

Same-day discharge after transvenous lead extraction: feasibility and outcomes

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Aims

Same-day discharge (SDD) is safe for patients undergoing electrophysiology procedures. There is no existing data regarding SDD for patients undergoing transvenous lead extraction (TLE). We report our experience with SDD for patients undergoing TLE.

Methods and results

The study group included patients undergoing TLE between February 2020 and July 2021 without an infectious indication. A modified SDD protocol for device implants/ablations was applied to TLE patients. Patient characteristics, extraction details, outcomes, and complications were reviewed. Of 239 patients undergoing TLE, 210 were excluded (94 infections and 116 did not meet SDD criteria). Of the remaining 29 patients, seven stayed due to patient preference and 22 were discharged home the same day. The SDD group had an average age of 65.9 ± 12 (47–84), 41% female, and LVEF of $52.2 \pm 18\%$ (10–80). The indication for TLE was malfunction (20), upgrade (4), advisory lead (2), and magnetic resonance imaging compatibility (1). Extractions included four implantable cardioverter-defibrillators (ICDs), 17 pacemakers (PPM), and one cardiac resynchronization therapy (CRT)-P system. The leads were 9.6 years (1.5–21.7) old, and 1.8 leads were removed per patient (1–3); the lead extraction difficulty (LED) score was 11.6 ± 7 . Twenty underwent cardiovascular implantable electronic device (CIED) re-implantation (2 ICD, 3 CRT-D, 13 PPM, and 2 CRT-P). For CIED re-implants, patients sent a remote transmission the next day, and all patients received a next-day call. There were no procedure or device-related issues, morbidities, or mortalities in the 30 days after discharge.

Conclusion

Same-day discharge after TLE for non-infectious aetiologies is safe and feasible in a select group of patients with early procedure completion who meet strict SDD criteria.

Keywords

Lead extraction • Cardiac implantable electronic devices • Safety • Outcomes • Same-day discharge

What's new?

- Multiple studies have shown same-day discharge (SDD) to be safe for patients undergoing various cardiac electrophysiology procedures. There is no data regarding SDD for patients undergoing transvenous lead extraction (TLE).
- Our study shows TLE performed for non-infectious aetiologies to be safe and feasible in a highly selected group of patients.
- Established SDD protocol, continuous re-assessment, patient education, and rigorous follow-up are critical components for the success of this novel approach.

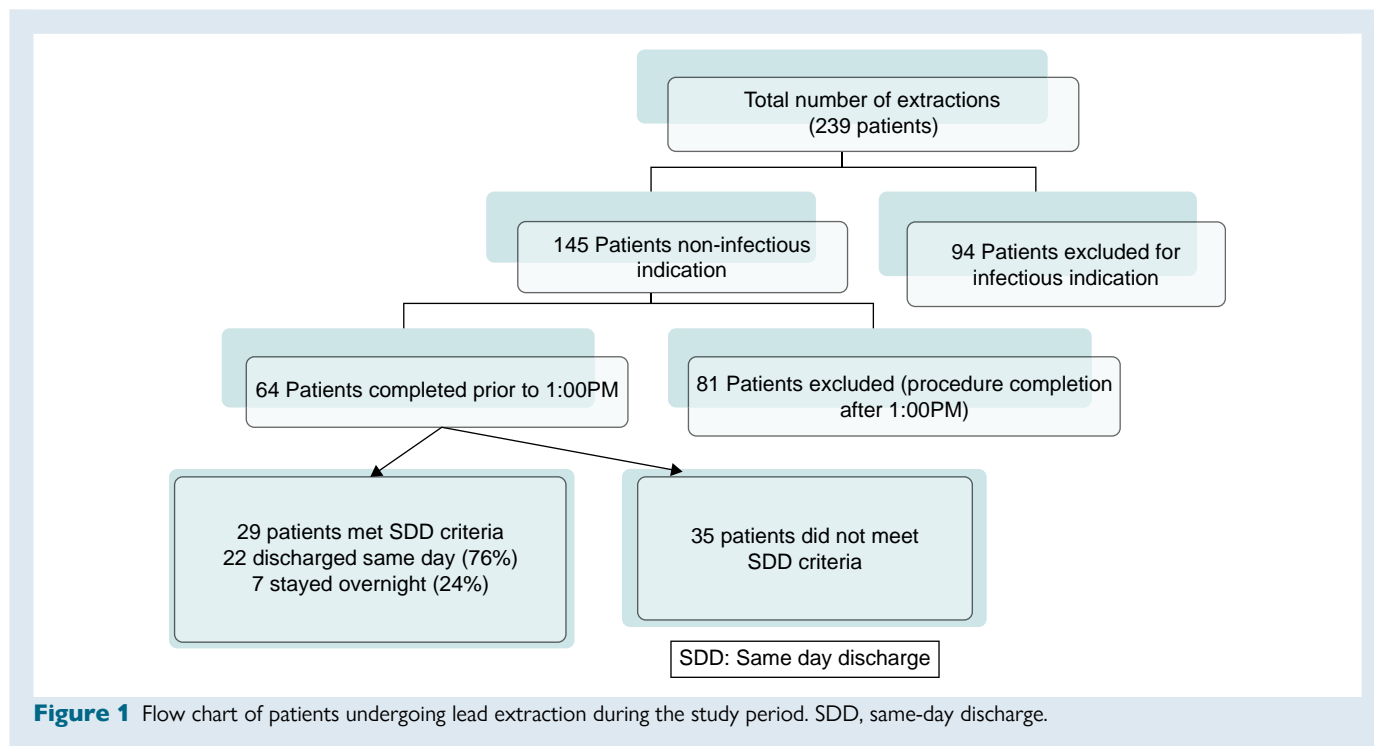
Introduction

Transvenous lead extraction (TLE) is increasingly required, given the increased numbers of cardiovascular implantable electronic devices (CIEDs), co-morbidities of implanted patients, and improved treatment for heart failure. As the population and their CIED age, components of the CIED system may need to be extracted for various reasons (local or systemic infection, lead malfunction, advisory lead, CIED upgrade, and others).¹ Over the past decade, there has been a shift to same-day discharge (SDD) for a variety of electrophysiology procedures.^{2–4} The COVID-19 pandemic has increased the need to limit the time patients

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spend in the hospital. The American College of Cardiology (ACC) has issued an expert decision pathway for SDD after percutaneous coronary intervention (PCI).⁵ Similarly, the Heart Rhythm Society (HRS) issued guidance for rebooting electrophysiology and recommended SDD to minimize contact with other patients or hospital personnel, whenever possible.⁶

The safety and success of TLE have improved over the years due to advances in extraction tools and techniques, as well as the adoption of the Bridge Occlusion Balloon® (Philips-Spectranetics, Colorado Springs, CO, USA).^{7,8} Although uncommon, major complications due to TLE can be catastrophic and require prompt surgical intervention. Given the perceived high-risk nature of the procedure, those patients typically stayed overnight in the hospital and were discharged the following day at a minimum. While there is growing data for SDD of CIED implantation and ablation patients, there is no data regarding the safety and feasibility of SDD for patients undergoing TLE. We describe our experience with SDD for a selected group of patients who underwent TLE at a high-volume centre.

Methods

Study population

The study was approved by the Institutional Review Board of Northwell Health. All TLE procedures performed at our institution from the beginning of the COVID-19 pandemic in New York until the end of July 2021 were reviewed. The cohort for this observational, retrospective study was obtained from a high-volume centre database of patients undergoing TLE (Figure 1).

Patients who underwent TLE between 1 February 2020 to 31 July 2021 were included in the analysis. Patients with local or systemic infections undergoing TLE were excluded as they all required additional treatment for their infection. Patient demographic characteristics, extraction details, outcomes, and complications were reviewed.

Transvenous lead extraction procedure

All lead extraction procedures were performed by an experienced operator in a hybrid operating room under general anaesthesia with transoesophageal echocardiography monitoring, invasive haemodynamic monitoring, central venous access, and cardiovascular surgical backup. Standard definitions for complete procedural success, clinical success, failure, and major and minor complications were used.⁹

Transvenous lead extraction was performed in a stepwise approach, targeting complete success using the minimum number of tools as has been previously described in detail.^{9,10} In brief, the lead was prepared by retracting the active fixation mechanism if present, removing the anchors, cutting the lead, placing a locking stylet, and tying a #5 silk suture to the insulation and the locking stylet. Gentle traction was attempted first and if unsuccessful a laser and/or mechanical sheath was employed. In the event of lead disruption, or a previously disrupted lead a femoral approach was employed. When appropriate, patients underwent re-implantation of a new CIED during the same procedure.

Same-day discharge protocol

We previously had created a 'same-day discharge' protocol for patients undergoing device implants and ablations. We applied the same protocol to the lead extraction population with an additional period of observation. The protocol was developed to ensure physician discretion and patient individualization with safety being the overriding goal. Same-day discharge exclusion criteria included the following: (i) late finishing cases that precluded at least 4 h of post-procedure recovery time. This was modified for TLE procedures where we used a finishing time of 1:00 p.m. to allow for at least 6 h of recovery/observation, (ii) anti-coagulation issues that required an overnight stay, (iii) patient's social situation did not allow for SDD, (iv) physician and/or patient judgment that precludes SDD, including, but not limited to procedural complications, uncontrolled co-morbidities, advanced age, and unfavourable distance/time/transportation to travel home.

Patients without exclusion criteria, who were amenable to SDD, underwent pre-procedure education reviewing the discharge and post-discharge process. This included a caregiver who would be responsible for taking the patient home upon discharge. Post-extraction, all patients were

continuously monitored in the post-anaesthesia care unit and then in a telemetry unit prior to discharge. While in the telemetry unit, standard nursing post-anaesthesia recovery protocols were followed. Transvenous lead extraction patients were recovered for a minimum of 6 h post-procedure. A wound check, device interrogation (if a new device was implanted), a 12-lead electrocardiogram (ECG) with and without pacing, and chest X-ray were all performed and reviewed prior to discharge. Post-operative teaching was performed and/or reinforced. Written materials, including the device booklet and temporary ID card, if re-implantation occurred were given to the patient/significant other. The patient's device was paired with a remote monitor, and the patient and caregiver were educated about its use. The expectation and importance of remote monitoring were reinforced. Prior to discharge, any respiratory or haemodynamic instability was addressed immediately, and disposition was continuously reassessed. The post-op Day 1 follow-up call was scheduled, and we ensured the patient and caregiver knew what to do in the case of an emergency. After bed rest, patients were ambulated. If ambulation was well tolerated with no groin access site bleeding, vital signs were stable and the patient met all established criteria for safe discharge, they were discharged from the hospital into the care of a family member or support person by a cardiology advanced clinical practitioner (ACP). The morning following discharge, if the patient underwent re-implantation, a remote transmission was sent. The transmission was reviewed, and all patients received a phone call from an electrophysiology ACP. The patient returned for a wound/device check in 10–14 days. Any unexpected calls, clinic/emergency department visits, hospital admission, morbidity, and mortalities were tracked for 30 days post-procedure.

Statistical analysis

Continuous variables are expressed as mean \pm standard deviation. Categorical variables are shown as counts and percentages. Continuous variables were compared using the independent samples *t*-test for normally distributed variables. Categorical variables were compared using the Pearson χ^2 test. *P* value <0.05 was considered statistically significant. All statistical analysis was performed using SPSS 27.0 (IBM Corp., Armonk, NY, USA).

Results

A total of 239 patients underwent TLE during the study period. Of those, 94 patients underwent TLE for local and/or systemic infection and were therefore excluded. Of the remaining 145 patients, 64 patients had their extraction completed prior to 1 p.m. allowing adequate time for recovery and observation and were therefore considered for SDD. Thirty-four of these 64 patients (53%) did not meet our institutional criteria for SDD as outlined above and hence were excluded. Reasons for exclusion included mild groin access site and/or extraction site haematoma requiring no intervention (6), groin observation after a Micra® sheath employed as a femoral workstation during the extraction and/or a Micra® leadless pacemaker implant (5), mild anaesthesia-related side effects including nausea, vomiting, dizziness, and mild hypotension (6), initiation of anti-coagulation prior to discharge (5), management of procedure-related complication (3). Last, 10 patients had various reasons for an overnight stay including mild hypoxia due to sleep apnoea, wheezing due to chronic obstructive pulmonary disease exacerbation, hyperkalaemia, mild drop in Hgb, allergic reaction, and pain management. Of the 29 patients who met the criteria for SDD, 22 patients were discharged home the same day and represented the study cohort (76%). The remaining seven patients (24%), while meeting the criteria, preferred to stay overnight for non-medical reasons.

Same-day discharge group

The baseline characteristics of the 22 patients who underwent SDD are found in Table 1. Those discharged home the same day had an average age of 65.9 ± 12 (range: 47–84) years old, were 41% female, with an average LVEF of $52.2 \pm 18\%$ (range: 10–80), and lived within an average of 138.5 ± 518 (range: 3–2454) miles from our institution. The patients

Table 1 Baseline characteristics of SDD group

Baseline characteristics	SDD (22 patients)
Age (years)	65.9 \pm 12 (47–84)
Female sex (%)	41
BMI (kg/m ²)	29.7 \pm 6
Medical history	
HTN (%)	77
DM (%)	18
CHF (%)	50
CAD (%)	18
CVA/PE/DVT (%)	14
AFib/flutter (%)	32
CKD (%)	0
Prior cardiac surgery (%)	18
CHA2DS2-VASc score	3
Left ventricular ejection fraction (%)	52.2 \pm 18 (10–80)
Distance from home to our institution (miles)	138.5 \pm 518 (3–2454)

BMI, body mass index; CAD, coronary artery disease; CHA2DS2-VASc, risk score for stroke in AF; CHF, congestive heart failure; CKD, chronic kidney disease; CVA, cerebral vascular accident; DM, dermatomyositis; DVT, deep vein thrombosis; HTN, hypertension; LVEF, left ventricular ejection fraction; PE, pulmonary embolus; SDD, same-day discharge; SVT, supraventricular tachycardia.

who travelled from out of state for their procedure stayed locally at a hotel the night following discharge. They had an history of hypertension (77%), congestive heart failure (50%), atrial arrhythmias (32%), and 18% had a history of prior cardiac surgery. The average CHA2DS2-VASc score was 3 (range: 1–5), and 32% of the patients were maintained on a direct oral anticoagulant.

The indication for TLE (some patients had more than one indication) was lead malfunction (20, 91%), CIED system upgrade (4, 18%) prophylactic removal of an advisory lead (2, 9%), and replacement of a non-magnetic resonance imaging compatible system (1, 5%). Four patients underwent implantable cardioverter-defibrillator (ICD) extraction (18% of all extractions). There was a total of five dual-coil ICD leads extracted (one patient had two dual-coil ICD leads extracted), and none of the extractions were for cardiac resynchronization therapy (CRT)-D. Seventeen patients underwent pacemaker extraction (77%), and one patient underwent CRT-P extraction (5%). The average age of the oldest lead extracted was 9.6 ± 6 (range: 1.5–21.7) years. The average number of leads extracted was 1.8 ± 1 (range: 1–3 leads) per patient. The LED score (LED score = number of leads to extract + years from the implant of oldest lead to remove + 1 if dual-coil ICD to be removed and –1 if vegetation confirmed on lead body) was 11.6 ± 7 (2.5–23.7).^{11,12} One patient required femoral extraction to achieve complete procedural success. Most of the patients (20/22, 91%) underwent re-implantation of a new CIED (10% ICD, 15% CRT-D, 55% PPM, and 20% CRT-P) (Tables 1 and 2). All SDD patients had complete procedural success.

Follow-up

All 22 patients who were discharged the same day received a next-day call, and all 20 patients who underwent CIED re-implantation sent a remote transmission the day following discharge which was reviewed prior to the follow-up call. There were no device-related issues found on remote monitoring. In addition, there were no unplanned calls, clinic

Table 2 Extraction and re-implant details in SDD group

Procedural details	SDD group (%)
ICD extraction	4 (18), 100% dual coil
ICD	4
CRT-D	None
Pacemaker extraction	17 (77)
CRT extraction (CRT-P)	1 (5)
Total leads extracted per patient	1.8 ± 1, range 1–3
Average age of oldest lead extracted (years)	9.6 ± 6, range 1.5–21.7
LED score	11.6 ± 7, range 2.5–23.7
CIED re-implant	20 (91)
Pacemaker re-implant	15
Transvenous	11 (55)
Leadless	None
CRT-P	4 (20)
ICD re-implant	5
ICD	2 (10)
CRT-D	3 (15)

CRT, cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator; LED, lead extraction difficulty; SDD, same-day discharge.

visits, emergency department visits, hospitalizations, or deaths in the 30 days post-procedure.

Discussion

This study is the first to report on the protocol and safety for SDD of a highly selected group of patients undergoing TLE. Over the past decade, there has been a shift towards SDD after various cardiac and electrophysiological procedures. There is growing data supporting the safety, feasibility, and cost-effectiveness of this approach after CIED implants (transvenous pacemaker/ICD/CRT, sub-cutaneous ICDs, and Micra® leadless pacemaker).^{2,4,13} Similarly, patients undergoing electrophysiological studies and ablation for SVT or right-sided atrial flutter/tachycardia have been safely discharged home on the same day for years.¹⁴ More recently there is mounting evidence on the safety and cost-effectiveness of SDD in patients undergoing ablation for atrial fibrillation.³

The COVID-19 pandemic has increased the need to limit the time patients spend in the hospital. The value of SDD after cardiovascular procedures has become paramount since the pandemic began. As a response, several cardiovascular associations issued recommendations for SDD. This has included the ACC issuing an expert decision pathway for SDD after PCI and HRS issuing guidance for rebooting electrophysiology and recommending SDD whenever possible.^{5,6}

To date, there is no data on the safety and feasibility of SDD in patients undergoing TLE. Transvenous lead extraction is associated with intraprocedural risks and mortality, with major complications and mortality range from 0.4 to 7.3% across various studies.^{8,10,15,16} The safety and success of TLE has improved due to advances in extraction tools and techniques.^{7,8} Recent data from the ELECTRa registry showed an overall safety profile for TLE (in-hospital major complications 1.7% and mortality rate of 0.5%).^{8,10} Operator experience has been shown to be a major determinant of safety.¹⁷ Despite this safety profile, the risk of a catastrophic complication continues to have TLE procedures perceived as a dangerous procedure requiring additional care.

While this is true during the TLE, for uncomplicated procedures, the post-procedure care is similar to other device and ablation procedures.

In our institution prior to the COVID-19 pandemic, we had developed a protocol for SDD for patients undergoing device implants and ablations. Given our operators' experience in TLE and being a high-volume extraction centre, we thought it also appropriate to apply the SDD protocol to the lead extraction population. In this study, we provide the first-available data on the safety and feasibility of SDD in a highly selected group of patients undergoing TLE for reasons other than local/systemic infection. Twenty-two patients who met our SDD criteria including having their procedure completed prior to 1 p.m., were safely discharged home the same day with no untoward outcomes. These patients represented a diverse group covering the spectrum of extraction patients. Seventy-seven per cent of patients had pacemaker extraction, 18% had ICD extraction and 5% had CRT-P extraction. The eldest patient was 84 years old, and the lowest ejection fraction was 10%. In addition, the majority (91%) of patients had CIED re-implant. In the 30 days post-discharge, there were no procedure or device-related issues, morbidities, or mortalities.

There is data from observational studies and a recent NCDR registry showing dual-coil ICD lead extraction to be predictive of higher complication rates.^{18–20} In our study, all patients undergoing ICD extraction had dual-coil ICD leads, and the average LED score was 11.6 ± 7 (range: 2.5–23.7). Our results show that even 'higher' risk extraction patients can be discharged the same day if a strict protocol is followed.

There is existing evidence supporting the safety and feasibility of SDD in patients undergoing CIED implantation.^{2,4,13} The majority of patients in our study (20 patients, 91%) had re-implant of a CIED. All patients considered for SDD had a wound check, device interrogation, a 12-lead ECG, and chest X-ray prior to discharge, and the importance of remote monitoring was reinforced.

Study limitations

This is a retrospective study with a relatively small sample size of patients discharged home the same day after an extraction procedure. It is important to note that this study was limited to a single high-volume centre with an established SDD process and therefore may not be generalizable. A larger study is required to confirm these results and may allow for a predictive model to be developed to better identify which patients are candidates for SDD.

Conclusions

Same-day discharge after TLE for non-infectious aetiologies is safe and feasible in a select group of patients with early procedure completion who follow a strict SDD protocol. There were no device-related issues, unexpected visits, morbidities, or mortalities in the 30 days after discharge. Having an established SDD protocol, continuous re-assessment, patient education, and rigorous follow-up are critical components for the success of this novel approach.

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Conflict of interest: L.M.E. is a speaker/consultant for Phillips, Medtronic. R.M.J. receives lecture honorarium from Abbot Inc. The rest of the authors have no conflict of interests.

Data availability

The data underlying this article cannot be shared publicly due to privacy reasons of the participants. Researchers can request the data by submitting a reasonable proposal to the corresponding author.

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