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## Transvenous lead extraction on uninterrupted anticoagulation: A safe approach?



Sawhney Vinit<sup>a,\*,1</sup>, Cobb Vanessa<sup>a,1</sup>, Breitenstein Alexander<sup>a,b,1</sup>, Baca Luisa<sup>a,1</sup>, Whittaker-Axon Sarah<sup>a,1</sup>, Steffel Jan<sup>b,1</sup>, Ezzat Vivienne<sup>a,1</sup>, Lambiase Pier<sup>a,1</sup>, Lowe Martin<sup>a,1</sup>, Hunter Ross<sup>a,1</sup>, Earley Mark<sup>a,1</sup>, Schilling Richard<sup>a,1</sup>, Sporton Simon<sup>a,1</sup>, Chow Anthony<sup>a,1</sup>, Dhinoja Mehul<sup>a,1</sup>

<sup>a</sup> Cardiology Department, St Bartholomew's Hospital, London, United Kingdom

<sup>b</sup> Cardiology Department, University of Zurich, Zurich, Switzerland

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### ABSTRACT

**Introduction:** Current guidelines advocate reviewing peri-procedural anticoagulation on individual case basis for transvenous lead extraction (TLE). We investigated the safety of TLE on uninterrupted warfarin with therapeutic INR.

**Methods:** Retrospective registry of consecutive patients undergoing TLE on uninterrupted warfarin (Warfarin Group) across two centres. Age and sex matched controls not on anticoagulation (No-Warfarin Group) and undergoing TLE over the same time-period were included. Both groups were compared over one-year.

**Results:** 121 TLEs over 18-months. 22 patients on uninterrupted anticoagulation were compared to 22 controls. Groups were well matched for baseline demographics other than INR. Warfarin group had mean INR of  $2.2 \pm 0.6$  (range 2–3.5). Primary end point was procedural safety and efficacy. Amongst cases, 43/45 (96%) leads were removed in their entirety compared to 37/40 (93%) in controls ( $p = 0.66$ ). In the cases, these included 44% defibrillator, 47% pace-sense and 9% CS leads of average duration 7yrs. There was no reported tamponade, haemothorax or procedural mortality in either group. One patient amongst cases required inotropic support while two patients amongst controls had device-site haematomas. No significant difference reported in Hb drop post-procedure or overall complication rate between the groups ( $p = 0.11, 0.32$ ). Cox regression showed a significant association between procedural success and device infection, number of leads extracted, serum creatinine ( $p = 0.03, 0.04, 0.02$ ). Over a 1-year follow-up, there was lead displacement in one case and one control had infection of the re-implanted device.

**Conclusion:** TLE can be carried out safely in anticoagulated patients with therapeutic INRs. Larger multicentre studies are required to confirm these findings.

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## 1. Introduction

Transvenous lead extraction (TLE) is associated with a risk of potentially life threatening haemorrhagic events [1,2]. This risk

might be potentiated by the use of oral anticoagulants. A large proportion of patients with a cardiac implantable electronic device (CIED) are on long-term oral anticoagulation for a variety of reasons [3]. [4] While interruption of anticoagulation at the time of invasive procedures can predispose these high risk patients to thromboembolic events; uninterrupted anticoagulation can increase bleeding risk. Peri-procedural management of anticoagulation in these patients is challenging. Current consensus guidelines advocate reviewing this on an individual case basis due to lack of safety data [5]

Uninterrupted anticoagulation with a vitamin K antagonist (VKA) has been shown to be safe in CIED implants [3,6]. When

\* Corresponding author. The Arrhythmia Research Unit, The Barts Heart Centre, St Bartholomew's Hospital, London, EC1A 7BE, UK.

E-mail address: [vinit.sawhney1@nhs.net](mailto:vinit.sawhney1@nhs.net) (S. Vinit).

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compared to interrupted VKA therapy and bridging with heparin, uninterrupted VKA use during CIED implants has been associated with fewer bleeding complications [5,7,8]. However, there are very limited data supporting the safety of TLE on uninterrupted anticoagulation [9] and no direct comparisons have been made with patients undergoing TLE on no oral anticoagulant.

In this study we report our experience of undertaking TLE in patients on uninterrupted warfarin with therapeutic INRs ( $\text{INR} \geq 2$ ). We compared patients who underwent TLE while on uninterrupted warfarin to those who were not taking an oral anticoagulant in a case-control study to determine the risks and benefits of both approaches.

## 2. Methods

### 2.1. Study design

This is a retrospective, case-control study of patients undergoing transvenous lead extraction (TLE). Consecutive patients undergoing TLE while on uninterrupted warfarin therapy (with therapeutic INRs) were compared to those not on any oral anticoagulant and undergoing TLE. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the institution's human research committee. All patients were recruited across two centres (The Barts Heart Centre, St Bartholomew's Hospital and University Hospital of Zurich, Switzerland). Prior to the procedure, all patients gave written informed consent.

### 2.2. Study patients

Consecutive patients undergoing TLE while on uninterrupted warfarin therapy between January 2017 and June 2018 were included in this study. Patients who underwent TLE while on uninterrupted warfarin (Warfarin Group) were in the case arm of the study. Age and sex matched patients who were not on an oral anticoagulant and underwent TLE during the same time period served as controls (No-warfarin group). Both groups were well matched for clinical and procedural characteristics. No patient underwent TLE on a DOAC during the study period.

### 2.3. Lead extraction procedure

Two consultant electrophysiologists performed all TLE procedures reported in this study. The decision regarding lead extraction technique (on uninterrupted warfarin therapy) was at the operator's discretion. Patients already on warfarin with therapeutic INRs were asked to continue this pre, peri and post-procedurally. A stepwise approach to lead extraction was implemented in every case with the primary goal being complete removal of all endocardial leads in the absence of complications.

All procedures were performed in the electrophysiology laboratory using general anaesthesia or moderate sedation at the operator's discretion. All patients had two separate group and save blood samples sent in case of emergent need for cross match for blood transfusion. The duty cardiothoracic surgeon was informed prior to starting the procedure and was available on-site for emergency sternotomy if required. Invasive arterial monitoring and large gauge peripheral or central access was obtained at the start of the procedure. In pacemaker dependent patients, a temporary pacing wire was placed via femoral access. Pre-procedural venogram was performed to look at vessel patency and extent of collaterals.

Initially, simple traction or traction on a locking stylet with insulation bound suture was attempted. If this was not sufficient to

extract the lead then powered or mechanical sheaths were used. The choice of primary sheath was the operators' discretion. These included Evolution Mechanical Dilator Sheath (Cook Medical) or Tightrail Rotating Dilator Sheath (Spectranetics). Snares and/or femoral workstation was reserved as a rescue tool for TLE.

An echocardiogram was performed post-procedure to rule out a pericardial effusion. Patients were monitored on the High Dependency Unit or Coronary Care unit for at least 24 h post procedure.

### 2.4. Follow up

Timing of hospital discharge was largely guided by the original indication of TLE. Patients requiring temporary pacing and those undergoing TLE for infected devices had an inpatient stay of at least a week. The remaining patients were typically discharged from hospital a day post TLE (i.e. approximately 24 h post procedure). Patients were followed up in clinic a month post TLE regarding study endpoints with a device check on the same visit. Additional review of electronic health records was carried out to obtain a complete dataset.

### 2.5. Study end points

#### 2.5.1. Primary safety end point

The primary safety end point was a composite of major and minor procedural complications. Major complications were (a) death from any cause (b)  $> 2$  g/dL drop in haemoglobin (c) need for surgical intervention (d) cardiac or vascular avulsion requiring intervention (e) pulmonary embolism (e) stroke. Minor complications included all other complications that do not meet the major complications criteria. These broad categories are inclusive of the complications listed in the EHRA expert consensus statement on lead extraction [10].

#### 2.5.2. Primary efficacy end point

The intra-procedural efficacy end point was acute procedural success. This comprised of two main components: (a) lead related and (b) procedure related as elaborated in the EHRA expert consensus statement on lead extraction [10]. In summary, complete success was defined as removal of all targeted lead material in the absence of major complications or procedure related death. Partial success was defined as removal of nearly all targeted leads and lead material with retention of a small portion of the lead that does not negatively impact patient safety or primary goal of the procedure.

#### 2.5.3. Secondary end points

These included baseline patient and lead characteristics, procedural characteristics and predictors of complete procedural success and complications.

### 2.6. Statistical analyses

Data were analysed on an intention-to-treat basis. All analyses were carried out using SAS version 9.3, statistical software at the primary coordinating centre (Barts Heart Centre, London). Continuous data were presented as mean  $\pm$  standard deviation or median (range) if not normally distributed. Categorical data were reported as a percentage. Continuous data were compared using unpaired *t*-test (if normally-distributed) and Mann-Whitney *U* test if not normally-distributed. Categorical data were compared using chi-square test. Cox regression analysis was carried out to assess impact of various clinical factors on the primary end point. A *p*-value of less than 0.05 was considered significant.

### 3. Results

#### 3.1. Study patients

121 TLEs were performed over a period of 18 months across the two centres. Of the 121 patients, 22 (18%) were on uninterrupted warfarin with therapeutic INR (Warfarin group) at the time of the procedure. These were matched to 22 patients who were not on any oral anticoagulant at the time of the procedure (No-Warfarin Group). Within the limitations of the current study design, the two groups were appropriately matched with regard to clinical and procedural characteristics other than for INR ( $2.2 \pm 0.6$  in warfarin group versus  $1.1 \pm 0.6$  in non-warfarin group;  $p = 0.0001$ ). In the warfarin group, the CHA2DS2-VASc ranged from 2 to 5 (mean  $\pm$  SD,  $3.2 \pm 1.8$ ) and the INR range was 2–3.5 (mean  $\pm$  SD,  $2.2 \pm 0.6$ ). Also, the range and mean  $\pm$  SD of the prothrombin time (PT) and activated partial thromboplastin time (APTT) for this group were 10.5–37.4 s and  $15.9 \pm 8.3$  s; and 22–42 s and  $29.2 \pm 5.8$  s respectively. The indication for anticoagulation was atrial fibrillation in 10/22 (45%), prosthetic valves in 11/22 (50%) and multiple pulmonary emboli in 1/22 (5%). The baseline clinical characteristics of the two groups are shown in Table 1.

#### 3.2. Procedural data

The vast majority of cases were performed as emergent or emergency cases. A consultant electrophysiologist performed all procedures and was assisted by a junior trainee. The indication for extraction was CIED infection in nearly half the cases in both groups. The mean procedure and fluoroscopy times across both groups were 211 and 31 min respectively. A total of 41 (out of the 45 intended) leads were extracted in the warfarin group and 35 (out of the 40 intended) in the no-warfarin group with a mean lead age (dwell time) of 7yrs and 8 yrs respectively. There was no significant difference in the procedural characteristics between the groups – Table 2.

In the warfarin group, the type of leads extracted included defibrillator leads (44%), pace-sense leads (47%) and coronary sinus leads (9%). All leads (across both groups) were extracted using a superior approach with locking stylets and tightrail rotating dilator sheath. Femoral workstation was not required in any case.

**Table 1**

Clinical Characteristics. The clinical characteristics of the warfarin ( $n = 22$ ) and no-warfarin ( $n = 22$ ) group are shown in this table. Data are reported as percentage or mean  $\pm$  SD. AF: atrial fibrillation, LVEF: left ventricular ejection fraction, INR: international normalised ratio, PPM: permanent pacemaker, ICD: implantable cardioverter defibrillator, CRT(P/D): cardiac resynchronisation therapy pacemaker/defibrillator \* Normal heart refers to absence of any structural abnormality on transthoracic echocardiogram and/or cardiac MRI.

N = 44	WARFARIN	NO WARFARIN	p-value
Age, years, (mean $\pm$ SD)	66 $\pm$ 15	65 $\pm$ 17	0.83
Sex, M, n (%)	81	76	0.68
Background heart disease			
Normal heart, n (%)	5 (23)	5 (23)	1.00
Ischemic heart disease, n (%)	8 (36)	8 (36)	1.00
Dilated cardiomyopathy, n (%)	7 (32)	6 (27)	0.72
Other, n (%)	2 (09)	3 (14)	0.60
AF, n (%)	55	35	0.18
LVEF, %, (mean $\pm$ SD)	38 $\pm$ 14	36 $\pm$ 16	0.66
INR at procedure, (mean $\pm$ SD)	2.2 $\pm$ 0.6	1.1 $\pm$ 0.6	0.0001
Platelets, $10^9/L$ , (mean $\pm$ SD)	247 $\pm$ 83	226 $\pm$ 80	0.39
Creat, $\mu mol/L$ , (mean $\pm$ SD)	101 $\pm$ 22	95 $\pm$ 20	0.34
Type of Device			
PPM, n (%)	7 (32)	7 (32)	1.0
ICD, n (%)	9 (41)	8 (36)	0.74
CRTP, n (%)	2 (09)	3 (14)	0.60
CRTD, n (%)	4 (18)	4 (18)	1.0

**Table 2**

Procedural characteristics. The procedural characteristics of the warfarin ( $n = 22$ ) and no-warfarin ( $n = 22$ ) group are shown in this table. Data are reported as percentage or mean  $\pm$  SD. Hb: haemoglobin.

N = 44	WARFARIN	NO-WARFARIN	p-value
<b>Extraction Indication</b>			
Infection, n (%)	10 (45.5)	11 (50)	0.77
Lead Malfunction, n (%)	10 (45.5)	8 (36)	0.54
Other, n (%)	2 (09)	3 (14)	0.60
<b>Elective Procedure, n (%)</b>	11 (50)	9 (41)	0.55
<b>Procedure Time, min, (mean <math>\pm</math> SD)</b>	229 $\pm$ 149	194 $\pm$ 100	0.36
<b>Fluoroscopy Time, min, (mean <math>\pm</math> SD)</b>	33 $\pm$ 18	30 $\pm$ 20	0.60
<b>No. of leads fully extracted, n/N, (%)</b>	43/45 (96)	37/40 (93)	0.66
<b>Dual coil defibrillator leads, n/N, (%)</b>	09/45 (20)	10/40 (25)	0.58
<b>Lead Age, yrs, (mean <math>\pm</math> SD)</b>	7.35 $\pm$ 2.12	8.21 $\pm$ 3.11	0.30
<b>Drop in Hb, g/L, (mean <math>\pm</math> SD)</b>	0.96 $\pm$ 0.47	0.7 $\pm$ 0.7	0.15

#### 3.3. Study endpoints

##### 3.3.1. Primary safety endpoint

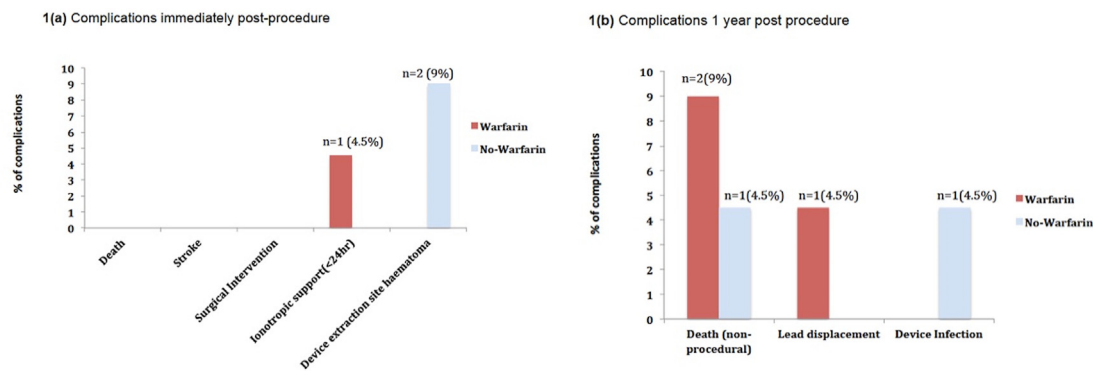
There were no deaths in this patient cohort and none of the patients' required surgical intervention. There were no reported immediate major complications post-procedure in both groups – (Fig. 1). The mean rate of drop of haemoglobin post procedure was slightly higher in the warfarin group compared to no warfarin group (0.96 versus 0.70). However, this had no clinical sequel and was not statistically significant ( $p = 0.15$ ).

Procedural complications included requirement of inotropic support for less than 24 h in one patient in the Warfarin group. This was a 64 yr old lady who a secondary prevention CRTD with an underlying diagnosis of ischaemic cardiomyopathy. Her LVEF was 10–15%. INR at time of procedure was 2.2. She underwent RV defibrillator lead (single coil, active fix lead, dwell time 4 yrs) extraction for lead failure. This was done under GA and new lead implanted at the same sitting. Immediately post procedure, it was difficult to maintain systolic blood pressure over 60 mm Hg. Echocardiogram showed no pericardial effusion and there was no drop in Hb. Also, a chest X-ray showed no evidence of pneumothorax. The patient was extubated successfully. However, she required a brief period of inotropic support on the coronary care unit to stabilise her haemodynamics. She was discharged home 48 h post procedure. In the Non-Warfarin group, two patients had post procedure device site haematoma. None of these were on an oral anticoagulant or low molecular weight heparin. Device pocket was pre-pectoral in one and sub-pectoral in the other. There was no significant Hb drop in either and they were managed conservatively. This did not cause a delay in hospital discharge.

Over a follow-up period of one year, two patients died in the Warfarin group and one in the No-Warfarin group. The cause of death was end stage heart failure ( $n = 2$ ) and small cell lung cancer ( $n = 1$ ). Complications on follow-up included displacement of the newly implanted RV pacing lead in one patient in the Warfarin group. This was re-sited with no clinical sequel. One patient in the No-Warfarin group had infection of their defibrillator. Prior to this, the extraction procedure was carried out for a failing RV lead and a new lead was implanted in the same sitting. This patient underwent ICD extraction and new device implant on the contralateral site after a course of intravenous antibiotics.

##### 3.3.2. Primary efficacy endpoint

Complete procedural success was achieved in 39 of the total 44 procedures (89%). This was not significantly different between the groups (20 out of 22–91% and 19 out of 22–86%;  $p = 0.60$  in the warfarin and non-warfarin group respectively. 43 out of the intended 45 leads (96%) were completely extracted in the warfarin



**Fig. 1. Procedural Complications:** Bar graph showing procedural complications 1(a) complications immediately post-procedure; 1(b) complications 1 year post procedure.

group. One patient had a <1 cm lead remnant at the RV apex. The 10 yr old passive fix right ventricular pacing lead snapped at the apex and a small remnant was left in situ. The second patient had a small remnant (1 cm) of a right atrial lead (passive fix in right atrial appendage). 37 out of the intended 40 leads (93%) were completely extracted in the non-warfarin group. We were unable to completely extract a 12 yr old dual coil defibrillator lead in one patient due to extensive fibrosis and adhesions at the subclavian/SVC junction. Nevertheless, a new single coil lead was implanted and the patient had a functioning ICD. In the remaining two patients, lead remnants of ≥2 cm in the right atrial appendage and right ventricular apex were left. Both of these were passive fix, pace-sense leads with dwell time of 6 yrs and 10 yrs respectively.

3.3.3. Secondary endpoints

A Cox regression analyses was carried out to assess the impact of different factors on the primary end point. There was a significant association between complete procedural success and extraction for infected devices, number of leads extracted and serum creatinine (p = 0.03, 0.04 and 0.02). Infected devices, greater number of leads extracted and high serum creatinine at baseline were associated with a poor prognosis – Table 3.

4. Discussion

In the present study we report our experience of performing TLE in patients on uninterrupted warfarin with therapeutic INRs. The main findings of our study indicate that the risk of performing TLE in anticoagulated patients is not significant. There was no significant impact on the rate of bleeding complications and no difference in the overall rate of major and minor complications between the warfarin and no-warfarin group.

**Table 3**

Cox regression analyses for Predictors of Success. Cox regression analysis was carried out to assess impact of various clinical factors on the primary end point. This included complete procedural success in the absence of major complications.

N = 44	HR	95% CI	p-value
<b>Anticoagulation</b>	1.83	0.87–1.94	0.97
<b>Age</b>	0.84	0.02–0.88	0.93
<b>Gender</b>	0.17	0.44–0.68	0.57
<b>Infection</b>	0.89	0.07–1.13	0.03
<b>Defib Leads</b>	0.11	0.61–0.75	0.79
<b>Number of leads extracted</b>	2.01	0.08–2.21	0.04
<b>Procedure Time</b>	1.05	0.01–1.07	0.14
<b>Time since implant</b>	0.21	0.11–0.17	0.63
<b>LVEF</b>	0.34	0.01–0.44	0.21
<b>Creatinine</b>	2.01	0.01–2.3	0.02

In the warfarin group, 43/45 leads were completely extracted and 37/40 in the no-warfarin group. The mean dwell time of these leads was 7yrs and just over half of these were defibrillator leads. There were no reported major complications in both groups. There were no deaths in this patient cohort and none of the patients' required surgical intervention. Despite therapeutic INRs at the time of procedure, there were no reported bleeding complications in the warfarin group. Although the warfarin group had a slightly higher drop in Hb post procedure (mean of 0.96 versus 0.70 g/L in no-warfarin group), this was not a significant difference and importantly had no clinical sequel. None of the patients required a blood transfusion.

Despite the evolution in lead extraction techniques over the last two decades, it is still associated with a small but significant procedure failure, morbidity and mortality [2]. In the present study, the overall complete procedural success rate was 89%. In the anticoagulated patients, 96% of the leads with a mean lead age of 7 yrs were extracted in their entirety. Accepting the limitation of varied study design, patient numbers and characteristics (including anticoagulation) these results compare favourably to previous reports. Kennergren et al. reported a success rate of 97.6% with major complications in 0.9% and no procedure-related deaths. They used mostly laser sheaths in 592 patients [11]. Gomes et al. report a success rate of 96% with a major complication rate of 0.3% [1]. In our study, uninterrupted anticoagulation did not appear to add to the risk of TLE.

Peri-procedural management of anticoagulation is perhaps one of the most challenging aspects of TLE. Current consensus guidelines advocate reviewing management of anticoagulation on an individual case basis [5]. Vast majority of studies advocate discontinuing anticoagulation given the high-risk of potentially life threatening haemorrhagic complications associated with TLE. However, this can't be applied as a standard protocol and individual patient risk for thromboembolic complications needs to be considered. Alternate strategies need to be considered in some patients (prosthetic valves, previous stroke) in whom discontinuing warfarin may put them at a high thromboembolic risk. In our patient cohort the mean CHA<sub>2</sub>DS<sub>2</sub>-VASc score was 3 and in the anticoagulated patients 50% had prosthetic valves. The present study showed that performing TLE on uninterrupted warfarin therapy is feasible and safe.

Bridging therapy with low molecular weight heparin (rather than continuous warfarin) has been investigated in CIED implants. Although this remains an option in patients undergoing device implantation, it is associated with significant bleeding complications especially device pocket haematomas (17%–31%) [3]. The risk of these bleeding complications was reduced significantly by implanting devices on uninterrupted warfarin with mean INR of 2.3

[12]. Although it is difficult to extrapolate these results to lead extraction procedures, it is reasonable to consider lead extraction on uninterrupted warfarin in high risk patients rather than bridging therapy with heparin.

Limited data exists on the safety and feasibility of performing TLE on uninterrupted warfarin. A recently published, single-centre observational study reports the safety and feasibility of performing TLE on uninterrupted warfarin [9]. This study included 62 patients over 5 yrs who underwent TLE on uninterrupted warfarin with a mean INR of 2.5. Procedural success rate was 98% with one potential major bleeding complication – femoral vein tear requiring vascular repair [9]. This was a single high volume centre experience with no direct comparison with patients who were not on oral anticoagulation. In addition to supplementing this dataset, the present study also provides direct comparison to a control group who were not anticoagulated. Our case control comparison did not give any alarming signal of increased risk with this strategy.

Whilst this is encouraging, it provides no data on the impact of oral anticoagulation on the severity of a major bleeding event should it occur. However, given the high surgical risk (especially in patients on uninterrupted warfarin), it is important to have a bailout strategy in event of a life threatening bleed or complication. All patients were cross-matched pre-procedure incase blood products were required. Moreover, rapid and complete reversal of warfarin is feasible using synthetic clotting factors. Peri-procedural imaging including *trans*-oesophageal echocardiogram (TOE) and intra-cardiac echocardiography (ICE) could potentially further minimise the bleeding risk but are not routinely used at our centre. However, routine echocardiography immediately post TLE and prior to discharge was performed to rule out pericardial effusion. Some TLE cases (based on operator preference) were performed in hybrid theatres to prevent any delays with surgical and perfusionist support. However, this was done in a small number of cases based on individual patient's risk and as directed by the operator. Also, there was easy access to the Bridge Balloon, which may help mitigate the bleeding risks from SVC tear during TLE.

Given the lack of randomised control trials and larger body of evidence, it is difficult to formulate fixed protocols for management of peri-procedural anticoagulation for TLE. However, the data from the present study certainly support the feasibility and safety of performing TLE on uninterrupted warfarin therapy. Going forward it would be reasonable to adopt this strategy in patients at moderate and high risk of thromboembolic events. Perhaps it could be initiated at high volume centres with experienced operators. Multicentre prospective registry studies are required to assess safety of TLE on uninterrupted anticoagulation before it can be adopted as a standard of clinical care.

#### 4.1. Study limitations

Several limitations of this study require consideration. This is a retrospective registry study, which is subject to limitations inherent to observational studies.

These data are limited to a small cohort of patients across two centres. The two groups were approximately matched, albeit a trend towards greater age and co-morbidity in the anticoagulated group. Although there was no significant difference in baseline demographics between the groups, the warfarinised group was older and frailer, with the oldest patient being 78 yrs. We recognise that as yet the safety and efficacy of TLE in the elderly and frail patients in general remains unclear. Given the limitations of clinical practice and relatively low event rate for bleeding complications, it would be challenging to perform a randomised trial in this area. Large multicentre studies are required to confirm these findings and establish the safety of peri-procedural anticoagulation during TLE.

All procedures reported in this study were performed at two high volume arrhythmia centres with expertise in performing TLE. The outcomes may be influenced by operator experience.

Nevertheless, these data give no indication of increased risk with this strategy. All oral anticoagulation was performed with warfarin, the safety of newer anticoagulants in this setting remains unknown.

## 5. Conclusions

This study suggests that TLE can be performed without significant increased risk in patients on uninterrupted warfarin with therapeutic INRs. Although the benefit versus risk of this approach remains incompletely defined, these data are promising for considering TLE on uninterrupted warfarin in patients with high thromboembolic risk and a strong indication for peri-procedural anticoagulation. Larger multicentre studies are required to confirm these findings and to test the safety of newer oral anticoagulants in this setting.

## Declaration of competing interest

Dr Breitenstein has received consultant and / or speaker fees from Abbott, Bayer Healthcare, Biosense Webster, Biotronik, Boston Scientific, Bristol-Myers Squibb, Cook Medical, Daiichi Sankyo, Medtronic, Pfizer, and Spectranetics/Philipps. Dr. Steffel has received consultant and / or speaker fees from Abbott, Amgen, Astra-Zeneca, Bayer, Berlin-Chemie, Biosense Webster, Biotronik, Boehringer-Ingelheim, Boston Scientific, Bristol-Myers Squibb, Daiichi Sankyo, Medscape, Medtronic, Merck/MSD, Novartis, Portola, Roche Diagnostics, Pfizer, Portola, Saja, Servier, and WebMD. He reports ownership of CorXL. Dr. Steffel has received grant support through his institution from Abbott, Bayer Healthcare, Biosense Webster, Biotronik, Boston Scientific, Daiichi Sankyo, and Medtronic. Other authors report no relationships that could be construed as a conflict of interest.

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