DOI: https://doi.org/10.2298/SARH160712062R
UDC: 616.25-003.219; 616.12-085.817.06

ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Pneumothorax as a complication of cardiac rhythm management devices implantation

Nikola N. Radovanović[1], Bratislav Kirćanski[1], Siniša U. Pavlović[1,2], Srđan Raspopović[1], Velibor Jovanović[1], Gabrijela Nikčević[1], Ana Novaković[1], Mirjana Živković[1], Goran Milašinović[1,2]

[1]Clinical Center of Serbia, Pacemaker Center, Belgrade, Serbia;
[2]University of Belgrade, School of Medicine, Belgrade, Serbia

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 devices were implanted, pacing system was upgraded, or lead revision was performed during 2012 at the Pacemaker Center, Clinical Center of Serbia. We determined the connection between different variables, including sex, 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 the procedure-related complication, using multiple logistic regression.

Results A total of 999 patients were included in this study. The patients' mean age was 68.1 ± 9.2 years; 665 (66.6%) patients were male. The incidence of pneumothorax was 1.8% and an invasive treatment of this complication was required in 13 (72.2%) patients. Pneumothorax was more frequent 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 a relatively rare complication of CRM device implantation, and for reducing 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

INTRODUCTION

The 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 a 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 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, the 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 the 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 a CRM device was implanted, pacing system was upgraded, or lead revision was performed at the Pacemaker Center, Clinical Center of Serbia, in 2012. 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 the data on all patients who underwent surgery at our center. It holds data on patient general characteristics, medical history, risk factors, on procedure details, including data on procedure-related complications, and on the physician who performed the operation. The registry is updated once a week.

In the study we determined the connection between different variables and the development

Примљено • Received: July 12, 2016
Прихваћено • Accepted: September 7, 2016
Online first: March 10, 2017

Correspondence to:
Nikola RADOVANOVIĆ
Pacemaker Center
Clinical Center of Serbia
Dr Koste Todorovića 8
11000 Belgrade, Serbia
nikolar86@gmail.com

of pneumothorax as a procedure-related complication. We examined many variables including sex, age, type of implanted device, prior history of chronic obstructive pulmonary disease (COPD), operator experience, venous access, and use of intravenous contrast during the procedure. The diagnosis of COPD had to be set by a 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 at our center – subclavian vein puncture, axillary vein puncture, and cephalic vein cut-down. Routine post-procedural chest X-ray was not performed at our center in 2012. If a patient complained of shortness of breath, chest pain or the 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 a decision on how this complication would be treated. Sometimes, specific treatment was not necessary, but occasionally thoracic surgeon had to perform aspiration of 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 IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp, Armonk, NY, USA) statistical software.

RESULTS

A total of 1,141 procedures were performed at our center in 2012. This study comprised 999 patients. We excluded 129 patients in whom a 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 patients received a dual-chamber pacemaker (46.8%) and most procedures were performed by experienced operators (77.6%).

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
Device type	VVI	266	26.6	4
	DDD	468	46.8	10
	ICD-VR	80	8.0	1
	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

In total, 618 atrial leads were implanted, dominantly by subclavian vein puncture, and 995 leads in the 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 reached in 65 (6.5%) patients before implantation. During the procedure, for easier visualization of the axillary and 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 punctures led to pneumothorax, as a procedure-related complication. Invasive treatment of pneumothorax was required in 13 (72.2%) patients, aspiration of free air was made in nine (50%) patients, and four (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 sex, venous access with subclavian vein puncture, and the use of intravenous contrast during procedure as risk factors for the occurrence of pneumothorax during the implantation of CRM devices (Table 3).

Table 2. Venous access technique in regard to the 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; CRT – cardiac resynchronization therapy; LR – lead revision; Ptx – pneumothorax

Table 3. Correlation between the patient, operator, and procedure characteristics with the 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; ICD – implantable cardioverter-defibrillator; CRT – cardiac resynchronization therapy; COPD – chronic obstructive pulmonary disease

DISCUSSION

The incidence of pneumothorax as a procedure-related complication after CRM devices implantation in our sample was 1.8%. Previous studies have found an incidence varying 0.7–5.2% [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 a study, it is important to analyze the study design, characteristics of study population, to consider differences in the surgical technique and clinical recognition of pneumothorax. In our observational retrospective one-year survey, population is large and widely selected. Our position is that the cephalic vein cut-down is preferred to subclavian vein puncture as venous access. Some operators in our center choose to implant two leads using cephalic vein, when diameter of the vein is sufficient. The puncturing of the axillary vein is routinely done at our center. We have not performed routine post-procedural chest X-ray, but our patients have been continuously monitored and every symptom that can indicate that pneumothorax has occurred, such as chest pain or respiratory distress, is followed by chest X-ray and then pulmonary examination. In a large, nationwide study performed in Denmark, based on the data in 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. Also, patients with implanted ICDs were not investigated. In a study from 2006, Pakarinen et al. [1] found that the incidence of pneumothorax after CRM devices implantation was 1.9%. 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 a Dutch multicenter study from 2007 [5]. Bond et al. [2] enrolled 1,286 patients and found a pneumothorax rate of 3.7%. In this study, post-procedural chest X-ray was performed 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 then 55% of patients [2].

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

In our study, pneumothorax was significantly more frequent in women. Some previous studies showed similar results. Peterson et al. [8] concluded that sex was an independent factor associated with adverse events, including pneumothorax, in patients receiving an ICD. Nowak et al. [9], in a study that included more than 17,000 patients, showed that women had significantly more frequent pneumothorax after a pacemaker implantation, regardless of the age and the implanted pacing system [9]. The same conclusion was made in the 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 a procedure-related risk factor for the development of pneumothorax during the 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 the subclavian vein is easy for an experienced operator and this vein can be used repeatedly [3, 11]. The most important drawbacks 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, the operator should have better surgical technique; also, sometimes, the cephalic vein cannot be located or used [3]. The third method used for venous access is axillary vein puncture. This approach is not used often due to fear of pneumothorax, but for an experienced operator, who knows the regional anatomy well, this should be the method of choice [11, 12, 13]. Considering these facts, cephalic vein cut-down is preferred to subclavian or axillary vein puncture as the venous access in most medical centers, but whenever the cephalic vein cannot be found, or it is too small and thin, puncturing of the subclavian or the axillary vein must be done. In our center, cephalic vein cut-down is preferable to subclavian vein puncture as well, and the puncturing of the subclavian and the axillary vein is performed routinely by cardiologists and surgeons.

It is expected that the risk of pneumothorax is higher after the implantation of dual-chamber devices compared to single-chamber ones due to the higher probability of vein puncture; also pneumothorax is expected to be more common after implanting resynchronization pacemakers

than after implanting antibradycardia ones because during the implantation of a CRT device at least one vein puncture is needed [14, 15]. However, in our study, we did not find significant relations between the type of an 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 a significant connection between COPD and pneumothorax, but none of our patients with COPD developed pneumothorax as a procedure-related complication. In the Danish study, COPD was a patient-related risk factor for this complication [4]. A possible explanation for our result is that the access via the cephalic vein was used in most patients with COPD, that intravenous contrast was routinely used, before the puncturing of the subclavian or the 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 a surprising result, since trainees at our center work under the strict supervision of their mentors. Pakarinen et al. [1] found that pneumothorax was much more common in pacemaker implantations performed by trainees, but in the Danish study significant relations between pneumothorax and the experience of operators was not found [4].

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

CONCLUSION

Our observational retrospective one-year single-center survey shows that pneumothorax is a relatively rare complication of CRM devices implantation that often requires an intervention by a thoracic surgeon. We identified the following four variables as risk factors for this complication: age of more than 75 years, female sex, venous access with subclavian vein puncture, and the use of intravenous contrast during the procedure. According to these findings, for reducing the incidence of pneumothorax as a procedure-related complication, cephalic vein cut-down should be preferred to subclavian or axillary vein puncture as venous access; in cases 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.

REFERENCES

1. Pakarinen S, Oikarinen L, Toivonen L. Short-term implantation-related complications of cardiac rhythm management device therapy: a retrospective single-centre 1-year survey. Europace. 2010; 12(1):103–8.
2. Bond R, Augustine D, Dayer M. Pacemaker complications in a district general hospital. Br J Cardiol. 2012; 19:90-4.
3. Kirkfeldt RE, Johansen JB, Nohr EA, Moller M, Arnsbo P, Nielsen JC. Pneumothorax in cardiac pacing: a population-based cohort study of 28 860 Danish patients. Europace. 2012; 14(8):1132–8.
4. Res JC, de Priester JA, van Lier AA, van Engelen CL, Bronzwaer PN, Tan PH, et al. Pneumothorax resulting from subclavian puncture: a complication of permanent pacemaker lead implantation. Neth Heart. 2004; 12(3):101–5.
5. van Eck JW, van Hemel NM, Zuithof P, van Asseldonk JP, Voskuil TL, Grobbee DE, et al. Incidence and predictors of in-hospital events after first implantation of pacemakers. Europace. 2007; 9(10):884–9.
6. Armaganijan LV, Toff WD, Nielsen JC, Andersen HR, Connolly SJ, Ellenbogen KA, et al. Are elderly patients at increased risk of complications following pacemaker implantation? A meta-analysis of randomized trials. Pacing Clin Electrophysiol. 2012; 35(2):131–4.
7. Link MS, Estes NA 3rd, Griffin JJ, Wang PJ, Maloney JD, Kirchhoffer JB, et al. Complications of dual chamber pacemaker implantation in the elderly. Pacemaker Selection in the Elderly (PASE) Investigators. J Interv Card Electrophysiol. 1998; 2(2):175–9.
8. Peterson PN, Daugherty SL, Wang Y, Vidaillet HJ, Heidenreich PA, Curtis JP, et al. Gender differences in procedure-related adverse events in patients receiving implantable cardioverter-defibrillator therapy. Circulation. 2009; 119(8):1078–84.
9. Nowak B, Misselwitz B, Erdogan A, Funck R, Irnich W, Israel CW, et al. Do gender differences exist in pacemaker implantation?-results of an obligatory external quality control program. Europace. 2010; 12(2):210–5.
10. Van Rees JB, de Bie MK, Thiissen J, Borleffs CJ, Schalii MJ, van Erven L. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. J Am Coll Cardiol. 2011; 58(10):995–1000.
11. Sharma G, Senguttuvan NB, Thachil A, Leonq D, Naik N, Yaday R, et al. A comparison of lead placement through the subclavian vein technique with fluoroscopy-guided axillary vein technique for permanent pacemaker insertion. Can J Cardiol. 2012; 28(5):542–6.
12. Antonelli D, Feldman A, Freedberg NA, Turgeman Y. Axillary vein puncture without contrast venography for pacemaker and defibrillator leads implantation. Pacing Clin Electrophysiol. 2013; 36(9):1107–10.
13. Hettiarachchi EMMS, Arsene C, Fares S, Faraj A, Saulitis E, Losito S, et al. Fluoroscopy-guided axillary vein puncture, a reliable method to prevent acute complications associated with pacemaker, defibrillator, and cardiac resynchronization therapy leads insertion. J Cardiovasc Dis Diagn. 2014; 2:136.
14. Kirkfeldt RE, Johansen JB, Nohr EA, Jorgensen OD, Nielsen JC. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J. 2014; 35(18):1186–94.
15. Ellenbogen KA, Hellkamp AS, Wilkoff BL, Camunãs JL, Love JC, Hadjis TA, et al. Complications arising after implantation of DDD pacemakers: the MOST experience. Am J Cardiol. 2003; 92(6):740–1.
16. Lin YS, Hung SP, Chen PR, Yang CH, Wo HT, Chang PC, et al. Risk factors influencing complications of cardiac implantable electronic device implantation: infection, pneumothorax and heart perforation: a nationwide population-based cohort study. Medicine (Baltimore). 2014; 93(27):e213.

Пнеумоторакс као компликација уградње уређаја за регулисање срчаног ритма

Никола Н. Радовановић[1], Братислав Кирћански[1], Синиша У. Павловић[1,2], Срђан Распоповић[1], Велибор Јовановић[1], Габријела Никчевић[1], Ана Новаковић[1], Мирјана Живковић[1], Горан Милашиновић[1,2]

[1]Клинички центар Србије, Пејсмејкер центар, Београд, Србија;
[2]Универзитет у Београду, Медицински факултет, Београд, Србија

САЖЕТАК

Увод/Циљ Пнеумоторакс је једна од најчешћих компликација уградње уређаја за регулисање срчаног ритма.
Циљ рада је био да се утврди учесталост пнеумоторакса после уградње ових апарата и да се одреде фактори ризика за његов настанак.

Методе У ретроспективну, опсервациону студију укључени су болесници којима су током 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, од којих је 665 (66,6%) било мушког пола. Учесталост пнеумоторакса је била 1,8%, а инвазивно лечење 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 смањење његове учесталости треба као венски приступ препарисати цефаличну вену пре него пунктирати поткључну или пазушну вену. У случају отежане пункције контрастну венографију треба одмах урадити, пре ризичних пункција.

Кључне речи: пејсмејкер; пнеумоторакс; компликација; фактор ризика