where venography was used, but pneumothorax requiring chest tube drainage developed at a rate of 1% in the group without venography guidance. Calkins et al.,[16] in their study evaluating the safety and effectiveness of venography-guided extrathoracic vein puncture, reported that pneumothorax that did not require chest tube drainage developed in 1% and that this technique was generally a reliable and effective technique in terms of major early/acute complications. In our study, although extrathoracic vein puncture was performed under venography guidance in 60.3% of our patients, the rate of pneumothorax was 0.9% in patients with venography guidance, while the rate of pneumothorax development was 1.9% in patients without venography guidance. In other words, 57.1% of the patients who developed pneumothorax in our study were patients whithout venography guidance.

The risk of pneumothorax development in the pacemaker implantation procedure is significantly higher in female gender due to anatomical structures such as small body structures and small diameter venous vessels. In a cohort study where Kirkfeldt et al.[17] evaluated 28860 pacemaker implanted patients, the risk of pneumothorax development was found to be significantly higher in female gender. In the literature, an analysis of 161470 patients receiving ICD therapy reported a significantly higher risk of developing any complications in women[18]. Similarly, in our study, although 36.4% of our patients were female, the female gender rate (57.1%) was found to be higher in our patient group who developed pneumothorax. Bradshaw et al.[19] reported that the mean age of more than 80% of patients who underwent pacemaker implantation was 75±10 years. In our study, although the average age of our patient group was lower (mean age 69.77±12.86 years), our patients were predominantly between the ages of 18-65. It is known that complications occur more frequently in elderly patients (≥75 years of age). In a meta-analysis including 4814 patients, the rate of pneumothorax development following pacemaker implantation was reported to be higher in patients ≥75 years of age than in patients <75 years of age (1.6% vs 0.8%, respectively)[20]. Similarly, the Pacemaker Selection in the Elderly (PASE) study reported that pneumothorax developed more frequently in patients aged ≥75 years[21]. Unlike the literature, in our study, the most common pneumothorax development was in patients between the ages of 18-65. The reason for this difference can be interpreted as the different puncture techniques used in the studies, the difference in the number of patients and the fact that the patients do not show a homogeneous distribution in age groups.

The risk of spontaneous pneumothorax is high in COPD, and pneumothorax causes more severe and aggressive symptoms in these patients[22]. In the presence of concomitant COPD in patients to be implanted with a pacemaker, the operator needs to be careful. Although a clear relationship between pacemaker implantation and the risk of secondary pneumothorax development in patients with concomitant COPD has not been reported in the literature to our knowledge, in our study, the development of pneumothorax was proportionally higher in our patient group with concomitant COPD.

The results of studies examining the relationship between the number of pacemaker leads and the development of complications are not consistent in the literature. There are also studies that emphasize the importance of operator experience rather than the number of leads[23,24]. Aggarwal et al.[25] reported that single or double lead implantation did not affect the rates of pneumothorax and general complication development. In our study, although the rate of patients implanted with two leads was higher among all patients, it was also high in the group of patients who developed pneumothorax.

An important limitation of our study is its retrospective design, and being a single-center and descriptive study, and therefore the sample size remains relatively small to make

strong and generalizable comments. Notable limitations include not classifying the extrathoracic venous anatomy and evaluating which segment of the subclavian vein or axillary vein punctures are made from, and also not evaluating the puncture times and the number of times the venous structures are successfully reached as a result of punctures, which may affect the development of pneumothorax.

As a result of our study, it is important to perform vein puncture under venography guidance to prevent the development of pneumothorax, which is an important complication of pacemaker implantation that increases morbidity and mortality. Venography-guided puncture technique, which allows the operator to evaluate venous anatomy and venous patency, is a safe and effective option for pacemaker implantation.

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