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ENDOCARDIAL LEAD IMPLANTATION IN PATIENTS WITH VEIN ACCESS OBSTRUCTION

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Aim. To present the experience of lead implantation in patients with cardiac implantable electronic devices (CIED) and access veins stenoses/occlusions, evaluate the effectiveness and safety of different methods and propose a decision-making algorithm for the method of new lead implantation in such patients.

Methods. The study includes 31 patients with CIED and access veins obstruction, which required implantation of new leads. Leads were implanted after recanalization of the veins with hydrophilic wires through long introducers, or after transvenous lead extraction (TLE) using TightRail sheath.

Results. Recanalization of veins using guidewires followed by lead implantation through a long introducer was performed in 24 patients, in 9 of them, after recanalization as the second step during the same procedure, TLE was performed. TLE without preliminary recanalization with guidewire was performed in 5 patients. In two patients, leads were implanted after vein puncture medial to the occlusion. Successful new leads implantation was performed in all patients. Decision making algorithm for the method of leads implantation through obstruction veins in various clinical situations is proposed.

Conclusions. Recanalization of occluded veins with guidewire and TLE in patients with CIED are effective methods for providing ipsilateral access for lead implantation through obstructed veins. The safety of TLE in patients with access vein obstruction requires further study.

Key words: venoplasty; implantable cardiac electronic devices; venous obstruction; venous recanalization; transvenous lead extraction

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Obstruction of access veins through which leads are implanted is one of the most common complications in patients with cardiac implantable electronic devices (CIEDs). This issue becomes particularly acute for patients requiring lead replacement due to dysfunction or the addition of new leads for more complex device implantation. In the largest study to date, Czajkowski M. et al. retrospectively analyzed 3,002 venographies in patients who subsequently underwent transvenous lead extraction (TLE). The study found moderate vein stenosis (50–80%) in 20.7% of patients, significant stenosis (>80%) in 19.9%, and complete vein occlusion in 22.5%. Thus, venous access difficulties may occur in 60% of patients requiring lead replacement or the addition of new leads [1].

In most cases, obstruction of veins within the superior vena cava (SVC) is asymptomatic due to the formation of an extensive collateral network that provides satisfactory blood drainage from the upper extremities. Vein occlusion is generally detected intraoperatively when lead replacement or addition is required. Antegrade venography via the cubital, subclavian, or axillary veins is useful for determining the location and extent of occlusion or stenosis [2].

For addressing vein obstruction, several techniques are available. Implantation of the entire system on the contralateral side is a straightforward approach; however, it necessitates the placement of additional leads, which can lead to contralateral vein occlusion and superior vena cava syndrome over time [3, 4]. Another approach is implanting leads on the contralateral side and connecting them to the device in the original pocket, tunneling the lead subcutaneously. This method carries similar drawbacks to the first technique [5].

Vein puncture medial to the occlusion or stenosis is another option, although it presents an elevated risk of pneumothorax. Over time, this approach may result in lead fractures caused by damage between the clavicle and the first rib [6]. Antegrade vein recanalization using a guidewire is also employed, and some authors recommend supplementing it with balloon angioplasty to ensure proper venous outflow from the extremity [7, 8]. The “inside-out” technique involves retrograde vein recanalization with the externalization of a guidewire at the site of occlusion [9].

Device implantation via femoral or iliac vein access is an alternative when lead placement through SVC basin veins is not feasible. However, this method carries a higher risk of infection at the CIED pocket site and thrombotic complications in the inferior vena cava (IVC) basin. Moreover, it requires longer-than-standard leads [10]. Epicardial lead implantation is another method, though its main drawback is its invasiveness [11]. The use of leadless pacemakers, which are not yet registered in the Russian Federation, represents another potential solution [12].

A significant limitation of these approaches is the presence of residual non-functional leads, which may lead to severe complications over time [13, 14]. TLE offers the advantage of simultaneously removing non-functional leads and performing vein recanalization for the implantation of new leads [15–17]. However, TLE carries a considerable risk of serious complications, including myocardial and major vein injury [18, 19]. Currently, there is no standardized approach for managing patients with access vein occlusions requiring pacing and/or defibrillation due to lead dysfunction or the need for a more complex device.

The aim of this study is to present our experience with lead implantation in patients with obstructed access veins, evaluate the effectiveness and safety of various techniques, and propose a decision-making algorithm for selecting the appropriate method for new lead implantation.

METHODS

This retrospective study included 31 patients with previously implanted CIEDs who, between January 2017 and December 2023, required the implantation of new leads due to the obstruction of veins through which the leads were originally implanted. For these patients, standard lead implantation was not feasible.

Standard lead implantation was defined as puncture of the axillary vein with an 18G needle, insertion of a 0.035” metal guidewire, placement of a peel-away introducer (7–9 Fr, 12 cm in length) over the guidewire, and implantation of the lead through the introducer, or implantation through the cephalic vein. For all patients with CIEDs requiring new lead implantation, venography was performed via a peripheral vein.

Computed tomography (CT) of the chest with contrast enhancement was performed in five patients to clarify the anatomical features of occlusive and stenotic lesions of the subclavian, brachiocephalic veins, and SVC, as well as to determine the position of leads within these veins (Fig. 1a).

Compromised leads were defined as those connected to the CIED at the time of surgery but rendered non-functional or prone to complications for various reasons: fractured leads; leads with high stimulation and/or defibrillation thresholds; leads with impaired sensitivity; leads causing ulceration at the pocket site due to looping; leads implanted during childhood positioned in the right ventricle as loops and inducing ventricular arrhythmias.

Abandoned leads were defined as implanted leads disconnected from the CIED: previously disabled, severed, or capped.

Vein recanalization with a guidewire

After venography via the cubital vein, puncture of the axillary vein was performed using an 18G needle. A 0.035” metal guidewire was advanced to the site of occlusion/stenosis. A dilator from a 5 Fr introducer or a 5 Fr introducer (12 cm in length) was advanced over the guidewire into the vein. Venography was repeated through the dilator or introducer. The metal guidewire was replaced with a hydrophilic guidewire. Preferred guidewires included the Roadrunner 0.035” (140 mm, COOK, USA), Hi-Torque Command 0.014” (Abbot, USA), or V-18 (Boston Scientific, USA). For complex cases, Corsair microcatheters (ASAHI, Japan) were used. After traversing the stenosis/occlusion, the guidewire was advanced into the right atrium, and a 23 cm-long introducer was positioned across the stenosis/occlusion. Contrast was injected through the introducer to confirm its tip placement within the vein or right atrium beyond the occlusion. A new lead was then implanted through the introducer.

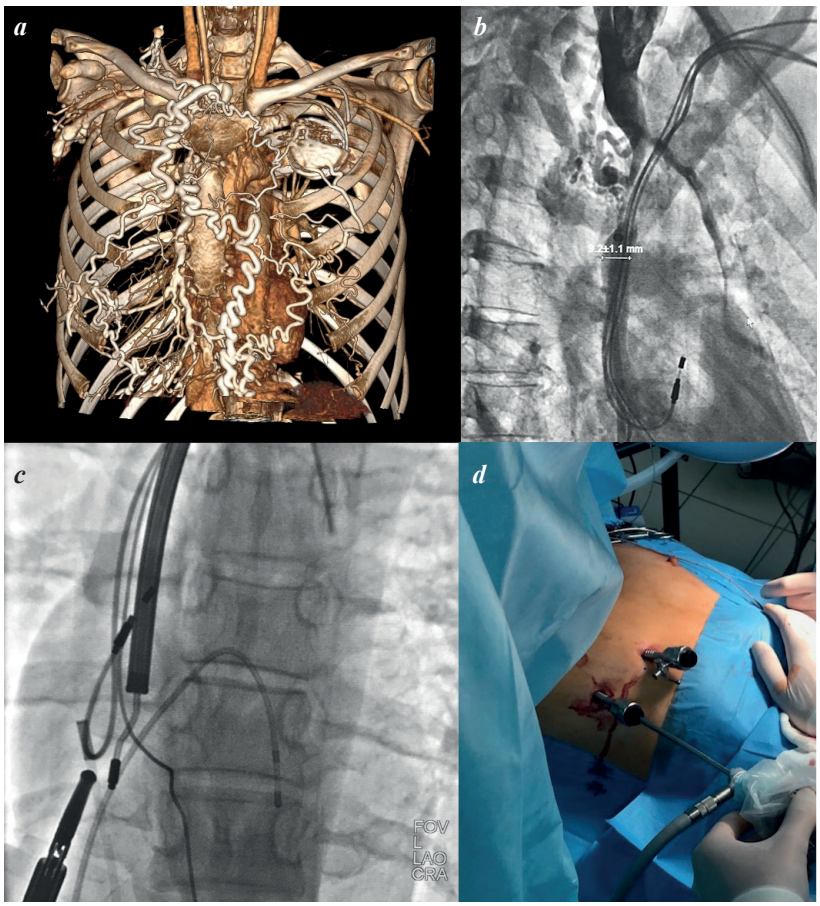

Figure 1. Video-assisted transvenous lead extraction (TLE) for a patient with superior vena cava (SVC) occlusion: a - computer tomography scan of the chest, developed collaterals visualisation; b - venography; c - TLE and recanalization SVC; d - ports for video thoracoscopy.

For patients requiring angioplasty, an 8×40 mm or 8×60 mm balloon catheter (Sterling, Boston Scientific, USA) was advanced over the guidewire post-recanalization. The balloon was inflated at the stenosis site to 8–12 atm. Balloon venoplasty was performed in cases of difficult lead manipulation or delivery device navigation across extensive occlusions.

For patients with SVC occlusion, venography was performed with simultaneous antegrade and retrograde contrast injection. Catheters were positioned in the right internal jugular vein and the proximal SVC via femoral access. Additional venography through the left axillary vein was performed as needed. This technique allowed detailed visualization of the extent and configuration of SVC occlusion and helped determine the optimal trajectory for guidewire advancement (Fig. 1b).

For patients with low risk of lead extraction, successful guidewire recanalization was followed by TLE using locking stylets, rotational dilators, and transfemoral lead extraction. TLE risks were assessed using the RISE protocol, Kancharla K. et al., and EROS scales [20–22].

Transvenous Lead Extraction Method

TLE was performed under total intravenous anesthesia with mechanical ventilation. All procedures were conducted by a cardiovascular surgeon prepared for immediate conversion to open surgery. Invasive arterial pressure monitoring was maintained via radial or femoral artery access. The target lead was dissected from scar tissue up to its entry into the subclavian/axillary vein. The connector portion was severed, leaving a 7–8 cm segment of the lead body. A locking stylet (LLD EZ or LLD 2, Spectranetics, USA) was advanced into the lead lumen. Rotational dilators (TightRail 11–13 Fr, Spectranetics, USA) were used to free the lead from fibrous encapsulation, simultaneously recanalizing the vein.

If the lead dislodged from the heart chamber during extraction before the vein occlusion was traversed, a triple-loop snare (EnSnare, Merit, USA) was introduced via femoral access to capture the lead tip and hold it in the right atrium. Recanalization was then completed with TightRail, followed by lead implantation (Fig. 2). Lead fragments resulting from TLE were removed with a triple-loop snare or a two-loop snare (Needle's Eye Snare, COOK Medical, USA) via femoral access.

For patients with SVC occlusion, hybrid video-assisted transvenous lead extraction was performed to minimize the risk of fatal complications associated with SVC injury [23] (Fig. 1). Following TLE, leads were implanted via the axillary vein to prevent future lead fractures, using standard access techniques [24]. Guidewires advanced through the rotational dilator lumen served as a safety backup.

Statistical Analysis

All data were recorded in Excel tables (Microsoft, 2021). Categorical variables were presented as absolute values and percentages. Continuous variables were assessed for normality and presented as medians with interquartile ranges, expressed as Me [Q1; Q3], as all continuous variables were found to deviate from normal distribution.

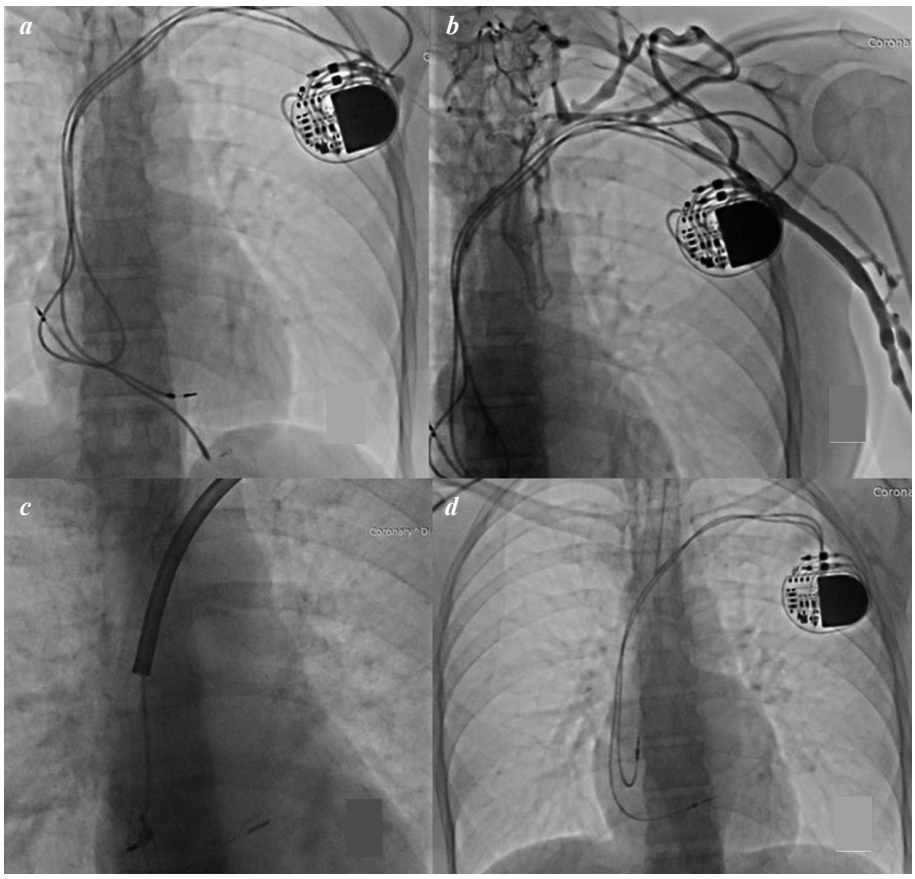

Figure 2. Extraction of broken lead with recanalization of occluded vein and new lead implantation. a - initial chest X-ray; b - venography, revealed occlusion of subclavian and innominate veins; c - fixation of the lead with endovascular snare system, femoral access for recanalization of the vein with a rotary dilator, d - chest X-ray after procedure, implanted new leads.

RESULTS

New lead implantation was performed in 149 patients with previously implanted CIEDs. Among them, 122 patients had compromised leads, and 27 required new leads for the implantation of a more advanced device. In 31 patients (21.5%), venous access obstruction or significant stenosis was identified. Cases involving reimplantation of devices after removal due to infection were excluded from the study.

The clinical characteristics of the patients included in the study are presented in Table 1. The median age of the patients was 65.5 [56.3; 72.0] years (range: 11 to 83 years). There were 18 female patients (56.3%). The median body mass index (BMI) was 26.6 [23.8; 29.7] kg/m². Three patients (9.7%) had previously undergone open-heart surgery (two coronary artery bypass grafting [CABG]

and one combined CABG and aortic valve replacement). The median left ventricular ejection fraction (LVEF) was 54.0 [48.3; 61.2]%.

The majority of patients had previously been implanted with dual-chamber pacemakers (64.5%). A small number of cases involved patients with implanted biventricular pacemakers or cardioverter defibrillators (Table 2). One patient had an implanted cardiac contractility modulator. The primary indication for surgery was lead dysfunction (high pacing thresholds or lead fracture) in 87% of cases. In two patients, new leads were implanted to upgrade the system to a dual-chamber device. The indication for surgery in the patient with a cardiac contractility modulator was impaired sensing of the left septal lead. It is noteworthy that seven patients had previously undergone three or more device-related surgeries. In three patients, the device had already been implanted on the contralateral side due to venous occlusion.

The median age of previously implanted leads was six [3; 9] years, ranging from one to 21 years. A high risk of TLE was identified in 16 (51.6%) patients with compromised leads based on the RISE scale, in eight (25.8%) patients based on the Kancharla scale, and in four (12.9%) patients based on the EROS scale (Tables 1, 2). These scales typically account for lead age, patient comorbidities, and the age at initial device implantation.

Venography revealed left subclavian vein obstruction in most cases (18 patients, 58%). Isolated severe stenosis/occlusion of the brachiocephalic vein was observed in eight (25.8%) patients. Isolated SVC occlusion was found in one (3.2%) patient. Extensive occlusions involving the subclavian, brachiocephalic veins, and SVC were identified in four (12.9%) cases.

Guidewire recanalization was performed in 24 (77.4%) patients. Long introducers were used for lead implantation in all cases. Balloon venoplasty was performed in only four (12.9%) cases. In 15 (48.4%) patients, lead extraction was not attempted due to the extremely high risk of TLE, attributed to lead age, comorbidities, or limited TLE experience at the time of intervention.

In nine (29%) patients, step-by-step TLE was performed as a second stage. All extracted leads were pacing leads. In four (12.9%) cases, leads were removed using traction with a locking stylet, in five (16.1%) cases using a rotational dilator, and in one (3.2%) case using a snare via femoral access. A total of 11 leads were extracted from this group of nine patients.

In five (16.1%) patients with venous occlusion, TLE was performed without prior guidewire recanalization. Rotational dilators were used for TLE in all these cases (Table 3). A total of 10 pacing leads were extracted in this group.

In one patient with SVC occlusion and a BMI of 18 kg/m², TLE was performed under thoracoscopic guidance. In two cases, femoral access was additionally utilized. In three cases, TLE was performed after failed guidewire recanalization, including one pediatric patient aged 11 years. In all these cases, new lead implantation was successfully performed via the axillary vein. Hydrophilic guidewires were advanced without technical difficulties through the

Table 1.

Clinical characteristics of patients with venous stenosis/occlusion

Total patients, n (%)	31 (100)
Age, years	60 [60; 75]
Age at initial implantation, years	59 [47; 69]
Female sex, n (%)	17 (54,8)
Body Mass Index, kg/m^2	26,6 [23,8; 29,7]
Heart failure (NYHA III-IV), n (%)	5 (16,1%)
Left ventricular ejection fraction, %	54,0 [48,3; 61,2]
History of open-heart surgery, n (%)	4 (12,9)
Atrial fibrillation, n (%)	8 (25,8)
Arterial hypertension, n (%)	15 (48,3)
Diabetes, n (%)	4 (12,9)
Chronic kidney disease (stage 3-4), n (%)	1 (3,2)
History of malignancy, n (%)	1 (3,2)
Number of procedures related to CIED, n (%)	2 [1; 3]
According to the RISE scale, n (%)	
According to the Kancharla K. et al. scale, n (%)	16 (51,6)
According to the EROS scale, n (%)	8 (25,8)
Total patients, n (%)	4 (12,9)

Note: CIED - cardiac implanted electronic device

Table 2.

Device characteristics and indications for surgery

Total devices, n (%)	31 (100)
AAIR P, n (%)	2 (6.5)
VVIR P, n (%)	6 (19.4)
DDDR P, n (%)	20 (64.5)
CRT-P, n (%)	1 (3.2)
ICD DR, n (%)	1 (3.2)
CRT-D, n (%)	0 (0)
CCM, n (%)	1 (3.2)
Number of compromised leads, n	41
Age of compromised leads, years	7 [4-12]
Indications for implantation of a new lead	
Mode switch from AAIR to DDDR, n (%)	2 (6.5)
Severe pain syndrome, n (%)	1 (3.2)
Lead loop in the RVOT, n (%)	1(3.2)
Lead dysfunction, n (%)	27(87.1)

Note: Hereinafter, P - Pacemaker; CRT-P - Biventricular pacemaker; ICD - Implantable cardioverter-defibrillator; CRT-D - Biventricular ICD; CCM - Cardiac contractility modulator; RVOT - Right ventricular outflow tract.

channel created by the rotational dilator into the right heart chambers. Subsequently, the safety guidewires inserted through the rotational dilator channel were removed.

Vein puncture medial to the subclavian vein occlusion was used for new lead implantation in two cases: once after unsuccessful guidewire recanalization and once without attempting recanalization. This method was used as an exception due to the high long-term risk of lead fracture associated with implantation from this access point.

In total, unnecessary leads were removed in 14 (48.2%) patients with compromised leads. New lead implantation via the axillary vein was performed in 29 (93.5%) patients. Successful new lead implantation through occluded/stenotic veins was achieved in all patients. None required lead implantation through contralateral veins or alternative methods.

Minor complications occurred in five (16.1%) cases (Table 4). During TLE, non-target functioning leads were damaged and/or dislodged in four patients, necessitating their removal and new lead implantation. In one case, the postoperative period was complicated by a hematoma at the CIED pocket site following lead removal with a rotational dilator, requiring pocket revision. No major complications or fatalities occurred in this patient cohort following TLE.

This experience allowed us to develop and propose a decision-making algorithm for patients with CIEDs and venous access obstruction requiring new lead implantation (Fig. 3).

Table 3.

Types of procedures in patients

Medial puncture of SV, n (%)	2 (6.5)
RG, n (%)	15 (48.3)
RG + balloon angioplasty, n (%)	4 (12.9)
RG and TLE (step-by-step), n (%)	9 (29.0)
- Traction with LS, n (%)	4 (12.9)
- RD, n (%)	5 (16.1)
- RD + FA, n (%)	1 (3.2)
TLE only, n (%)	5 (16.1)
- RD, n (%)	4 (12.9)
- RD + thoracoscopy, n (%)	1 (3.2)
- RD + FA, n (%)	3 (9.7)
Total procedures, n (%)	31(100)
RD in all cases, n (%)	10 (32.3)
FA in all cases, n (%)	4 (12.9)

Note: Hereinafter, SV - Subclavian vein; RG - Recanalization with a guidewire; TLE - Transvenous lead extraction; LS - Locking stylet; RD - Rotational dilator; FA - Femoral access.

Table 4.

Procedure results

Number of patients who underwent lead implantation, n (%)	31 (100)
Number of patients who underwent TLE, n (%)	14 (45.2)
Number of patients without retained leads, n (%)	14 (45.2)
Number of patients with retained leads, n (%)	17 (54.8)
Number of implanted leads, n	40
Number of removed leads, n	21
Number of retained non-functional leads, n	20
Complications	
Dislocation/damage to non-target lead, n (%)	4 (12.9)
Hematoma at the pocket site requiring reoperation, n (%)	1 (3.2)
Operative mortality, n (%)	0 (0)

DISCUSSION

A search of the MEDLINE/PubMed database identified over 10 different approaches for addressing venous stenosis/occlusion in patients with CIEDs [5-12]. This diversity highlights the lack of a universal solution for these patients. In routine clinical practice, the most commonly used method involves implanting new leads and devices on the contralateral side without removing compromised leads.

Contralateral lead implantation can eventually result in bilateral venous obstruction within the SVC or SVC syndrome [3, 4]. In cases of SVC occlusion, epicardial lead implantation is a more invasive method with a shorter lifespan for epicardial leads compared to endocardial leads [25]. Implanting leads via femoral/iliac veins is associated with a higher risk of infectious complications.

Based on our experience, guidewire recanalization is an effective and safe technique. Successful advancement of a hydrophilic guidewire through the stenosis/occlusion was achieved in 77.4% of cases. In facilities lacking expertise in TLE, guidewire recanalization followed by lead implantation using a long introducer may be a preferred approach. This technique can be further complemented by balloon venoplasty.

Lead implantation through occluded veins following TLE has been recognized in several studies as an effective and safe method, with the added advantage of removing compromised leads. However, most specialists approach TLE cautiously, given its association with serious complications and mortality [13, 14, 18, 19]. Nevertheless, in high-volume centers performing over 30 TLEs annually, the rates of major complications and mortality are minimal [26]. Based on our experience of over 200 TLEs, we consider leads older than 10 years as high risk, consistent with the Kancharla scale [21]. For patients with SVC-related occlusion/stenosis caused by leads, TLE is the method of choice for providing access for new lead implantation [27].

Our experience with guidewire recanalization and TLE suggests that combining these techniques is optimal and both should be available in a clinic's repertoire. We were highly cautious in using TLE without prior guidewire recanalization, employing this approach in only two cases.

The first case involved a 35-year-old female patient with a BMI of 18 kg/m², third-de-

gree atrioventricular block, SVC occlusion, and a fractured ventricular lead. The patient had three leads in the heart chambers. Hybrid thoracoscopically-assisted TLE was performed, removing the atrial and ventricular leads implanted five years ago while leaving and sealing a lead implanted 12 years ago.

The second case involved a 74-year-old male patient with bilateral subclavian and brachiocephalic vein occlusion, SVC occlusion, and a fractured ventricular lead implanted five years ago. The lead was removed with transfemoral assistance, and a new lead was implanted.

In our clinical practice, TLE decisions are carefully balanced between risk and benefit, guided by TLE risk scales. Even with this measured approach, we performed TLE in 14 patients with venous occlusions, including nine patients who underwent successful guidewire recanalization as a first step.

Why aim to perform TLE in as many patients as possible? This stems from a desire to minimize the number of non-functional leads and from the expertise accumulated in our clinic, which helps reduce complication risks.

Our primary goal was to implant new leads. Once venous access for lead implantation was secured, we proceeded with TLE, prepared to stop at any point and leave the lead if necessary. Expanding TLE experience and using risk scales in our clinic have allowed us to broaden TLE indications for patients with venous occlusions. In high-risk cases, guidewire recanalization is recommended; for low and intermediate risks, TLE can be performed.

The proposed algorithm attempts to systematize methods for lead implantation in patients with venous access obstruction. However, numerous other factors must be considered, including lead model, availability of a complete TLE toolkit, anesthetic protocol nuances, the ability for immediate conversion to open surgery, and the patient's life expectancy.

TLE risk is challenging to determine in some cases. Risk assessment scales, such as the RISE protocol or MB score, where leads younger than five years indicate low TLE risk, can help reduce the number of abandoned leads [28].

A drawback of removing compromised leads is the risk of damaging or dislodging functional leads. This risk must also be considered when planning TLE, and the necessary leads and consumables should be readily available, particularly for patients with biventricular devices.

A limitation of implanting new leads through guidewires advanced via rotational dilator channels is the repeated use of the subclavian vein, as most extracted leads were implanted via this access. This approach increases the risk of lead fractures, especially when the reason for re-operation is an existing lead fracture. For this reason, all new leads were implanted via the axillary vein. After TLE, hydrophilic guidewires were advanced without technical difficulties through channels formed by rotational dilators into the right heart chambers, serving as a safety backup.

For short subclavian vein occlusions, vein puncture medial to the occlusion is a possible venous access option. We employed this technique in two cases but subsequently abandoned it due to the high risk of pneumothorax and long-term lead fracture.

Study Limitations

A significant limitation of our study is the small number of patients with biventricular devices and cardioverter-defibrillators. This reflects the low number of such patients under observation in our clinic. According to the literature, patients with multi-lead systems are most frequently affected by venous access obstruction.

CONLUSION

Guidewire recanalization of occluded veins and transvenous lead extraction in patients with cardiac implantable electronic devices are effective and safe methods for providing ipsilateral access for lead implantation in cases of lead dysfunction or when a change in pacing mode is required. These techniques help avoid device implantation on the contralateral side. We believe it is essential for specialists performing device implantations to master vein recanalization methods and for operating rooms to be equipped with the necessary tools.

TLE reduces the number of abandoned leads. The choice of method depends on the level of TLE expertise in each clinic. TLE risk assessment scales can assist in decision-making, and the algorithm we propose may prove useful in daily practice.

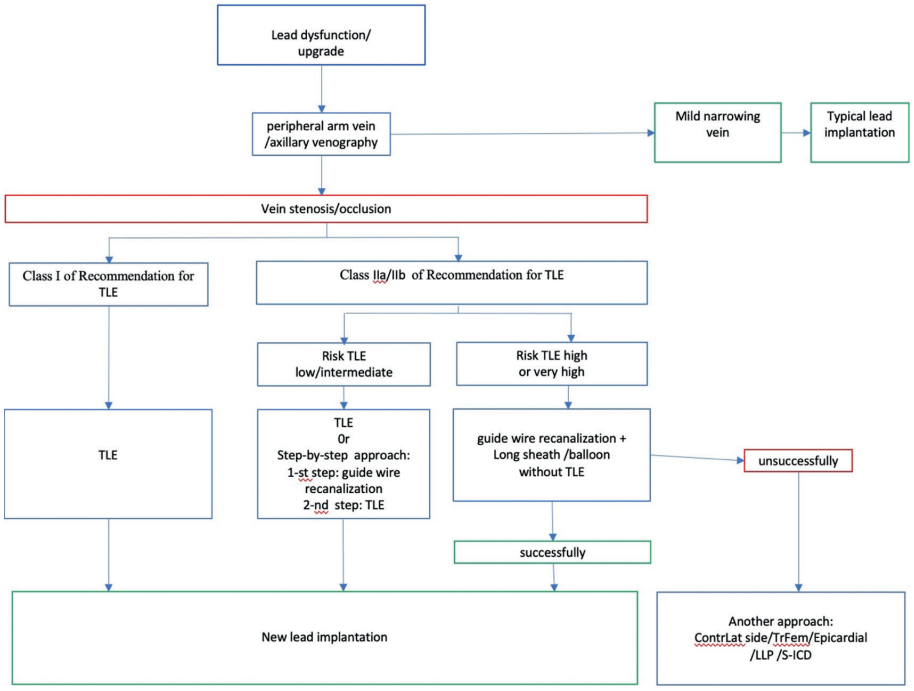

Figure 3. Deciding algorithm on the method of lead implantation in non-infection patients with vein obstruction. TLE - transvenous lead extraction; ContrLat - contralateral; TrFem - transfemoral; LLP - leadless pacemaker; S-ICD - subcutaneus implantable cardioverter-defibrillator.

In cases where vein recanalization is unsuccessful and TLE is not feasible, one of the following approaches should be considered, taking into account the clinic's capabilities and the patient's comorbidities: epicardial lead implantation, implantation via femoral/iliac veins, leadless pacemaker implantation, or subcutaneous cardioverter-defibrillator implantation. In our study, the use of these methods was successfully avoided.

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