





ORIGINAL ARTICLE

Working on the dirty side—the ipsilateral subclavian access for temporary pacing after lead extraction

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Abstract

Background: Temporary pacing is necessary in pacemaker-dependent patients after transvenous lead extraction (TLE) for cardiac implantable electronic device infection. In case of unavailability of other accesses, we propose to use the ipsilateral subclavian access (ISA) combined with a standard permanent active fixation lead for the temporary pacemaker and present preliminary data.

Methods: We consecutively enrolled patients undergoing TLE who received a temporary pacemaker using the ISA between August 2016 and April 2020 at our centre.

Results: During the observation period, 36 patients undergoing TLE for pocket infection (72.2%), endocarditis (25.0%) or other causes received a temporary pacemaker over the ISA. Their mean age was 77.0 ± 10.7 years, and 13.9% were female. Complete TLE was achieved in 94.4%. There were no major periprocedural complications. Intra-hospital mortality was 11.1%. Pocket revision was performed in 19.4%. During long-term follow-up (23 ± 13 months), 8.3% had a relapse of local pocket infection and 2.8% needed rehospitalization for reintervention.

Conclusions: Temporary pacing using a standard permanent active fixation lead using the ISA is a convenient alternative to conventional venous accesses. However, risks of implanting a lead into a previously infected area have to be taken into account.

KEYWORDS

cardiovascular implantable electrical device, pocket infection, subclavian access, Transvenous lead extraction

1 | INTRODUCTION

In the previous years, an increase of cardiac implantable electronic device (CIED) infections has been documented¹ as a result of rising

implantation rates and increasing implant complexity. In certain situations, such as pocket infection or endocarditis with particular microbial strains, a complete removal of the CIED system has been indicated.^{2,3} In CIED systems older than one year, transvenous lead extraction

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(TLE) using special tools may be necessary.⁴ While antibiotic therapy is usually administered for 2–6 weeks,² the reimplantation of a new CIED system may be delayed for more than 2 weeks to avoid the spread of infection. In the meantime, temporary pacing is essential for pacemaker-dependent patients; however, it is associated with an elevated complication rate: The establishment of an additional venous access for the pacing lead may increase the overall risk of the extraction procedure, and this facilitates bloodstream (re)infections in already compromised patients.^{5,6} Furthermore, traditional temporary pacing leads have a higher possibility of dislodgement. In certain cases, we use the ipsilateral subclavian access (ISA) with a standard permanent active-fixation lead. We hereby present a high-volume centre experience using the ISA for temporary pacing after TLE.

2 | METHODS

We performed a prospective analysis of all patients receiving a temporary pacemaker over the ISA following TLE at our centre from its first application (August 2016) until April 2020. The analysis was approved by the institutional review board.

2.1 | Indication for TLE

Our centre serves as one of the major national reference centres for TLE in Italy, with over 70 advanced TLE procedures per year. Patients received TLE with a temporary external pacemaker via the ISA in case of pacemaker dependency and CIED infection or other indications that limited the use of the same pocket for the new CIED system.

2.2 | TLE and post-procedural management

Depending on the clinical condition, patients were put into general anaesthesia or local anaesthesia was performed. First, a quadripolar fixed curve catheter was introduced via the right femoral vein and advanced into the right ventricle to serve as temporary pacemaker. The right femoral vein was accessed with a second introducer to allow transfemoral extraction techniques. Then, the generator and the extravascular parts of the leads were exposed. In presence of a pocket infection, affected tissue and debris were removed, and also scar tissue. Then, TLE was performed with cardiac surgery ready on-site as previously described.⁷ We used a stepwise approach starting with simple extraction methods, such as manual traction with regular stylets, locking stylets and non-powered dilator sheaths. If those methods failed, we continued with powered sheaths, using either Evolution RL (Cook Inc)⁸ and TightRail (Spectranetics Corp)⁹ bidirectional mechanical or a snare (ONE Gooseneck Snare; Merit Medical Systems) via the femoral route. After complete retrieval of the leads, the temporary pacing lead was placed. We preferably established subclavian access at the ipsilateral side directly from the open CIED bed. When a sheath

had been used for TLE, the venous system was directly accessed through this sheath using a guidewire. Otherwise, subclavian access was gained with the Seldinger technique. A standard permanent active fixation lead was positioned in the apex or septum of the right ventricle and sutured onto the skin in direct proximity of the wound. In case of bleeding from the vein into the pocket, a tobacco-pouch suture around the lead was applied without fixating the lead. After closure of the wound, the lead was fixed onto the skin at the entrance of the wound with non-absorbable suture material (Graphical abstract). Afterwards, either the previously extracted and disinfected generator or a new generator was sutured onto the skin caudal of the wound and connected to the pacing lead. Unless chosen by the operator, no drain was installed.

After the procedure, the patient either stayed at our institution or was transferred back to the referring hospital. Antibiotic therapy was completed according to international guidelines.² A new CIED system was implanted preferably on the contralateral side when deemed safe after discussion with an infectiology specialist. The temporary pacing system was then removed without opening of the wound.

2.3 | Follow Up

Ambulatory follow-up visits for device checks were scheduled 1–3 months after the procedure and every 6–12 months thereafter. For referred patients from other centres, follow up was performed by the telephone.

2.4 | Statistical analysis

Continuous values were expressed as mean \pm standard deviation or median (interquartile range), as appropriate. Proportions were used for categorical variables. Bivariate analysis using the functions “wilcox.test” and “fisher.test” was performed. We used R 4.0.3 (The R Project) for all analyses.

3 | RESULTS

In the observation period, a total of 208 patients underwent TLE. Of those, 36 patients (17.3%) received a temporary pacemaker via the ISA.

3.1 | Study population

The mean age was 77 years, and 13.9% of the subjects were female (Table 1). The most common comorbidities were arterial hypertension, chronic kidney disease and dyslipidaemia. Structural heart disease was present in 41.7% of cases and patients previously had had cardiac surgery in 25.0%.

TABLE 1 Baseline characteristics of treated patients

	Patients (n = 36)
Age (years)	77.0 ± 10.7
Female gender	13.9% (n = 5)
Body Mass Index, kg*m ⁻¹	28.3 ± 4.2
Smoker	41.7% (n = 15)
Arterial hypertension	94.4% (n = 34)
Chronic kidney disease	61.1% (n = 22)
Dyslipidaemia	50.0% (n = 18)
Diabetes mellitus	36.1% (n = 13)
COPD	27.8% (n = 10)
Coronary artery disease	27.8% (n = 19)
Periphery arterial disease	16.7% (n = 6)
LVEF	46.9 ± 12.2%
Structural heart disease	41.7% (n = 15)
Ischaemic	25.0% (n = 9)
Idiopathic	19.4% (n = 7)
Valvular	16.7% (n = 6)
Previous cardiac surgery	25.0% (n = 9)
Prosthetic heart valve	16.7% (n = 6)
Coronary artery bypass grafting	8.3% (n = 3)
Previous interventional procedures	19.4% (n = 7)
PCI	16.7% (n = 6)
TAVI	8.3% (n = 3)
Mitral valve repair	2.8% (n = 1)
CIED details	
Indication for first CIED implantation	
AV block	50.0% (n = 18)
Sick sinus syndrome	22.2% (n = 8)
AF with slow conduction	2.8% (n = 1)
Tachyarrhythmia—primary prevention	22.2% (n = 8)
Tachyarrhythmia—secondary prevention	8.3% (n = 3)
Device type	
Dual-chamber pacemaker	47.2% (n = 17)
CRT-D	33.3% (n = 12)
CRT-P	5.6% (n = 2)
Single-chamber pacemaker	5.6% (n = 2)
Dual-chamber ICD	5.6% (n = 2)
Single-chamber ICD	2.8% (n = 1)
Pocket location	
Left	94.4% (n = 34)
Right	5.6% (n = 2)
Device brand	
Medtronic	41.7% (n = 15)
St. Jude Medical/Abbott	16.7% (n = 6)
Boston Scientific	13.9% (n = 5)
Sorin	8.3% (n = 3)
Biotronik	2.8% (n = 1)

TABLE 1 (Continued)

	Patients (n = 36)
Number of leads per patient	2.6 ± 0.8 (1–4)
Lead age (months)	108 ± 90
RA lead	80.6% (n = 29)
Active fixation	36.1% (n = 13)
Passive fixation	44.4% (n = 16)
RV lead	100% (n = 36)
>1 RV lead present	30.6% (n = 11)
Any defibrillation lead	41.7% (n = 15)
Single-coil defibrillation lead	19.4% (n = 7)
Dual-coil defibrillation lead	25.0% (n = 9)
Active fixation	58.3% (n = 21)
Passive fixation	55.6% (n = 20)
LV lead	36.1% (n = 13)
Previous generator replacement	58.3% (n = 21)
Previous lead replacement/addition	36.1% (n = 13)
Previous extraction	8.3% (n = 3)
Previous upgrade	27.8% (n = 10)
Previous pocket revision	33.3% (n = 12)

Chronic kidney disease: eGFR <60 ml/min.

The most common CIED was a dual-chamber pacemaker (47.2%). In total, 41.2% had an ICD. The most common indication for implant was bradyarrhythmia (75.0%), mostly due to AV block (50.0%). The average number of leads extracted per patient was 2.6 ± 0.8. All patients had an RV lead present, and 30.6% had an additional abandoned RV lead. An atrial lead was present in 80.6% and a LV lead in 36.1%. The leads had been implanted 108 ± 90 months before the explant procedure (Table 1). Compared to remaining TLE patients without temporary pacing in the observation period, we found patients with ISA to be older (mean 77 vs. 67 years), sicker (with a higher prevalence of arterial hypertension and chronic kidney disease) and more CIED leads to explant (2.6 vs. 2.0 per patient, $p < 0.01$ for all, Table S1).

3.2 | Procedural outcome

The main indication for TLE was CIED infection localized to the pocket (72.2%), followed by endocarditis (25.0%). One patient (2.8%) had a spontaneous displacement of the RV lead during sepsis with positive blood cultures. Before the procedure, transoesophageal echocardiography (TOE) was performed in all patients, which confirmed vegetations on the CIED leads in 27.8% of cases. Positive blood cultures were present in 38.9%. A third of the patients had already had undergone previous pocket revision due to infection. Intra-operative cultures were positive in 55.6%, with *Staphylococcus epidermidis* (30.6%) and *Staphylococcus aureus* (5.6%) being the most prevalent microorganisms (Table 2).

Advanced extraction techniques were used in 83.3%, using the Cook Evolution RL sheath in 55.6%, the Spectranetics TightRail

TABLE 2 Results of intraoperative cultures

Parameter	Value
Positive intraoperative cultures	55.6% (n = 20)
<i>Staphylococcus epidermidis</i>	30.6% (n = 11)
<i>Staphylococcus aureus</i>	5.6% (n = 2)
<i>Corynebacterium striatum</i>	5.6% (n = 2)
<i>Staphylococcus haemolyticus</i>	2.8% (n = 1)
<i>Bacillus</i> spp.	2.8% (n = 1)
<i>Pseudomonas aeruginosa</i>	2.8% (n = 1)
<i>Proteus mirabilis</i>	2.8% (n = 1)
<i>Aspergillus</i> spp.	2.8% (n = 1)

TABLE 3 Procedural and in-hospital outcome

Parameter	Value
Simple extraction	16.7% (n = 6)
Advanced extraction	83.3% (n = 30)
Cook evolution RL	55.6% (n = 20)
Spectranetics TightRail	30.6% (n = 11)
ONE Snare	8.3% (n = 3)
Lead removal	
Complete	94.4% (n = 34)
Partial	5.6% (n = 2)
Intra-hospital mortality	11.1% (n = 4)
Sepsis	8.3% (n = 3)
Heart failure	2.8% (n = 1)
Need for pocket revision	19.4% (n = 7)
Blood transfusion	13.9% (n = 5)
Reimplantation of permanent pacing device	94.4% ^a (n = 34)
Standard pacemaker	41.7% (n = 15)
Defibrillator	38.9% (n = 14)
Leadless pacemaker	13.9% (n = 5)
Days from extraction to reimplantation	14 (11–19)
Referral to secondary care centre	33.3% (n = 12)
Days from procedure to hospital discharge	
Discharge to secondary care centre	4 (2–6)
Discharge home	23 (16–30)

a5.6% of patients (n = 2) died in hospital before permanent CIED implantation.

sheath in 30.6% and a snare in 8.3% (Table 3). Complete lead removal was achieved in 94.4% of cases. In remaining two patients, the distal end of a lead could not be retrieved; one in the right atrium and another in the coronary sinus. In both cases, the remaining parts were deemed to be endothelialized and therefore, no further explant was attempted. The ipsilateral subclavian vein was accessed and the pacing lead was successfully implanted in all patients. There were no procedural complications requiring intervention and immediate procedural survival was 100%.

3.3 | In-hospital outcome

In total, three patients (8.3%) had lead displacement, of whom two had already been transferred into a secondary centre at time of the event (graphical abstract). Those two patients received a temporary lead using a different venous access. The third patient (2.8%) received pocket revision to reposition the lead at the TLE centre. Other reasons for pocket revision, which was performed in 19.4% of patients before discharge, were haematoma (11.1%) and relapsing infection (5.6%).

Intra-hospital mortality was 11.1% due to sepsis in three patients with active endocarditis (8.3%) and post-procedural acute heart failure in one patient with previous pocket infection (2.8%).

Blood transfusions were performed in five patients (13.9%), with one case directly associated with the procedure and two cases related to pocket haematoma. The remaining two patients developed severe sepsis with anaemia and died in the hospital. There was one case of pneumothorax (2.8%) and another case of minor pericardial effusion (2.8%) with spontaneous restitution in both cases.

After TLE, a third of the patients were transferred back to the secondary referring centre for antimicrobial therapy. A new permanent pacing system was implanted before discharge in 94.4% of cases, the remaining two patients died in the hospital before reimplantation. The median time from TLE to reimplantation was 14 days; there was a significant difference of time to reimplantation between patients being transferred to a secondary centre and those who remained at the TLE centre (median 20 vs. 12 days, $p < 0.001$). All reimplanted conventional pacemakers (38.9%) and ICDs (38.9%) were positioned on the contralateral side, except for one patient (2.8%), who received a pacemaker on the ipsilateral right side. A leadless pacemaker was used in 13.9%. Median duration of hospital stay from TLE to discharge home was 23 days with longer duration in patients with endocarditis (median 27 vs. no endocarditis 17 days) and bacteraemia (29 vs. no bacteraemia 17 days; $p = 0.002$ for both).

3.4 | Long-term outcome

Patients were followed for a mean of 23 months. During follow up, 16.7% of patients were hospitalized (graphical abstract). One patient died of sepsis after readmission 251 days after procedure, and another patient died from unknown cause 2 years after procedure. A relapse of local infection at the initial CIED pocket was seen in 8.3% of cases >6 months after procedure, which were all cured with a course of oral antibiotics. One patient (2.8%) was hospitalized for pocket revision after one month due to recurring haematoma (Table 4).

4 | DISCUSSION

In this case series, consecutive patients undergoing temporary pacing via the ISA after TLE had no increased risk of local or systemic adverse events.

TABLE 4 Long-term outcome

Parameter	Value
Mean follow up duration (months)	23 ± 13
Rehospitalization rate	16.7% (n = 6)
Mortality during follow up	5.6% (n = 2)
Refractory heart failure/sepsis	2.8% (n = 1)
Unknown	2.8% (n = 1)
Relapse of local infection	8.3% (n = 3)
Need for reintervention	2.8% (n = 1)

The ISA may be considered as an alternative to conventional venous accesses, especially in case of unavailability of jugular, femoral or contralateral subclavian accesses. It may be advantageous due to the following reasons: First, the access can be gained without additional puncture in case of TLE with sheaths. After removal of the extracted lead, the sheath is simply used to advance a guidewire. Second, no additional entry gate for infections is created. Third, the position of the temporary pacemaker is beneficial for the patient; the neck is free from accesses and the generator is safely secured at the trunk near the pocket wound. This configuration may reduce the risk of dislocation of the lead and the generator. Fourth, remaining veins are available for central venous catheters, which may be replaced many times in patients with complicated bloodstream infections. Fifth, the contralateral subclavian access is not affected and can therefore be safely used for a new CIED system to be implanted. Sixth, the ISA approach may be associated with lower costs to the healthcare system as it saves time resources of the medical staff during establishment and maintenance. These advantages have to be weighted against the risk opposed by the pacing lead being directly placed into a previously infected area: the pacing lead represents a foreign body in an infected pocket and may therefore facilitate reinfection and bleeding. Furthermore, in case of pocket infection, it may lead to spread of the local infection into the bloodstream or even facilitate endocarditis. In fact, 13.9% received blood transfusions after the procedure, 11% developed haematoma necessitating pocket revision before discharge and one patient (2.8%) needed pocket revision at follow up. It is unclear if these bleeding complications were facilitated by the temporary pacing lead or if the revisions could have been prevented by more liberal use of wound drainage systems. A causal relationship between the use of ISA for temporary pacing and pocket reinfections at follow up also cannot be ruled out. Fortunately, the number of pocket reinfections was not excessively high (8.3%).

While a classic temporary pacing lead could theoretically be used via the ISA, our centre only uses standard permanent pacing leads. The advantages of standard permanent active fixation leads have already been shown in other studies^{10,11} and are considered preferable by guidelines,³ even though they may be associated with higher cost. Despite active fixation, a small but considerable proportion of patients (8.3%) experienced lead displacement, probably due to pathophysiological changes during sepsis. However, the proportion

was comparable to other studies examining a similar patient population.¹⁰ Temporary pacing in VVI using a standard lead allows the use of the extracted generator; however, this has negative haemodynamic effects compared to synchronized pacing. As an alternative, VDD leads may be used instead,¹² especially in patients with severe sepsis and haemodynamic compromise. The bloodstream could also completely be avoided by the implantation of epicardial leads, which however requires surgery with pericardiectomy.^{13,14}

The strength of this study is the consecutive enrolment of patients undergoing temporary pacing with ISA at our centre, taking into account the learning curve of the first cases.

We report an in-hospital mortality of 11.1%, which is higher than in all-comer lead extraction studies that report rates below 2%.^{15,16} However, this study includes only pacing-dependent patients with a higher age, more leads and more comorbidities compared to the remaining TLE cohort (Table S1). Furthermore, all patients had an ongoing infection, which is associated with a high mortality.¹⁷ Short-term mortality was similar to other studies requiring temporary pacing after TLE (10.1%).¹⁰

In comparison to the two largest analyses using standard pacing leads for temporary pacing so far, including 334¹⁸ and 158 patients,¹⁰ the patients' baseline characteristics and the success of complete TLE were similar (95.6% vs. 97.5%), and also was their short-term survival. The analysis by Zhou et al. used the subclavian vein for temporary pacing in the majority of patients (78.9%); the ISA as described in this manuscript was used in 14.1%.¹⁸ By contrast, the jugular access was preferred in the TPEAF trial.¹⁰ The median duration until reimplantation was the longest in this analysis (median 14 vs. 6–10 days). A possible reason may be the convenience of temporary pacing via the ISA, which may have prolonged the time to definite CIED implantation until optimal conditions arise. The time until reimplantation was even longer in patients transferred to secondary centres (median 20 days). The rate of dislocation was comparable to that of the TPEAF trial (8.3 vs. 8.2%), although in the TPEAF trial, late dislocation after transfer to secondary centres were not documented. On the contrary, Zhou et al report a much lower temporary lead revision rate (1.2%). It is unclear if the unproportionally high rate of lead displacements in transferred patients in our analysis (16.7% vs. 4.2% in remaining patients) could have been lower by a shorter waiting time until reimplantation. Median hospital stay was also longer in our cohort compared to the TPEAF study (23 vs. 12–16 days).

In patients with CIED pocket infection without signs of systemic affection, the same-day implantation of a new CIED system at the contralateral side has been suggested, but there are only data of 15 patients available.¹⁹

Concerning the selection of a suitable definite CIED system for reimplantation, leadless pacing evolves as a new alternative. In this analysis, only 13.9% of patients received leadless pacemakers, but the possibility of synchronous pacing²⁰ will probably increase this number in the future.²¹ There is only limited data about the use of leadless pacing directly after TLE instead of using temporary pacing leads.²²

4.1 | Limitations

Although this analysis includes consecutive well-characterized cases, a few limitations have to be acknowledged. The main limitation is the lack of a control group, which would enable a better comparison with conventional venous accesses for temporary pacing after TLE. Furthermore, the one-centre design limits the generalization to centres with a lower number of cases. Further studies are needed to confirm the safety of this approach.

5 | CONCLUSION

Temporary pacing using an ipsilateral subclavian approach together with a standard permanent active fixation lead after TLE may be an alternative to conventional venous accesses in selected cases. However, potential risks of inserting a new lead into a previous infected area have to be taken into account.

AUTHOR CONTRIBUTIONS

Concept/design: DZ, PM. Data analysis/interpretation: DZ, FM, PM. Drafting article: DZ, FM, PM. Critical revision and approval of the article: DZ, FM, GD, AR, AM, LC, SA, LRL, GP, AF, KN, PDB, PM. Statistics: DZ. Funding secured by: not applicable. Data collection: DZ, FM, GD, AR, AM, LC, SA, LRL, GP, AF, KN. Other: not applicable.

DATA AVAILABILITY STATEMENT

The authors declare that all source data are available upon request.

CONFLICT OF INTERESTS

David Zweiker received speaker honoraria and travel grants from Daiichi Sankyo and research grants from Boston Scientific. Patrizio Mazzone is a proctor for Cook Medical. All other authors report no conflict of interest whatsoever.

ETHICS APPROVAL STATEMENT

The authors declare that the study has been approved by the local ethics committee.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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