Transcatheter aspiration of large pacemaker and implantable cardioverter-defibrillator lead vegetations facilitating safe transvenous lead extraction

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Abstract: AIMS Treatment of patients with systemic cardiac implantable electronic device (CIED) infection with large lead vegetations is challenging and associated with relevant morbidity and mortality. To avoid complications from open surgical extraction, a novel approach with percutaneous aspiration of large vegetations prior to transvenous lead extraction was instituted. The results of this treatment concept were retrospectively analysed in this multicentre study. METHODS AND RESULTS One hundred and one patients [mean age 68.2 ± 13.1 (30-92) years] were treated in four centres for endovascular CIED infection with large lead vegetations. Mean lead vegetation size was 30.7 ± 13.5 mm. Two hundred and forty-seven leads were targeted for extraction (170 pacemaker leads, 77 implantable cardioverter-defibrillator leads). Mean lead implant duration was 81.7 (1-254) months. The transcatheter aspiration system with a specialized long venous drainage cannula and a funnel-shaped tip was based on a veno-venous extracorporeal circuit with an in-line filter. The aspiration of vegetations showed complete procedural success in 94.0% (n = 95), partial success in 5.0% (n = 5). Three major complications (3.0%) were encountered. Complete procedural success (per lead) of the subsequently performed transvenous lead extraction procedure was 99.2% (n = 245). Thirty-day mortality was 3.0% (n = 3). Five patients (5.0%) died in the further course on Days 51, 54, 68, 134, and 182 post-procedure (septic complications: n = 4; heart failure: n = 1). CONCLUSION The transcatheter aspiration procedure is highly effective and is associated with a low complication profile. The aspiration of vegetations immediately prior and during the lead extraction procedure may avoid septic embolization into the pulmonary circulation. This may potentially lead to a long-term survival benefit.

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Transcatheter aspiration of large pacemaker and implantable cardioverter-defibrillator lead vegetations facilitating safe transvenous lead extraction

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Aims
Treatment of patients with systemic cardiac implantable electronic device (CIED) infection with large lead vegetations is challenging and associated with relevant morbidity and mortality. To avoid complications from open surgical extraction, a novel approach with percutaneous aspiration of large vegetations prior to transvenous lead extraction was instituted. The results of this treatment concept were retrospectively analysed in this multicentre study.

Methods and results
One hundred and one patients [mean age 68.2 ± 13.1 (30–92) years] were treated in four centres for endovascular CIED infection with large lead vegetations. Mean lead vegetation size was 30.7 ± 13.5 mm. Two hundred and forty-seven leads were targeted for extraction (170 pacemaker leads, 77 implantable cardioverter-defibrillator leads). Mean lead implant duration was 81.7 (1–254) months. The transcatheter aspiration system with a specialized long venous drainage cannula and a funnel-shaped tip was based on a veno-venous extracorporeal circuit with an in-line filter. The aspiration of vegetations showed complete procedural success in 94.0% (n = 95), partial success in 5.0% (n = 5). Three major complications (3.0%) were encountered. Complete procedural success (per lead) of the subsequently performed transvenous lead extraction procedure was 99.2% (n = 245). Thirty-day mortality was 3.0% (n = 3). Five patients (5.0%) died in the further course on Days 51, 54, 68, 134, and 182 post-procedure (septic complications: n = 4; heart failure: n = 1).

Conclusion
The percutaneous aspiration procedure is highly effective and is associated with a low complication profile. The aspiration of vegetations immediately prior and during the lead extraction procedure may avoid septic embolization into the pulmonary circulation. This may potentially lead to a long-term survival benefit.

Keywords
Cardiac implantable electronic device infection • Lead extraction • Lead vegetation • Pacemaker • Implantable cardioverter-defibrillator
What's new?
• A novel, minimally-invasive approach to treat patients with cardiac implantable electronic device infections with large lead vegetations is described.
• The percutaneous aspiration procedure of lead vegetations, which is performed concomitant to the required transvenous lead extraction, proved to be safe and effective.

Introduction
Optimal treatment of endovascular infections of cardiac implantable electronic devices (CIEDs) remains a challenge, especially in the setting of large lead vegetations. Lead vegetation size of >20 mm in diameter is a cut-off parameter to discuss open surgical extraction as opposed to transvenous lead extraction. 1 The 2015 ESC/EACTS guidelines on infective endocarditis refer to surgical extraction in the setting of large lead vegetations (>20 mm) as a Class IIb indication. 2 Open surgical extraction in such situations carries a relevant risk of morbidity and mortality. 3 On the other hand, there exist case reports and case series, that report successful transvenous extraction procedures in large lead vegetations with low perioperative mortality. 4,5 In this context, it remains unclear why endovascular CIED infection carries a 1-year mortality rate of up to 30% despite state of the art treatment (complete CIED explantation and antibiotic therapy). 6 To avoid open extraction, a novel approach with percutaneous aspiration of large vegetations (defined as ≥20 mm) prior to and during transvenous lead extraction procedures was introduced.

Methods
Indication for percutaneous aspiration procedure
The indications for the described concomitant aspiration procedure in patients undergoing transvenous lead extraction procedures were defined as follows:
• Patients with systemic CIED infection with lead vegetations and a vegetation size of equal to or more than 20 mm in the longest axis measured by transoesophageal echocardiography (TOE).
• Patients with smaller vegetation size (10–20 mm) and persistent foramen ovale.

Transcatheter aspiration procedure using an extracorporeal circuit
The transcatheter aspiration system is based on an extracorporeal circuit used in a veno-venous configuration similar to an extracorporeal membrane oxygenation circuit, except it uses a filter system instead of an oxygenator (Figure 1). Venous access was achieved by cannulating both femoral veins. Before placement of the cannulas, heparin was administered intravenously with a target activated clotting time of >250 s. The right femoral vein was used to place a 26-Fr Gore DrySeal Sheath (Gore Medical, USA) percutaneously as access for the AngioVac drainage cannula (Angiodynamics, USA). The AngioVac cannula is a 22-Fr coil-reinforced cannula with a length of 90 cm, an expandable funnel shaped distal tip and a 20°-angulation of the tip. The expanded funnel-shaped tip improves venous drainage and the aspiration of vegetation material (Figure 2). To return the filtered blood, an 18-Fr FemFlex II cannula (Edwards Life Sciences, USA) was placed percutaneously via the left femoral vein. The aspiration procedure was guided by TOE and fluoroscopy, which allows for immediate monitoring of procedural success and potential intraprocedural complications.

Definitions of success of the aspiration procedure
Complete procedural success of the transcatheter aspiration procedure was defined as complete removal of all vegetative material determined by TOE.

Partial success of the aspiration procedure was defined by removal of most vegetative material with a maximum portion of 30% or less of remaining vegetation.

Failure was defined any procedure which left more than 30% of vegetation in situ.

All patients were continuously monitored by TOE during the entire procedure to evaluate the success of the aspiration using the above described definitions and to rule out partial or complete pulmonary embolization of vegetations, while recognizing the limitations of TOE with regard to this aspect.

Transvenous lead extraction procedure
The subclavian approach was primarily chosen for lead extraction procedures. For leads that could not be extracted by simple traction, a multi-step staged lead extraction approach was performed. Application of traction was performed with the help of a locking stylet (Liberator, Cook Medical, USA). Additional lead control was achieved by the application of a compression coil (One-Tie, Cook Medical, USA). In case of severe fibrotic or calcified adhesions at the site of the vessel entry below the clavicle, the Evolution Shortie RL (Cook Medical, USA) was used. To apply counterpressure or countertraction along the course of a targeted lead either a simple polypropylene extraction sheath (Byrd Dilator Sheath, Cook Medical, USA) or a rotational mechanical dilator sheath (Evolution RL, Cook Medical, USA) were used in most cases. In a small number of leads (n = 14), a laser sheath (SLS II, Spectranetics, USA) was used. In case of failed or impossible superior approach, a femoral approach using a snare (Needle’s Eye Snare, Cook Medical, USA) was performed.

All procedures were performed in a hybrid operating room under general anesthesia by a cardiac surgeon (n = 100) or a cardiologist (n = 1) with standby extracorporeal circulation and a perfusionist. Patients were monitored by electrocardiogram, invasive blood pressure measurement, pulse oximetry, and TOE.
Success was defined either as clinical success or as complete procedural success according to the definitions of the 2017 Heart Rhythm Society expert consensus.\(^7\)

**Statistics**

Categorical variables are presented as numbers and percentages. Continuous variables are presented as mean ± standard deviation or as mean and range from minimum to maximum. Differences between groups were analysed by two sample \(t\)-test. A \(P\)-value of <0.05 was considered significant.

The local review boards approved the research protocol. The results obtained were analysed retrospectively with regard to efficacy and safety.

**Results**

**Patient population**

From July 2014 until November 2018, 101 patients [mean age 68.2 ± 13.1 (30–92) years; 71 male, 30 female] were treated for endovascular CIED infection with large lead vegetations at four high-volume lead extraction centres (German Heart Center Berlin, Germany; Providence Saint Joseph Medical Center, Burbank, CA, USA; Smidt Heart Institute, Cedars Sinai Medical Center, Los Angeles, CA, USA; and University Hospital Zurich, Zurich, Switzerland). Mean lead vegetation size determined in preoperative echocardiography was 30.7 ± 13.5 mm. The distribution of vegetation sizes were as follows: vegetation <20 mm: \(n = 16\) (15.8%); \(\geq 20\) mm and <25 mm: \(n = 19\) (18.8%); \(\geq 25\) mm and <30 mm: \(n = 24\) (23.8%); >30 mm: \(n = 42\) (41.6%). The minimum size of lead vegetation included was 15 mm. Most lead vegetations were found to be adhering to the lead course in the right atrium. Less frequently vegetations were found to be in...
the superior vena cava (SVC) or in the right ventricle. In seldom cases, there was concomitant involvement of the tricuspid valve.

Blood cultures were positive in 94 patients (93.1%) \([\text{Staphylococci in 56 patients (55.4%)]}\]. Blood cultures were negative in 7 patients (6.9%).

In these 101 patients 247 leads were targeted for extraction \([170 \text{ pacemaker leads, 77 implantable cardioverter-defibrillator (ICD) leads}].\) Mean lead implant duration was 81.7 (1–254) months. Table 1 provides the patient and lead characteristics.

| Number of patients | 101 |
|--------------------|-----|
| Mean age (years)   | 68.2 (30–92) |
| Gender             |     |
| Male               | 71 (70.3%) |
| Female             | 30 (29.7%) |
| Diabetes mellitus  | 29 (28.7%) |
| Chronic kidney disease | 41 (40.6%) |
| Bacteria           |     |
| Staphylococcus aureus | 22 (21.7%) |
| Staphylococcus epidermidis | 25 (24.8%) |
| Other Staphylococcus | 12 (11.9%) |
| Enterococcus faecalis | 4 (4.0%) |
| Escherichia coli    | 1 (1.0%) |
| Streptococcus       | 9 (8.9%) |
| Other bacteria      | 12 (11.9%) |
| Culture negative    | 7 (6.9%) |
| Number of targeted leads | 247 |
| Mean lead implant duration (months) | 81.7 (1–254) |
| Number of targeted leads per patient | 2.4 ± 1.2 |

### Procedural outcomes-aspiration procedure

The veno-venous configuration of the extracorporeal circuit to facilitate the percutaneous aspiration procedure was achieved by femoro-femoral cannulation in 98 patients. In three patients, the aspiration cannula was placed via the right internal jugular vein and the return cannula in the left femoral vein. The average perfusion time of the extracorporeal circuit was 30.2 ± 18.3 min.

The aspiration of the vegetations \((\text{Figure 3})\) showed complete procedural success in 94.0% \((n = 95)\) of all cases. In one case, a highly mobile vegetation embolized into the pulmonary circulation prior to aspiration. This embolus did not result in any haemodynamic consequences and the subsequent transvenous lead extraction procedure was carried out successfully.

Three major complications related to the aspiration procedure were encountered. In one case, the right iliac vein was perforated and needed subsequent repair with a covered stent. The patient recovered uneventfully. In the second case, a patient with systemic CIED infection with large lead vegetations died intraoperatively due to refractory septic shock prior to completion of the procedure. Cannula placement was uneventful and the extracorporeal circuit of the AngioVac system worked correctly. Pericardial tamponade was ruled out in TOE. Due to severe septic shock with haemodynamic compromise despite maximal dose of vasopressors, it was regarded as highly unlikely that this event was related to the aspiration procedure, but it cannot be completely ruled out, that the aspiration procedure did not affect the outcome at all. In the third case, a patient had haemodynamic collapse shortly after initiation of the aspiration procedure and needed intraoperative resuscitation with return of spontaneous circulation in less than 2 min. The procedure was successfully completed and patient recovered uneventful without any neurologic deficiencies post-operatively. The patient was discharged on post-operative Day 2.

### Discussion

Cardiac implantable electronic device infections are a relevant clinical problem with a disproportional increase in relation to the rising
numbers of CIED implantations. The main principle of treating such infections is the complete removal of the device system, which represents a Class I indication for lead extraction.

According to the 2015 ESC guidelines for the management of infective endocarditis, cardiac device-related infective endocarditis is a Class I indication for percutaneous extraction even in the presence of vegetations >10 mm. According to these guidelines, surgical extraction may be considered in patients with large vegetations (>20 mm), however, this is merely a Class IIb indication.

Grammes et al. reported the results of a single-centre experience in percutaneous lead extraction in 100 patients with intracardiac vegetations. Mean vegetation diameter was reported to be 1.6 cm, ranging from 0.2 to 4.0 cm. They reported no operative mortality, but a 30-day mortality of 10% in this patient cohort. There exists several case reports and series reporting successful transvenous lead extraction procedures in patients with large lead vegetations. Open surgical extraction in case of large lead vegetations becomes uncommon and has become a bail-out option nowadays. There is data showing that open surgical extraction carries a higher mortality at 1 and 12 months than percutaneous extraction procedures. The study reporting these mortality differences also showed that patients undergoing surgical extraction had a higher comorbidity index and larger vegetations, suggesting a selection bias in the reported results.

There is enough evidence showing that endovascular infection of CIED systems carries a relevant long-term mortality, even though the patients were treated according to current recommendations with complete system replacement and antibiotic therapy. In the published results of the ELECTRa registry, systemic infection was identified as a predictor for increased all-cause mortality (odds ratio 4.93, 95% confidence interval 2.72–8.93; P < 0.0001). Tarakji et al. reported a 1-year mortality rate of 20% in patients with endovascular infection in an overall patient cohort of 502 patients with CIED infection (endovascular and pocket infection). Compared to the patients with pocket infections the mortality rate in the patients with endovascular infection was significantly higher (hazard ratio 2.1; P = 0.0008). However, the authors could not find a correlation between patient mortality and the presence of vegetations in the patient group with endovascular infection. Greenspon et al. showed in a group of 129 patients with lead associated endocarditis that 6-month mortality significantly increased as a function of vegetation size. Six-month mortality in patients with lead vegetations smaller than 1.0 cm was 10.1% vs. 18.4% in patients with a vegetation size of more than 1.0 cm.

Percutaneous lead extraction in patients with lead vegetations without prior aspiration of the vegetations may lead to septic embolism into the pulmonary circulation. Hypothetically, these septic emboli remaining in the pulmonary circulation may be a source for future fatal septic complications, despite accurate initial treatment. This aspect is adequately addressed by the described percutaneous aspiration procedure prior to and during the transvenous extraction procedure. As our results show the aspiration procedure using the AngioVac cannula (Angiodynamics, Latham, NY, USA) is highly effective and successful (94% complete procedural success) with a low complication risk. The addition of this procedure to the transvenous lead extraction facilitates a safe extraction procedure and avoids the need for an open surgical approach especially in cases with large lead vegetations and a high risk for septic embolizations into the pulmonary circulation. Additionally, avoiding the surgical trauma of a thoracotomy reflects a further clinical benefit for this high-risk patient cohort.

To our knowledge, this is the largest published series using this novel percutaneous aspiration procedure in transvenous lead extractions. Early data from two of the participating institutions of this study has been published before as initial experiences. One series comprised 20 patients (Burbank, California, USA) and the other experience 35 patients (Berlin, Germany). The findings of these two separate initial experiences are consolidated by the outcome data of this multicentre study.

It is important to mention two current restrictions in the use of the AngioVac device. The first one is the gap between device costs...
and missing specific or inadequate reimbursement of the procedure. Elimination of this gap by adjusting reimbursement and/or device costs are highly desirable to create options for a wider clinical use. The second restriction is missing familiarity of electrophysiologists or cardiology in the use of a veno-venous extracorporeal circuit.

Limitations of the study

The current study has a few limitations, which need to be outlined. Specifically, data were collected retrospectively with a relatively small number of patients. Moreover, the results obtained from this study can only be viewed as hypothesis generating and should be validated by a larger prospective randomized trial. Furthermore, the lack of evaluating the presence or extent of septic embolism by computed tomography scan, or ideally by FDG/PET-CT scan, pre- and post-operatively is a shortcoming of the described study. Especially, this aspect is an important topic that needs to be investigated in future prospective studies.

Conclusions

In summary, the presented percutaneous aspiration procedure is highly effective and is associated with a low complication profile. The aspiration of vegetations immediately prior to and during the lead extraction procedure avoids septic embolization into the pulmonary circulation and potentially based on this mechanism leads to a survival benefit.

Conflict of interest: C.T.S. and R.H.M.S. are paid consultants for AngioDynamics, Inc. in the area of Vascular Interventions and Therapies. C.T.S. and R.H.M.S. are paid consultants for Cook Medical in the area of Lead Management. C.T.S. and T.D. have received consultant honoraria from Liva Nova. C.T.S. has received consultant honoraria from Spectranetics. All other authors report no conflict of interest with regard to this article.

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