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**Pneumothorax as complication of cardiac rhythm
management devices implantation**

Пнеумоторакс као компликација уградње
уређаја за регулисање срчаног ритма

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SUMMARY

Introduction/Objective Pneumothorax is one of the most common complications of cardiac rhythm management (CRM) devices implantation.

We aimed to assess the incidence of pneumothorax after implantation of these devices and to determine risk factors for this complication.

Methods A retrospective, observational study included patients in whom CRM device was implanted, pacing system was upgraded or lead revision was performed during 2012. We determined the connection between different variables, including gender, age, type of implanted device, prior history of chronic obstructive pulmonary disease, operator experience, venous access, the use of intravenous contrast during procedure, and the development of pneumothorax as procedure related complication, using multiple logistic regression.

Results In this study 999 patients were included. Mean age was 68.1±9.2 years and 665 (66.6%) were man. The incidence of pneumothorax was 1.8% and an invasive treatment of this complication was required in 13 (72.2%) patients. Pneumothorax was more often in women ($B=-2.136$, $p=0.015$), in patients with age >75 years ($B=4.315$, $p=0.001$), venous access with subclavian vein puncture ($B=2.672$, $p=0.045$), and use of intravenous contrast during procedure ($B=3.155$, $p=0.007$).

Conclusion Pneumothorax is relatively rare complication of CRM devices implantation and for reducing of its incidence cephalic vein cut-down should be preferred to subclavian or axillary vein puncture as venous access, axillary vein puncture should not be avoided when cephalic vein cannot be found or used and in the case of difficult vein puncture contrast venography should be done immediately, before risky punctures.

Keywords: pacemaker; pneumothorax; complication; risk factor

САЖЕТАК

Увод/Циљ Пнеумоторакс је једна од најчешћих компликација уградње уређаја за регулисање срчаног ритма.

Циљ рада је био да се утврди учесталост пнеумоторакса након уградње ових апарата и да се одреде фактори ризика за његов настанак.

Методе рада У ретроспективну, опсервациону студију укључени су болесници којима су 2012. године уграђени ови уређаји, учињена надоградња пејсмејкер система, или ревизија електроде. Користећи мултиплу логистичку регресиону анализу, испитали смо повезаност настанка пнеумоторакса и различитих варијабли: пол, старост, тип уграђеног апарата, присуство хроничне опструктивне болести плућа, искуство имплантера, венски приступ и интраоперативно коришћење интравенског контраста.

Резултати У студију је укључено 999 болесника, старости 68,1±9,2 година, 665 (66,6%) је било мушког пола. Учесталост пнеумоторакса је била 1,8%, а инвазивно лечење истог је било неопходно код 13 (72,2%) болесника. Пнеумоторакс је био чешћи код жена ($B=-2,136$, $p=0,015$), болесника старијих од 75 година ($B=4,315$, $p=0,001$), када је као венски приступ коришћена пункција поткључне вене ($B=2,672$, $p=0,045$) и када је коришћено контрастно средство ($B=3,155$, $p=0,007$).

Закључак Пнеумоторакс је релативно ретка компликација уградње уређаја за регулисање срчаног ритма. За смењене његове учесталости треба као венски приступ препарирати цефаличну вену пре него пункцирати поткључну или пазушну вену. У случају отежане пункције контрастну венографију треба одмах урадити, пре ризичних пункција.

Кључне речи: пејсмејкер; пнеумоторакс; компликација; фактор ризика

INTRODUCTION

Term cardiac rhythm management (CRM) devices refers to antibradycardia pacemakers, implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices with or without defibrillation function [1]. Nowadays, implantation of these devices is routine and safe procedure associated with infrequent complications, which are rarely life-threatening [2,3]. However, implantation related complications often require reintervention, prolong hospitalization and increase treatment cost [1]. Pneumothorax, lead dislodgement, infection and pocket hematoma are the most common complications of CRM devices implantation [1,2]. The incidence of iatrogenic

pneumothorax varies from 1-5% according to literature, and depends on many factors [4]. The exact definition of this complication, its clinical recognition and data collection are important, but also patients characteristics, surgical technique and operator experience have an impact on its incidence [3,4].

This study aimed to assess the incidence of pneumothorax after implantation of antibradycardia pacemakers, ICDs and CRT devices, after pacing system upgrade procedures and lead revisions. We aimed to determine procedure, patient, and operator related risk factors for this complication.

METHODS

This has been a retrospective, observational, single centre study. We included patients in whom CRM device was implanted, pacing system was upgraded or lead revision was performed in the year 2012 in Pacemaker Center, Clinical Center of Serbia. We excluded replacements and implantations of implantable loop recorders.

Data were collected from the registry that has existed in our center since 2010. It contains data on all patients who underwent surgery in our center. It holds data on patient general characteristics, medical history, risk factors, on procedure details, including data on procedure related complications, and on physician who performed the operation. The registry has updated every Monday.

In this study we determined the connection between different variables and the development of pneumothorax as procedure related complication. We examined many variables including gender, age, type of implanted device, prior history of chronic obstructive pulmonary disease (COPD), operator experience, venous access, the use of intravenous contrast during procedure. The diagnosis of COPD had to be set by pulmonologist, confirmed by spirometry. We believe that an experienced operator should have over 200 interventions in the last three years and/or over 400 interventions in his career. There are three methods used for venous access in our center, subclavian vein puncture, axillary vein puncture and cephalic vein cut-down. In our center in 2012 a routine post-procedural chest X-ray was not done. If patient complained of shortness of breath, chest pain or doctor noticed decreased or absent breath sounds over the affected lung, chest X-ray would be done. The diagnosis of pneumothorax was confirmed by thoracic surgeon, who made decision how this complication would be treated. Sometimes specific treatment was not necessary, but sometimes thoracic surgeon had to make an aspiration of the free air and/or place a chest tube to evacuate the air.

For statistical analysis we used descriptive and analytic statistic methods. From descriptive methods mean and standard deviation were used for continuous variables and absolute and relative numbers for categorical variables. Multiple binary logistic regression analysis was used to identify the characteristics associated with a higher rate of pneumothorax. All p values less than 0.05 were considered significant. All data were analyzed using SPSS 20.0 (IBM corp.) statistical software.

RESULTS

During 2012, in our center, 1141 procedures were performed. In this study 999 patients were included. We excluded 129 patients in whom CRM device was replaced and 13 patients in whom an ILR was implanted. Patient, operator and procedure characteristics are presented in Table 1. The majority of patients were males (66.6%) and the mean age at implantation was 68.1±9.2 years. Most

Table 1. Patient, operator and procedure characteristics.

Parameter	n	%	Ptx(n)
Male	665	66.6	10
Age	68.1 ± 9.2		73.4 ± 7.3
Chronic obstructive pulmonary disease	65	6.5	0
VVI	266	26.6	4
DDD	468	46.8	10
ICD-VR	80	8.0	1
Device type			
ICD-DR	16	1.6	1
CRT-P	123	12.3	1
CRT-D	22	2.2	1
Lead revision	24	2.4	0
Operator experience			
Experienced	775	77.6	13
Not experienced	224	22.4	5
Intravenous contrast	49	4.9	3

ICD - Implantable cardioverter-defibrillator; CRT - Cardiac resynchronization therapy; Ptx - pneumothorax

patients received a dual-chamber pacemaker (46.8%) and most procedures were performed by experienced operators (77.6%). In total, 618 atrial leads were implanted, dominantly by subclavian vein puncture and 995 leads in right ventricle, mainly by cephalic vein cut-down (Table 2). Venous access for all 146 leads for coronary sinus was with vein puncture, subclavian or axillary. In some patients double cut-down of the cephalic vein was used to implant atrial and ventricle lead, and in some multiple punctures of the subclavian vein were required. The diagnosis of COPD was set in 65 (6.5%) patients before implantation. During procedure, for easier visualization of the axillary and

Table 2. Venous access technique in regard to lead type.

	VVI	DDD	ICD-VR	ICD-DR	CRT-P	CRT-D	Upgrade	LR	Total (%)	Venous access technique	n (%)	Ptx -n
AL	0	465	0	14	111	20	3 VVI → DDD + 2 ICDVR → DR	3	618 (35.1)	Cephalic vein cut-down	202 (32.7)	0
										Subclavian vein puncture	362 (58.6)	7
										Axillary vein puncture	54 (8.7)	1
RVL	266	468	80	16	123	22	0	20	995 (56.6)	Cephalic vein cut-down	600 (60.3)	0
										Subclavian vein puncture	364 (36.6)	9
										Axillary vein puncture	31 (3.1)	0
CSL	0	0	0	0	123	22	0	1	146 (8.3)	Cephalic vein cut-down	0 (0.0)	0
										Subclavian vein puncture	137 (93.8)	1
										Axillary vein puncture	9 (6.2)	0

AL - atrial lead; RVL - right ventricle lead; CSL - coronary sinus lead; ICD - implantable cardioverter-defibrillator;

subclavian vein, intravenous contrast injection in the peripheral arm vein was used in 49 (4.9%) patients.

In our study population, the incidence of pneumothorax was 1.8%. If we know that the total number of vein punctures, subclavian or axillary, is 957, than we can conclude that 1.9% of all

Table 3. Correlation between patient, operator and procedure characteristics with occurrence of pneumothorax (dependent variable).

Predictor	B	p
Sex	- 2.136	0.015
Age	4.315	0.001
VVI	16.479	0.998
DDD	19.712	0.998
ICD-VR	21.169	0.996
ICD-DR	21.614	0.998
CRT-P	18.136	0.997
CRT-D	23.464	0.998
COPD	- 17.147	0.997
Operator experience	- 0.485	0.650
Subclavian vein puncture	2.672	0.045
Axillary vein puncture	- 0.646	0.606
Intravenous contrast	3.155	0.007

B - Regression coefficient; COPD - Chronic obstructive pulmonary diseases.

punctures led to pneumothorax, as procedure related complication. Invasive treatment of pneumothorax was required in 13 (72.2%) patients, an aspiration of free air was made in 9 (50.0%) and 4 (22.2%) patients were treated with a chest tube. There were no fatalities due to detected pneumothorax. In multiple logistic regression analysis we identified age >75 years, female gender, venous access with subclavian vein puncture and use of intravenous contrast during procedure as risk factors for the occurrence of pneumothorax during implantation of CRM devices (Table 3).

DISCUSSION

The incidence of pneumothorax as procedure-related complication after CRM devices implantation in our sample was 1.8%. Previous studies have found an incidence varying from 0.7 to 5.2% [3]. It is difficult to compare our results with findings of other studies, because many factors have an impact on this variation in the incidence of pneumothorax. When we examine the results of some study it is important to analyze the study design, characteristics of study population, to consider differences in surgical technique and clinical recognition of pneumothorax. In our observational retrospective 1-year survey, population is large and widely selected. Our position is that cephalic vein cut-down is preferred to subclavian vein puncture as venous access. Some of operators in our center choose to implant two leads using cephalic vein, when diameter of vein is sufficient. The puncturing the axillary vein is routinely done in our center. We have not done routine post-procedural chest X-ray, but our patients have been continuously monitored and every symptom that can indicate that pneumothorax is occurred, such as chest pain or respiratory distress, is followed by chest X-ray and then pulmonary examination. In large, nationwide study that was performed in Denmark, based on data from the Danish pacemaker register, the incidence of pneumothorax was 0.66% [4]. In this study only patients with pneumothorax treated with a chest tube were abstracted. As well, patients with implanted ICDs were not investigated. In a study from 2006 Pakarinen et al. found that the incidence of pneumothorax after CRM devices implantation was 1.9% [1]. In this study pre-discharge chest X ray was routinely done and axillary vein puncture was preferred as venous access. The same incidence

of pneumothorax was seen in Dutch multicenter study from 2007 [5]. Bond et al. enrolled 1286 patients and found a pneumothorax rate of 3.7% [2]. In this study post-procedural chest X ray was done for all patients, the favored method of venous access was via the subclavian vein, procedures were done by 16 different operators with very differing levels of experience and pneumothorax was managed conservatively in even more than 55% of patients [2].

This study confirms that patients older than 75 years have higher risk of developing of pneumothorax as procedure related complication. This finding is in accordance to previous studies [6]. In PASE study age >75 years was associated with higher risk of pneumothorax and in Danish study this complication was statistically more frequent in patient >80 years [4,7].

In our study pneumothorax was significantly more often in women. Some previous studies showed similar results. Peterson et al. concluded that gender was independent factor associated with adverse events, including pneumothorax, in patients receiving an ICD [8]. Nowak et al., in study that included more than 17 000 patients, showed that women had significantly more frequent pneumothorax after pacemaker implantation, regardless of age and implanted pacing system [9]. The same conclusion was made in Danish study [4]. There are many possible explanations for this finding, from differences in anatomy, smaller body size, to hormonal differences and higher prevalence of comorbidities and risk factors in women.

We found that subclavian vein puncture is procedure related risk factor for the development of pneumothorax during implantation of CRM devices. This finding is confirmed in many previous studies [3,4,10]. There are many advantages of puncturing the subclavian vein. Extensive skin and muscle dissection is not needed, the access to subclavian vein is easy for experienced operator and this vein can be used repeatedly [3,11]. The most important disadvantages of this approach are increased incidence of intraoperative complications such as pneumothorax or bleeding and chronic complications like lead damage (insulation damage or lead fracture) and venous thrombosis [3]. On the other hand, cephalic vein cut-down rarely leads to procedure related complications, but for this approach operator should have better surgical technique and sometimes cephalic vein cannot be located or used [3]. Third method used for venous access is axillary vein puncture. This approach is not often used due to a fear of pneumothorax, but for experienced operator, who well knows the regional anatomy, this should be the method of choice [11-13]. Considering these facts, in most centers cephalic vein cut-down is preferred to subclavian or axillary vein puncture as venous access, but whenever the cephalic vein cannot be found, or it is too small and thin, puncturing of subclavian or axillary vein must be done. In our center cephalic vein cut-down is preferable to subclavian vein puncture as well, and the puncturing the subclavian and axillary vein is done routinely by cardiologists and surgeons.

It is expected that risk of pneumothorax is higher after implantation of dual than single chamber devices due to the higher probability of vein puncture, but also that pneumothorax is more common after implantation of resynchronization than antibradycardia pacemakers because during implantation

of CRT at least one vein puncture is needed [14,15]. But in our study, we did not find significant relation between type of implanted device and pneumothorax.

Although we expected that the incidence of pneumothorax will be higher in patients with COPD, our results are somewhat surprising [16]. Not only that we did not find significant connection between COPD and pneumothorax, but none of our patients with COPD developed pneumothorax as procedure related complication. In Danish study COPD was patient related risk factor for this complication [4]. A possible explanation for our result is that access via cephalic vein was used in most patients with COPD, that intravenous contrast was routinely used, before the puncturing of subclavian or axillary vein in this subpopulation and that our operators are quite experienced.

In our study the incidence of pneumothorax was not lower in implantations performed by experienced doctors. This is not surprising result because trainees in our center work under the strict supervision of their mentors. Pakarinen et al. found that pneumothorax was much more common in pacemaker implantations performed by trainees, but in Danish study significant relation between pneumothorax and experience of operator was not found [1,4].

In our center, when cephalic vein cannot be located or used and the puncturing of subclavian or axillary vein is difficult intravenous contrast injection in the peripheral arm vein is used. Contrast venography did not lead to a reduction in the frequency of the pneumothorax in our study. On the contrary, we found that the use of intravenous contrast during procedure is a risk factor for the development of pneumothorax. Possible explanation for this finding is the fact that operators in our center choose to give intravenous contrast after multiple unsuccessful punctures, when high risk of pneumothorax has already exist. In other studies the role of contrast venography in reducing of incidence of pneumothorax was not tested.

CONCLUSION

Our observational retrospective 1-year single-center survey shows that pneumothorax is relatively rare complication of CRM devices implantation that often requires intervention of thoracic surgeon. We identified 4 variables as risk factors for this complication, age >75 years, female gender, venous access with subclavian vein puncture and use of intravenous contrast during procedure. According to these findings, for reducing the incidence of pneumothorax as procedure related complication, cephalic vein cut-down should be preferred to subclavian or axillary vein puncture as venous access, in the case of difficult vein puncture contrast venography should be done immediately, before risky punctures, axillary vein puncture should not be avoided and trainees should work under the strict supervision of their mentors.

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