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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Long-term follow-up of the patients with pacemaker leads implanted through persistent left superior vena cava

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SUMMARY

Introduction/Objective Persistent left superior vena cava (PLSVC) is the most common congenital malformation of the thoracic venous system and may often complicate cardiac implantable electronic device (CIED) lead implantation. The purpose of this study was to assess feasibility and safety of CIED lead implantation through PLSVC and its long-term efficacy.

Methods This is a retrospective observational study performed in a tertiary center from July 2005 to July 2019 among patients with fully successful implantation of all intended CIED leads through PLSVC.

Results CIED implantation was successfully completed with left-side approach in 26 of 32 (81.3%) patients with PLSVC. The average implantation time was 62, 73.5, 120, 74, 103.3, and 130 minutes and the average fluoroscopy time was 13.3, 20.8, 35.7, 17.1, 45.6, and 42.6 minutes for single and dual-chamber pacemakers, ICD-VR, ICD-DR, CRT-P, and CRT-D devices, respectively. The average follow-up period was 43.5 ± 29.9 months. During the follow-up period no CIED leads-related complications were noticed.

Conclusion The results of our study showed that the presence of PLSVC is not an obstacle for CIED implantation. The long-term follow-up proved stability of CIED leads implanted through PLSVC.

Keywords: persistent left superior vena cava; cardiac implantable electronic device; lead; implantation

INTRODUCTION

Persistent left superior vena cava (PLSVC) is the most represented congenital malformation of thoracic venous system that affects less than 0.5% of the general population and up to 10% of individuals with congenital heart defects [1, 2]. It represents the residue of the left cardinal vein that predominantly regresses in the early stages of fetal life [2, 3]. Most often, PLSVC drains into the right atrium through the dilated coronary sinus, but in 8–20% it drains in the left atrium directly or via an unroofed coronary sinus causing right to left cardiac shunt with paradoxical embolism potential [4, 5]. Beside PLSVC, right superior vena cava (RSVC) is usually present and bridged with PLSVC via an innominate vein. Rarely, in less than 10% of cases, PLSVC exists without RSVC and that phenomenon is called "isolated PLSVC" or "absent RSVC" [6, 7]. PLSVC is primarily an asymptomatic anomaly that can be suspected based on the echocardiographic finding of a dilated coronary sinus in the absence of elevated right-sided pressures [8]. However, it is typically identified incidentally during anesthetic, nephrological, oncological, and cardiological procedures involving a left cephalic or subclavian venous approach, along with instances occurring during cardiac surgery. It can be confirmed by contrast venography [9, 10]. Heart rhythm disturbances related to the formation and conduction of impulses can be observed among these patients, requiring pacemaker therapy [3, 11]. The unusual venous anatomy may complicate cardiac implantable electronic device (CIED) leads implantation [8, 12].

The purpose of this study was to assess feasibility and safety of CIED lead implantation through PLSVC and its long-term efficacy.

METHODS

This retrospective, observational study was conducted at the Pacemaker Center of the University Clinical Center of Serbia. The investigation conforms to the principles outlined in the Declaration of Helsinki. The study was approved by an institutional review committee. We included patients who underwent CIED implantation for the first time, from July 2005 to July 2019, in whom PLSVC was incidentally recognized during procedure and implantation of all intended leads was completed with left-side approach through PLSVC. All patients signed informed consent before the implantation procedure. All the procedures were performed by four experienced physicians in the cardiac catheterization laboratory, under local anesthesia, commenced with left-sided approach, opposite the patients' dominant arm.

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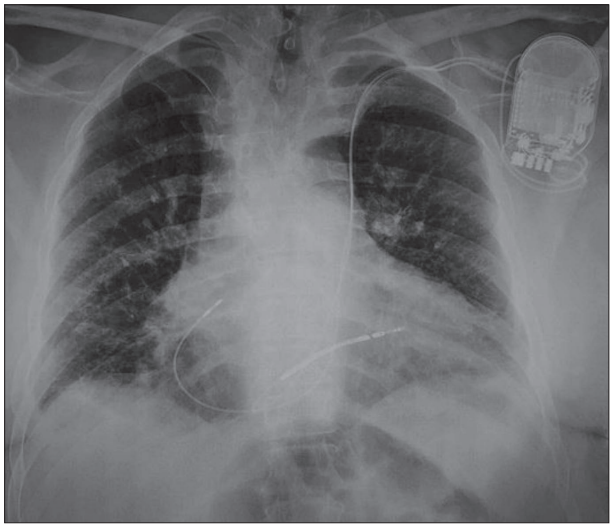

Figure 1. Chest X-ray demonstrating dual-chamber implantable cardioverter defibrillator implanted through persistent left superior vena cava

For venous access we used the cephalic vein cutdown technique (always when possible) or the subclavian/axillary vein puncture. The atypical transvenous lead tracing was suspected on PLSVC and confirmed by intraprocedural venography. Afterwards, CIED lead implantation was proceeded through PLSVC. For the right ventricle (RV) lead implantation we used the loop technique – making a loop in the right atrium (RA) before fixing the lead in the RV (as shown in the Figure). The rest of the procedure was performed in the usual manner. After implantation, follow-up, with device function assessing, was exerted after one, three, and six months, and later on six to 12 months according to the type of the implanted device. All the data were collected from the patients' medical records. The patients in whom it was not possible to implant at least one of intended CIED leads through the PLSVC were excluded from the study.

Statistical analysis

For data processing, descriptive and analytic statistic methods were used. Data are presented as mean ± standard errors, or n (%) depending on data type. Normal distribution of data was checked by the Shapiro–Wilk test. T-test and χ^2 test were used to assess differences between examined groups. All p-values less than 0.05 were considered significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 19.0 (IBM Corp., Armonk, NY, USA).

RESULTS

In the course of a 14-year period, PLSVC was recognized in 32 out of 14,186 (0.22%) patients. CIED implantation was successfully completed with the left-side approach in 26 of 32 (81.3%) patients, and these 26 patients were included in our analysis. In two patients, lead positioning through PLSVC was not possible, so left-side approach was abandoned and pacemakers [single-chamber (VVI) and dual-chamber (DDD)] were implanted on the opposite (right) side without complications. In four CRT patients, it was not possible to implant left ventricle (LV) leads endovenously, so they were implanted subsequently, epicardially, using mini-thoracotomy approach. Limited availability of suitable tributaries due to thrombosis of coronary sinus or the unfavorable coronary venous anatomy were the reasons for transvenous approach failure. These six patients were excluded from the further analysis. There were 15 VVI and 6 DDD pacemakers, one single-chamber implantable cardioverter defibrillator (ICD-VR) and two dual-chamber implantable cardioverter defibrillators (ICD-DR), and two cardiac resynchronization therapy (CRT) devices implanted without complications. Of a total of 38 leads implanted through PLSVC and monitored in this study, two RV leads, one RA lead, and both CS were passive fixation leads, while all others were active fixation leads. Procedures were always started with standard length leads, and as needed, longer leads were used during the intervention. In seven cases the procedure was completed with a longer RV and in two cases with longer RA leads. Patient characteristics and indications for CIED implantation are presented in Table 1. The average implantation and fluoroscopy time in the group of patients with and without PLSVC and the existence of statistically significant differences in these parameters between the groups are shown in Table 2. For comparison, we used the mean values of these parameters obtained in patients without PLSVC who were implanted in our center in 2012. During the follow-up period 10 patients died and for statistical analysis we used the values of the parameters recorded at the last control if it was done at least one year after the implantation. The average follow-up period was 43.5 ± 29.9 months. No CIED related perioperative or late complications were noticed. We were monitoring 22 RV and 10 RA leads implanted through PLSVC, and its parameters were stable throughout follow-up period (presented in Tables 3 and 4). Four high-voltage (HV) leads implanted in one CRT-ICD, two dual-chamber ICDs, and one single-chamber ICD were observed. Mean values of HV leads' parameters did not change significantly at primo-implantation and at the time of the last checkup (HV impedance 60.5 ± 5 Ω and 63 ± 6.7 Ω, sense/pace impedance 609.5 ± 178.8 Ω and 400.3 ± 33.6 Ω, R wave 9.4 ± 4.7 V and 9.1 ± 2.6 V, threshold 0.9 ± 0.3 V / 0.4 ms and 0.7 ± 0.1 V / 0.4 ms). There were two LV leads implanted via coronary sinus. Baseline impedances were 936 Ω and 1050 Ω and at the last control 850 Ω and 965 Ω, while baseline thresholds were 1.7 V / 0.4 ms and 2.5 V / 0.4 ms and at the last control 1.5 V / 0.4 ms and 2 V / 0.4 ms.

DISCUSSION

While PLSVC is considered an uncommon venous anomaly, in specialized referral centers such as ours, where over 1000 CIED implantations are performed annually, it does

Table 1. Basic characteristics of patients with cardiac implantable electronic device leads implanted through persistent left superior vena cava

Patient	Age	Sex	Indication for CIED implantation	Device type
1	74	Male	Chronic AF with slow ventricular response	VVI
2	80	Female	CHB	VVI
3	81	Male	CHB	VVI
4	77	Female	Chronic AF with slow ventricular response	VVI
5	73	Female	CHB	VVI
6	69	Male	Chronic AF with slow ventricular response	VVI
7	72	Female	Chronic AF with slow ventricular response	VVI
8	66	Male	Chronic AF with slow ventricular response	VVI
9	73	Female	SND	VVI
10	75	Female	CHB	VVI
11	77	Male	AV block Mobitz II	VVI
12	73	Male	Chronic AF with slow ventricular response	VVI
13	79	Female	Chronic AF with slow ventricular response	VVI
14	56	Male	SND, paroxysmal AF	VVI
15	80	Female	SND, paroxysmal AF	VVI
16	38	Male	CHB	DDD
17	71	Male	CHB	DDD
18	62	Female	CHB	DDD
19	67	Female	SND	DDD
20	70	Female	SND	DDD
21	59	Male	CHB	DDD
22	68	Male	DCM, NYHA III, LBBB	CRT-ICD
23	62	Male	DCM, NYHA II, LBBB	CRT-P
24	44	Male	Sustained VT, NYHA II/III	ICD-VR
25	70	Male	DCM, NYHA II, non-sustained VT	ICD-DR
26	60	Male	Sustained VT, NYHA II, paroxysmal AF	ICD-DR

CIED – cardiac implantable electronic device; PLSVC – persistent left superior vena cava; SND – sinus node dysfunction; CHB – complete heart block; AF – atrial fibrillation; LBBB – left bundle branch block; VT – ventricular tachycardia; DCM – dilated cardiomyopathy; NYHA – New York Heart Association; ICD-VR – implantable cardioverter defibrillator; CRT – cardiac resynchronization therapy; VVI – single-chamber device; DDD – dual-chamber device; CRT-P – cardiac resynchronization therapy pacemaker

Table 2. Cardiac implantable electronic device implantation procedures in patients with and without persistent left superior vena cava

Parameter	The average CIED implantation time (min)		The average fluoroscopy time (min)		p
	With PLSVC	Without PLSVC	With PLSVC	Without PLSVC	
VVI	62.0 ± 37.9	31.2 ± 14.2	13.3 ± 16.8	2.4 ± 2.3	< 0.01
DDD	73.5 ± 37.1	38.4 ± 16.1	20.8 ± 22.8	3.4 ± 3.2	< 0.01
ICD-VR	120 ± 0	31 ± 8.6	35.7 ± 0	2 ± 1.6	< 0.01
ICD-DR	74 ± 18.3	37.8 ± 13.8	17.1 ± 9.9	3.6 ± 2.3	< 0.01
CRT-P	103.3 ± 19.3	63 ± 24.6	45.6 ± 13.4	14.8 ± 10.8	< 0.01
CRT-ICD	130 ± 50	59 ± 23	42.6 ± 19.6	11 ± 7.6	< 0.01

CIED – cardiac implantable electronic device; PLSVC – persistent left superior vena cava; ICD-VR – implantable cardioverter defibrillator; VVI – single-chamber device; DDD – dual-chamber device

Table 3. Right ventricle lead parameters after implantation and at the last follow-up

Parameters	N	Baseline		Follow-up		p
		$\bar{x}$	SD	$\bar{x}$	SD	
Impedance (Ω)	22	733	79.3	519.1	89.8	< 0.001
Sensing (mV)	22	11.3	6.7	10.8	3.6	0.945
Threshold (V / 0.4 ms)	22	1	0.2	0.8	0.4	0.007

Table 4. Right atrium lead parameters after implantation and at the last follow-up

Parameter	N	Baseline		Follow-up		p
		$\bar{x}$	SD	$\bar{x}$	SD	
Impedance (Ω)	10	656.7	151.2	518.2	164.2	0.002
Sensing (mV)	10	2.9	1.2	3.4	1.3	0.221
Threshold (V / 0.4 ms)	10	1.5	0.6	0.8	0.3	0.005

not even qualify as a rarity. The atypical venous anatomy may complicate the procedure, prolong duration and fluoroscopy time and it requires particular skill and experience of the physician [8]. To our best knowledge, our series of the patients with CIED lead(s) implanted through PLSVC, presented in this paper, is one of the largest reported.

The incidence of PLSVC was estimated at less than 0.5% in general population, as mentioned previously [1]. The true incidence of this congenital anomaly is unknown because it usually does not affect systematic venous return, so it has no physiological consequences. However, PLSVC may have significant clinical implications, especially when it drains in the left atrium creating left to right shunt, provoking possible hypoxemia, increasing the risk of paradoxical embolism and direct systemic effect of i.v. ordinated drugs [4, 5]. Also, it should always be thought of in the context of the association of PLSVC with congenital heart disease, as well as with extracardiac anomalies [2]. Because of all of the above, we believe that only large series, as shown in our study, with over 14,000 patients included, can give relevant estimate of the frequency of such anomalies. In our study, the incidence of PLSVC is 0.22% and we assert that this is a realistic assessment.

The implantation of CIED leads through PLSVC is challenging but feasible. Previous studies do not provide the information about duration and fluoroscopy time of CIED implantation through PLSVC. As expected, this study showed a significantly longer duration of the procedure and radiation exposure when implantation is performed through PLSVC for all types of CIED. Numerous factors have the potential to prolong the duration of X-ray exposure as well as the duration of the procedure itself, such as passing the lead by an unusual venous pathway, lead placement at the desired position, which always requires additional lead maneuvering, achieving lead stability and optimized values of its parameters. Many approaches for implanting and positioning of pacemaker/ICD leads have been described. Although, there are many approaches for RV lead implantation, in our center we use loop technique – making a loop in the RA before fixing the lead in the RV. Sometimes, during the procedure, it is necessary to

switch the standard-length lead (58 cm) with a longer one to facilitate lead placement in the RV. RA lead implantation also has its specificities in relation to routine procedures. After leaving the CS and entering the RA, the RA lead is typically directed towards the RA lateral wall. It is preferable to avoid fixing the electrode in that position due to the higher risk of lead displacement and cardiac perforation. The use of a curved stylet allows directing the lead towards the RA appendage, which is the preferred position for lead fixation [8].

However, implantation of the endocardial LV lead for CRT in the presence of the PLSVC remains very challenging. PLSVC can markedly increase the size of coronary sinus that makes LV lead placement difficult. On the other hand, increasing physician experience, cardiac imaging, and appropriate tools contribute to a positive outcome [13]. Nair et al. [14] showed that using the right-sided approach when RSVC is present makes it more likely that LV lead can be implanted using an endovascular approach. For this reason, some physicians decide to abandon the left-sided approach and implant the entire CRT system on the right side, while others use the right-sided approach to implant only the LV lead and then to tunnel it to the left prepectoral pacemaker pocket [8, 13]. Crossing to the other side and eventual tunneling that requires the application of analgosedation can significantly prolong the duration of these procedures. If LV lead implantation through PLSVC is not possible, it could be done epicardially, using mini-thoracotomy, as we did in four of our patients. Since 2005, a HEART team has existed in our institution with the idea of establishing a new protocol introducing a surgical approach into the standard therapy algorithm, following global trends. Until recently, LV lead implantation via lateral mini-thoracotomy was used as an alternative technique only when transvenous CRT was not possible, and nowadays we use this approach in CRT-non-responder patients who had the LV lead implanted in suboptimal CS tributary group. Therefore, we consider an LV lead implantation via mini-thoracotomy an elegant approach that does not depend on the anatomy of the coronary sinus, with significantly lower risk of phrenic nerve stimulation and lead dislodgement, without unnecessary prolonged radiation exposure, which all makes us often choose this technique when we encounter a problem like PLSVC.

In our study, no periprocedural complications were noticed in patients with CIED leads implanted through PLSVC. The absence of complications, within the certainly small number of cases for proper statistical prediction, could be explained by the experience and expertise of our operators and their increased caution on timely spotting this venous malformation.

During the follow-up period, no late complications were detected and there was no need to replace any lead implanted through PLSVC. Pacing parameters including impedance, sensing (of P and R waves), and threshold capture (for atrial RA, RV, and LV leads) were regularly checked by our physicians. All crucial lead parameters were stable during the follow-up period. Therefore, this is the very first study that provides long-term follow-up data of the CIED lead stability implanted through PLSVC.

CONCLUSION

The results of our study showed that the presence of PLSVC is not an obstacle for CIED implantation. The long-term follow-up proved the stability of CIED leads implanted through PLSVC. Longer implantation and fluoroscopy times are inherent to the procedure complexity. However, implantation of the endocardial LV leads for CRT in the presence of the PLSVC remains challenging and in some patients should be done epicardially.

Conflict of interest: None declared.

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Дугорочно праћење болесника са пејсмејкер електродама имплантираним кроз перзистентну леву горњу шупљу вену

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САЖЕТАК

Увод/Циљ Перзистентна лева горња шупља вена је најчешћа конгенитална малформација венског система грудног коша и често може компликовати уградњу електрода срчаних имплантабилних електронских уређаја.

Циљ овог рада је да се процени изводљивост и безбедност имплантације електрода срчаних имплантабилних електронских уређаја кроз перзистентну леву горњу шупљу вену, као и њена дугорочна ефикасност.

Методе Ово је ретроспективна, опсервациона студија, спроведена у терцијарном центру у периоду од јула 2005. до јула 2019. године међу болесницима којима су успешно имплантиране све предвиђене електроде срчаних имплантабилних електронских уређаја кроз перзистентну леву горњу шупљу вену.

Резултати Срчани имплантабилни електронски уређаји успешно су имплантирани у целости левостраним приступом код 26 од 32 (81,3%) болесника са перзистентном левом горњом шупљом веном. Просечно трајање имплантације износило је 62, 73,5, 120, 74,0, 103,3 и 130 минута, а просечно трајање флуороскопије износило је 13,3, 20,8, 35,7, 17,1, 45,6 и 42,6 минута за једнокоморске и двокоморске пејсмејкере, *ICD-VR*, *ICD-DR*, *CRT-P* и *CRT-ICD* уређаје, редом. Просечан период праћења је био 43,5 ± 29,9 месеци. Током периода праћења нису забележене компликације у вези са електродама срчаних имплантабилних електронских уређаја.

Закључак Резултати наше студије су показали да присуство перзистентне леве горње шупље вене није препрека за имплантацију срчаних имплантабилних електронских уређаја. Дугорочним праћењем је доказана стабилност електрода срчаних имплантабилних електронских уређаја имплантираних кроз перзистентну леву горњу шупљу вену.

Кључне речи: перзистентна лева горња шупља вена; срчани имплантабилни електронски уређај; електрода; имплантација