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Full title: Prolonged lead dwell time and lead burden predict bailout transfemoral lead extraction

Short title: Predictors of transfemoral lead extraction

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Abbreviations

TLE	Transvenous lead extraction	ICD	Implantable cardioverter-defibrillator
ROC	Receiver operator characteristic	NS	Not significant
LVEF	Left ventricular ejection fraction	OR	Odds ratio
UK	United Kingdom	CRT	Cardiac resynchronization therapy
LLD	Lead locking device	LV	Left ventricular
CI	Confidence interval	CABG	Coronary artery bypass graft
LVEF	Left ventricular ejection fraction		

Structured Abstract

Background: Transvenous lead extraction (TLE) may be performed by superior approach using the original implant vein or via a femoral approach, however, limited comparative data exists. We compare outcomes between femoral versus non-femoral TLE approaches and determine predictors of bailout transfemoral lead extraction in patients undergoing initial TLE via the original implant vein by a superior approach.

Methods: All consecutive TLEs between October 2000 and March 2018 were prospectively collected (n=1052). Patients were dichotomized into femoral (n=118) and non-femoral (n=934) groups.

Results: Demographics were balanced between femoral vs. non-femoral groups. Patients in the femoral group had significantly higher mean lead dwell times (11.6±9.7 vs. 6.6±6.6 years, $p<0.001$), mean number of leads extracted (2.7±1.3 vs. 2.0±1.0, $p<0.001$), 30-day procedure related major complications (including deaths) (8.5% vs. 1.1%, $p<0.001$) and emergency thoracotomy rates (4.2% vs. 0.7%, $p=0.007$). All-cause 30-day mortality rates were similar between groups (3.4% vs. 2.0%, $p=0.315$). Prolonged lead dwell time and increased number of leads extracted were predictive of a bailout transfemoral approach at multivariable analysis.

Conclusion: Femoral approach TLE is associated with increased risk of 30-day procedure related major complications but not 30-day all-cause mortality. Prolonged lead dwell time and increased number of leads extracted are independent predictors for bailout transfemoral lead extraction. Such patients should be considered high risk of major complications and performed by high-volume lead extraction centres with experience in multiple approaches and techniques including experience with transfemoral lead extraction.

Key words: Transvenous lead extraction; femoral lead extraction; bailout femoral extraction

Introduction

Transvenous lead extraction (TLE) is considered the first-line approach when extraction of a transvenous lead is indicated and is most commonly performed from the superior approach using the original implant vein.(1,2) The femoral approach utilizing snares was often preferred before the advent of powered sheaths,(3–5) however, operator preference, expertise and availability of powered sheathes now play a role in selecting the initial TLE approach, usually favouring the superior approach.(4,6–8) The femoral approach, however, remains important as a 'bailout' procedure for complex TLE where an initial superior approach via the original implant vein is unsuccessful. The femoral approach may also be required as a primary approach in situations of intra-vascular (previously cut/abandoned) leads when complete lead extraction is desired in the setting of systemic infection, if there is the need for distal support to maintain superior venous access or where a lead was implanted via the femoral venous route.(4) The femoral approach, as both a bailout procedure and a primary procedure, is therefore an essential but rarely practiced skill in the armamentarium of lead extractors. Limited data exist comparing femoral versus non-femoral TLE approaches, however the ELECTRa study showed that femoral extraction was associated with a greater than threefold risk of clinical failure and a similar increased risk of procedure related major complications including death.(2) Prediction of the need for bailout extraction procedures is therefore critical in terms of risk stratification and procedural planning of TLE. We acknowledge the internal transjugular approach, first described by Bongiorni et al (2000) as an alternative bailout procedure where extraction via the original implant vein is unsuccessful, however this is not something practiced routinely in our institution and hence does not feature in our analysis.(8,9) We therefore set out to assess differences in outcomes between femoral versus non-femoral groups and define predictors of bailout transfemoral lead extraction from a prospectively collected TLE registry.

Methods

Consecutive patients undergoing TLE at a high-volume UK lead extraction centre between October 2000 and March 2018 were prospectively recorded onto a computer registry. Multiple parameters including procedural outcomes were incorporated into the registry. The registry collection and analysis were approved by the Institutional Review Board of Guy's and St Thomas' Hospital. For the current analysis, TLE procedures were dichotomized into 'femoral' and 'non-femoral' approaches. Excluding the 14 patients that had a primary femoral approach, we also assessed procedural outcomes and clinical characteristics of the bailout transfemoral lead extraction subgroup (n=104). Excluding the 14 patients that had a primary femoral approach, we also analyzed predictors of bailout transfemoral lead extraction for the remaining 1038 patients. Clinical records were reviewed to determine mortality aetiology for patients who died within 30 days of TLE.

Extraction procedure

Procedures were performed by the same six experienced operators in a cardiac catheter laboratory, hybrid laboratory or operating room with immediate onsite cardiothoracic surgical cover as previously described.(10–14) The majority of TLEs were undertaken in the cardiac catheterization laboratory with informal surgical cover. Patients deemed to be higher risk due to factors such as prolonged lead dwell time underwent TLE in a dedicated cardiac hybrid laboratory or operating room with a cardiothoracic surgeon present. At our centre, patients are currently discussed in an electrophysiology multidisciplinary meeting including the presence of transvenous lead extractors, cardiothoracic surgeons, anesthetists and nurse specialists. Whilst we currently do not have strict criteria to determine procedure location, patients with one or more pacemaker lead with a dwell time of ≥10 years or an ICD lead with a dwell time of ≥5 years usually undergo TLE in the cardiac hybrid laboratory with a surgeon present and the patient's chest cleaned and prepared for emergency thoracotomy. In addition, older patients (≥ 70 years old), systemic infection indication and multiple advanced co-morbidities are typically considered higher risk at our centre and performed in the cardiac hybrid laboratory. The preferred initial route was a superior approach via the original implant vein wherever possible with a subsequent stepwise approach undertaken including the use of cross-over tools. Initially manual traction with the aid of a locking stylet (e.g. Liberator Universal Locking Stylet, Cook Medical, Leechburg, PA, USA or LLD® Lead locking device, Spectranetics, Colorado Springs, CO, USA) was performed. If a lead was not extractable with manual traction, a powered laser (e.g. Excimer laser CVX- 300, Spectranetics Colorado Springs, CO, USA) and/or mechanical sheath was used (Tightrail Rotating dilator sheath, Spectranetics Colorado Springs, CO, USA) and we attempted upsizing the powered sheaths in a step-wise fashion if initially unsuccessful. Laser lead extraction has been in regular use at our centre since 1998 and therefore throughout the study period. More recently, the Tightrail rotating dilator sheath has been in use at our centre. If the superior approach via the original implant vein was unsuccessful despite using a stepwise technique including the use of cross-over tools, we employed the femoral work station as the initial bailout technique. If this was unsuccessful, we then proceeded to use the Needles Eye Snare (Cook Medical, Leechburg, PA, USA,) if there were no free ends to either snare or pull the leads inferiorly. The leads were then either fully extracted using the Needles Eye Snare or if there were still free ends, a 20mm or 25mm Goose neck snare (Cook Medical, Leechburg, PA, USA,) was employed. Patients underwent transthoracic echocardiography post TLE (unless intra-operative transesophageal echocardiography was used) to assess for hemodynamically significant pericardial collections and valve damage and a chest radiograph.

Definitions

Renal impairment was defined as an estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m^2. The Heart Rhythm Society (2009 and 2017)(1,15) consensus documents were used to define procedural techniques, approaches and outcomes. Safety and efficacy of TLE were calculated by evaluating the rate of procedure related major complications and clinical failure rate. Major complication was defined as any outcome related to the procedure which was life threatening or resulted in death, an unexpected event that caused persistent or significant disability or any event requiring significant surgical intervention to prevent any of these outcomes within 30 days of TLE. The association of a major complication or death to the procedure was defined by two experienced cardiologists. Intra-procedural complications were defined as any event related to the performance of the procedure that occurred or became evident from the time the patient entered the operating room until the time the patient left the room where the TLE was performed. Intra-procedural complications also included complications related to patient preparation, anesthesia and incision opening or closing. Post-procedural complications were defined as any event occurring within 30 days after TLE. Clinical failure was assessed for each TLE procedure and was defined as the inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complication or procedure related death.

For the analysis, the 'femoral' group included any TLE procedure involving a transfemoral approach. The 'non-femoral' group included all superior TLE procedures via the original implant vein that did not involve a transfemoral approach. The 'bailout transfemoral lead extraction' subgroup included all TLE procedures that were unsuccessful from a superior approach via the original implant vein despite the use of a stepwise approach using cross-over tools (as outlined in the extraction procedure methods section) and required a bailout transfemoral lead extraction approach during the same procedure, regardless of whether the procedure was ultimately deemed to be clinically successful or not. There were no lead extractions performed via the internal transjugular approach.

Statistical analysis

Discrete data are presented as n values with corresponding percentages in parentheses and continuous data as mean ± 1 standard deviation. Categorical variables were compared using Fisher's exact test. Continuous data were assessed for normality with the Shapiro-Wilk test where $p \geq 0.05$ was considered normally distributed data. Normally distributed data were compared with an independent samples t-test. Non-normally distributed data were compared using the Wilcoxon signed-rank test. Univariable and multivariable binary logistic regression were performed to determine independent predictors of bailout transfemoral extraction in the femoral group, excluding the 14 patients that had a primary femoral approach. Variables found to be statistically significant at univariable analysis, as well as important clinical covariables were used as the basis for multivariable analysis, where $p \leq 0.05$ was considered statistically significant. All reported associations are presented as odds ratio (ORs) with corresponding 95% confidence intervals (CI). Odds ratio for continuous variables represents the relative increased risk of endpoint per unit increase (e.g. per one year increase in time for lead dwell time). Statistical analysis was performed using SPSS Statistics (IBM Corporation. Released 2017. IBM Statistical Package for the Social Sciences (SPSS) Statistics for Macintosh, Version 24.0.0.1. Armonk, NY: IBM Corporation).

Results

A total of 1052 TLEs were performed by six different first operators during the study period. Of these, we identified 118 TLE procedures performed involving the transfemoral approach (femoral group) and 934 TLE procedures performed exclusively via the superior approach using the original implant vein (non-femoral group), meaning that a femoral approach was required in 11.2% (118/1052) of all cases. There were 104 bailout transfemoral cases out of 1038 TLEs (excluding the 14 primary femoral extractions). Therefore, 10% of cases were unsuccessful from the superior route alone and subsequently required transfemoral techniques during the same procedure.

Femoral versus non-femoral group characteristics

Device and lead characteristics are shown in Table 1 for femoral and non-femoral groups. Demographics were balanced between the femoral vs. non-femoral groups (Table 2). Patients were of similar age (63.9±16.3 vs. 65.6±14.8, *p*=0.402), predominantly male (75.4% vs. 73.4%, *p*=0.739) and had similar mean left ventricular ejection fraction (LVEF) (46.7%±14.7% vs. 44.0%±14.50%, *p*=0.120). Multiplicity of comorbidities were balanced for both groups. Within the femoral group, 44.1% of leads had a dwell time of ≥10 years and 50% had ≥1 ICD lead extracted. Additionally, 14.4% (17/118) had both a lead dwell time of ≥10 years and an ICD lead extracted in the femoral group. Within the non-femoral group, 22.4% (210/934) had a lead dwell time of ≥10 years, 39.9% (373/934) had ≥1 ICD lead extracted and 6.3% (59/934) had a combination of these factors.

Clinical features and procedural characteristics for femoral versus non-femoral groups

Table 3 demonstrates clinical features and procedural characteristics for femoral and non-femoral groups. Notably the mean lead dwell time was significantly longer (approximately double) in the femoral group (11.6±9.7 years vs. 6.6±6.6 years, *p*<0.001) as was the mean number of leads extracted per case (2.7±1.3 vs. 2.0±1.0, *p*<0.001). There was a significantly greater number of patients with positive microbiology in the femoral group (51.7% vs. 37.0%, *p*=0.003) as well as valvular or lead vegetations (18.3% vs. 7.8%, *p*=0.003). Powered sheath extraction was more frequently required in the femoral group (76.3% vs. 52.3%, p<0.001).

Clinical failure rates were also higher in the femoral group but not significantly different between groups (3.4% vs. 1.1%, p=0.064). Notably femoral cases were more likely to be performed in the operating room/hybrid laboratory (28.0% vs 0.5%, p<0.001).

Complications and mortality for femoral versus non-femoral groups

Table 3 shows procedural outcomes for femoral versus non-femoral groups. The 30-day procedure related major complication rate including procedure related deaths for all cases was 20/1052 (1.9%). Procedure related major complications including deaths was significantly higher in the femoral group (10/118, 8.5% vs. 10/934, 1.1%, p<0.001) and this remained the case when divided into intra-procedural (9/118, 7.6% vs. 9/934, 1.0%, p<0.001) and post-procedural (2/118, 1.7% vs. 1/934, 0.1%, p=0.035) related major complications including procedure related deaths. The overall procedure related mortality rate was 3/1052 (0.3%) and was similar between the femoral and non-femoral groups (1/118, 0.8% vs. 2/934, 0.2%, p=0.300). This was again consistent between the two groups when divided into intra-procedural (0, 0% vs. 1/934, 0.1%, p=NS) and post-procedural (1/118, 0.8% vs. 1/934, 0.1%, p=NS) deaths. The overall emergency thoracotomy rate was 12/1052 (1.1%) and was significantly higher in the femoral group (5/118, 4.2% vs. 7/934, 0.7%, p=0.007). Cardiac and vascular avulsion were drivers for procedural related major complications with only 5/11 proceeding to emergency thoracotomy in the femoral group (4 of these were due to vascular avulsion, 1 due to cardiac avulsion). The remaining 1 vascular avulsion (which was of the left subclavian vein causing a haemothorax) was managed with pleural drainage & the other 5 cardiac avulsions (causing cardiac tamponade) were managed with pericardiocentesis. The overall all-cause 30-day major complication rate including deaths was 40/1052 (3.8%) and all-cause 30-day mortality was 23/1052 (2.2%). The all-cause 30-day major complication rate including deaths was significantly higher in the femoral group (13/118, 11.0% vs. 27/934, 2.9%, p<0.001), however, the all-cause 30-day mortality rate was similar between femoral and non-femoral groups (4/118, 3.4% vs. 19/934, 2.0%, p=0.315) as was the 30-day non-procedure related mortality rate (3/118, 2.5% vs. 17/934, 1.8%, p=0.483). Table 4 demonstrates that the majority of deaths was due to sepsis in both groups.

Bailout transfemoral lead extraction demographics

Patient demographics for the bailout transfemoral lead extraction subgroup are included in Table 5. This subgroup were predominantly male with a mean age of 63.9 ± 16.1 years and a mean LVEF at time of the extraction of 47.0% ± 14.9%. Over half of the bailout transfemoral lead extraction subgroup had 2 or more comorbidities and just over a third had 3 or more comorbidities.

Clinical features and procedural characteristics for the bailout transfemoral group

Table 6 demonstrates clinical features and procedural characteristics for the bailout transfemoral subgroup. The mean lead dwell time was 11.8 ± 9.6 years and the mean number of leads extracted per case was 2.8 ± 1.3. A greater number of patients underwent TLE for local infection and/or erosion indications (41.3%) compared to systemic infection indications (15.4%).

Complications and mortality for bailout transfemoral lead extraction

Table 6 shows procedural outcomes for the bailout transfemoral lead extraction subgroup. The 30-day procedure related major complication rate including procedure related deaths was 9.6% and the emergency thoracotomy rate was 4.8%. The overall procedure related mortality rate was 1%. The all-cause 30-day major complication rate including all deaths was 11.5% and the all-cause 30-day mortality rate was 2.9%. Furthermore, the 30-day non-procedure related mortality rate was 1.9%.

Predictors of bailout transfemoral lead extraction

We performed binary logistic regression analysis to predict the need for bailout transfemoral lead extraction on all patients except those that had a primary transfemoral lead extraction (n=1038). Univariable analysis showed prolonged lead dwell time, increased number of leads extracted, ICD lead extraction, prior stroke and vegetation were associated with requiring bailout transfemoral lead extraction (Figure 1A). Prolonged lead dwell time (OR 1.080, 95% CI 1.050-1.112, $p<0.001$) and increased number of leads extracted (OR 1.766, 95% CI 1.407-2.215, *p*<0.001) remained independent predictors of bailout transfemoral lead extraction at multivariable analysis (Figure 1B).

Discussion

We present a detailed analysis on predictors of bailout transfemoral lead extraction and compare outcomes between femoral and non-femoral groups.

Femoral versus non-femoral groups

Patients in the femoral group were more likely to have positive microbiology and vegetations present which most likely reflects the need for complete removal of leads without leaving residual lead fragments in such patients. As expected, the mean lead dwell time was significantly longer in the femoral group (almost double that of the non-femoral group) since longer lead dwell times are associated with more challenging lead extractions due to adhesions which sometimes require a transfemoral approach. Additionally, the mean number of leads extracted per case and the use of a powered sheaths were both significantly higher in the femoral group which reflects the increased complexity of procedures within this group requiring a transfemoral approach.

Predictors of bailout transfemoral lead extraction

Prolonged lead dwell time and increased number of leads extracted should alert clinicians that in such cases, bailout femoral extraction may be required to allow necessary pre-procedural planning in terms of surgical cover, procedure location and availability of the necessary tools and operator experience to perform bailout transfemoral lead extraction if required. Although such cases are associated with a higher rate of emergency thoracotomy, these are often cases of systemic infection where a superior approach via the original implant vein has failed to remove the leads, and there would likely be a need to proceed to surgical extraction to achieve clinical success if femoral extraction was not an option. One could argue that without such femoral extraction techniques, the need for thoracotomy may in fact be higher to remove infected lead fragments that could otherwise be removed by femoral snaring.

Female gender is generally considered to be a poor prognostic marker as shown in the ELECTRa study (2017) where female gender was a predictor of procedure related major complications including deaths as well as clinical failure.[Bongiorni et al, EHJ, 2017] The female gender results in the present study differ between the univariable (Figure 1A) and multivariable (Figure 1B) binary logistic regression analyses in our cohort. However, neither results were significant and given the relatively small numbers of female compared to male patients in the bailout transfemoral lead extraction group (25/104, 24.0% females vs. 79/104, 76% males) as well as other important demographic factors, it's difficult to draw any firm conclusions and an in-depth analysis on gender difference is beyond the scope of the current manuscript. Additionally, prior stroke was significant at univariable analysis (Figure 1A) but became non-significant in the multivariable model (Figure 1B). We suspect this most likely reflects an association with other comorbidities rather than represent a new finding, however, future detailed analyses may be of interest to explore this futher. We also identified that the presence of vegetations was significant at univariable analysis and became non-significant at multivariable analysis. The reasons for this are not entirely clear but may be related to the fact that there is a requirement to attempt to remove all lead material in the setting of infection whereas in non-infected cases it may not always be necessary to complete the lead extraction and in such cases leads or lead fragments may have been abandoned after a failed superior approach rather than progress to a bailout transfemoral procedure.

Comparison with previous studies

Bordachar et al. (2010) studied 101 patients randomized to superior approach TLE using laser (n=50) versus transfemoral lead extraction (n=51) as the initial approach at a single centre over 15 months.(3) They demonstrated similar major complication rates between the laser extraction group and femoral group with no procedure related deaths in either group,(3) however procedure duration and fluoroscopy were significantly shorter in the non-femoral group.(3) They also compared non-randomized registries in France from three TLE centres using superior approach laser extraction (n=218) versus three other centres using transfemoral lead extraction (n=138). There were two procedure-related deaths in the superior extraction group (0.9%) versus one in the femoral group (0.7%).(3) Major procedural complication rates were similar between superior versus femoral groups in contrast to the present study which identified significant differences between procedure related major complications including deaths in the femoral versus non-femoral groups. This is likely to be explained by the fact that the vast majority of our femoral cases were performed as bailout procedures in cases where superior TLE had failed, therefore identifying them as a high-risk group. However, we found the major procedure related complication rate including deaths was 0% where TLE was undertaken as a primary procedure in keeping with Bordachar et al. Our overall procedure related major complication rate of 1.9% and procedure related mortality rate of 0.3% is in line with the ELECTRa study (1.7% and 0.5% respectively),(2) the largest published experience of contemporary lead extraction, although the mean lead dwell time and number of leads extracted per case in the present study was higher compared to ELECTRa (7.2±7.2 vs. 6.4±5.4 years and 2.1±1.0 vs. 1.8±0.9 leads). In keeping with ELECTRa, we found that femoral extraction versus superior extraction via the original implant vein was associated with an approximately 3-fold higher rate of clinical failure 3.4% vs 1.1% (ELECTRa study OR 3.93).(2) Similarly, in ELECTRa a femoral approach was associated with a higher incidence of procedure related major complications including mortality (odds ratio of 3.6) without an increase in all-cause mortality(2) as in the present study. El-Chami et al. previously collated two registries to assess predictors and outcomes of the bailout femoral approach.(16) A total of 50/1080 (4.6%) patients required a bailout transfemoral lead extraction in their study compared to 104/1038 (10.0%) in the present study.(16) Patients undergoing bailout transfemoral extraction in our cohort had longer lead dwell times (11.8 ± 9.6 vs 9.5 ± 6.0 years), more leads extracted per procedure (2.8 ± 1.3 vs. 2.0 ± 1.0) and a distinctly lower clinical failure rate (3.8% vs. 24%) compared to their combined cohort.(16) These marked differences between our bailout transfemoral lead extraction cohort and that described by El-Chami most likely explains the higher procedural major complication and mortality rates in our cohort (10/104, 9.6% vs 0/50, 0%).(16) Whilst El-Chami et al. did not perform regression analysis to assess independent predictors of bailout transfemoral extraction, they did conclude from analysis of their outcomes similar findings to the present study that longer lead dwells times and greater number of leads extracted were significantly higher in the bailout femoral group compared to their non-femoral group.(16) Additionally, they found that infection indication was significantly higher in the bailout femoral group.(16)

Clinical importance

In the vast majority of our cases, lead extraction was performed successfully and safely from the superior approach using the original implant veins with an overall procedure related mortality rate of 0.3%. Importantly, the current study highlights that in patients where an initial superior approach using the original implant veins has failed and bailout transfemoral extraction is required, there is a significant risk of procedure related major complications (9.6%) with the need for emergency thoracotomy (4.8%) but with low procedure related mortality rates (1%) and high clinical success rates (>96% of cases). This is likely to reflect good pre- and intra-procedural planning with use of a hybrid lab or cardiac operating room being more frequently used in the femoral group with a cardiothoracic surgeon present in case emergency thoracotomy was required.

Due to the increased risk of procedure related major complications requiring an emergency thoracotomy in patients progressing to a bailout transfemoral approach, identifying these at-risk patients therefore appears critically important to facilitate better procedural planning to ensure the correct expertise are present during the procedure in order to minimize but also deal with procedure related major complications effectively. The current findings also underpin the need for adequate procedure location planning to identify high-risk cases that may require a bailout transfemoral procedure so that they are performed in a setting where emergency surgery can be performed immediately (in the cardiac hybrid lab) and that if this is undertaken the majority of patients will survive. It also highlights the need for operator training and experience in femoral snaring techniques which were required in 118/1052 (11.2%) of all patients requiring lead extraction in our institution. One could argue that if such risk factors are identified (long lead dwell time, multiple leads with an infectious indication mandating removal of all leads) that these cases should be performed in centres and by operators with appropriate training and experience in femoral snaring techniques. This is important as the use of femoral snaring techniques is likely to be become increasingly prevalent and important in the future with the advent of leadless pacing technologies which may require such snaring techniques to allow removal. When planning procedure location, lead dwell time and number of leads requiring extraction should be taken into account in addition to older age, systemic infection indication and renal impairment which we have previously demonstrated are independent predictors of 30-day mortality.(13) Currently in our institution, all prospective lead extraction cases are discussed in a multi-disciplinary meeting involving cardiac surgeons with a risk stratification process to determine the manner and location of a TLE.

Limitations

The findings in our study are subject to inherent limitations with observational studies. However, one of the key strengths of this study being a single-centred experience is that it is an all comers prospectively collected registry for TLE with real-world outcome data which excludes any selection bias that may occur with multi-centre trials. In addition, it is possible that there are unknown confounders and bias between operator management strategies and techniques employed given there was no formal standardized protocol for TLE. Furthermore, modification of TLE techniques and use of new equipment over the study period are not considered in the analysis. Patients undergoing surgical lead extraction were excluded from the TLE registry and therefore this analysis is not entirely representative of all patients requiring lead extraction. Predictors of bailout transfemoral extraction were identified, however, the exact cause and effect relationship remains speculative. Additionally, identifying data on abandoned leads would have allowed further analysis with regards to identifying predictors of bailout transfemoral lead extraction, however, this information was not available in our prospectively collected database. Abandoned leads in the setting of device infection would mandate their removal and therefore may have contributed to the increased failure rate of transvenous lead extraction from the superior approach, for example, due to prolonged lead dwell times. Furthermore, abandoned leads may also have been a driver of increased complications as reported in the recent ELECTRa registry sub-analysis on procedural outcomes associated with transvenous lead extraction in patients with abandoned leads.(17) The study was also not designed to compare the effect of different techniques, equipment and approaches on bailout transfemoral lead extraction and additional data are warranted to explore this further. Importantly, femoral extraction was only undertaken in patients where a superior approach via the original implant vein was initially unsuccessful (bailout procedure) or not feasible (due to intravascular leads). The risks of femoral extraction are likely to be biased by this and this may be a significantly lower risk procedure if it is performed in all-comers as a primary procedure. Moreover, the analysis does not include leads extracted via the internal transjugular approach as this is not routinely practiced at our institution and therefore this analysis is not entirely representative of all lead extraction techniques but rather focuses on the use of transfemoral approach as a bailout technique.

Conclusion

Bailout transfemoral lead extraction is associated with increased risk of 30-day procedure related major complications but not 30-day all-cause mortality. Prolonged lead dwell time and increased number of leads extracted were independent predictors for bailout transfemoral lead extraction. Such patients should be considered high risk of major complications and requiring emergency thoracotomy and therefore performed by high-volume lead extraction centres with experience in multiple approaches and techniques including experience with transfemoral lead extraction and cardiothoracic facilities immediately available.

Author contributions

Justin Gould – concept/design, data acquisition, data analysis/interpretation, statistics, drafting article, approval of submitted final version

Baldeep S Sidhu – data acquisition, data analysis/interpretation, critical revision of article, approval of submitted final version

Bradley Porter – data acquisition, data analysis/interpretation, statistics, critical revision of article, approval of submitted final version

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Jaswinder Gill – data acquisition, data analysis/interpretation, critical revision of article, approval of submitted final version

Christopher A Rinaldi – concept/design, data acquisition, data analysis/interpretation, statistics, critical revision of article, approval of submitted final version

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Legends

Table 1: Device and lead characteristics

Device characteristics calculated on a total of 1052 procedures. Lead characteristics calculated on a total of 2182 leads extracted.

CRT-cardiac resynchronization therapy

ICD-implantable cardioverter-defibrillator

Table 2: Patient demographics comparing femoral and non-femoral groups

Patient demographics calculated on a total of 1052 procedures. Unknown values excluded from analysis denoted by varying denominators.

LVEF-left ventricular ejection fraction

Table 3: Procedural outcomes and clinical characteristics for femoral and non-femoral groups

Procedural outcomes and clinical characteristics calculated on a total of 1052 procedures. Unknown values excluded from analysis denoted by varying denominators.

[a] If >1 major complication (including death) occurred for a single transvenous lead extraction procedure, only one major complication or death was counted when calculating the 'procedure related major complication including procedure related death' rate.

[b] One patient in the Femoral group had an intra-procedural and post-procedural major complication which are recorded separately but not double counted for the overall 30-day procedure related major complication.

Table 4: Breakdown of causes of all-cause 30-day Mortality

Clinical records were reviewed to determine cause of death of patients who died within 30 days following lead extraction.

Table 5: Demographics of patients undergoing bailout transfemoral lead extraction

Patient demographics calculated on a total of 104 bailout transfemoral lead extraction procedures. Unknown values excluded from analysis denoted by varying denominators.

LVEF-left ventricular ejection fraction

Table 6: Procedural outcomes and clinical characteristics of bailout transfemoral lead extraction procedures

Procedural outcomes and clinical characteristics calculated on a total of 104 bailout transfemoral lead extraction procedures. Unknown values excluded from the analysis denoted by varying denominators.

[a]If >1 major complication (including death) occurred for a single transvenous lead extraction procedure, only one major complication or death was counted when calculating the 'procedure related major complication including procedure related death' rate.

[b]One patient undergoing bailout transfemoral lead extraction had an intra-procedural and post-procedural major complication which are recorded separately but not double counted for the overall 30-day procedure related major complication.

Figure 1: (A) Univariable analysis to determine variables associated with bailout transfemoral lead extraction **(B)** Multivariable analysis to determine independent predictors of bailout transfemoral lead extraction

Odds ratio for continuous variables represents the relative increased risk of endpoint per unit increase (e.g. per one year increase in time for lead dwell time).

ICD = implantable cardioverter-defibrillator, LV = left ventricular, LVEF = left ventricular ejection fraction, CABG = coronary artery bypass graft surgery

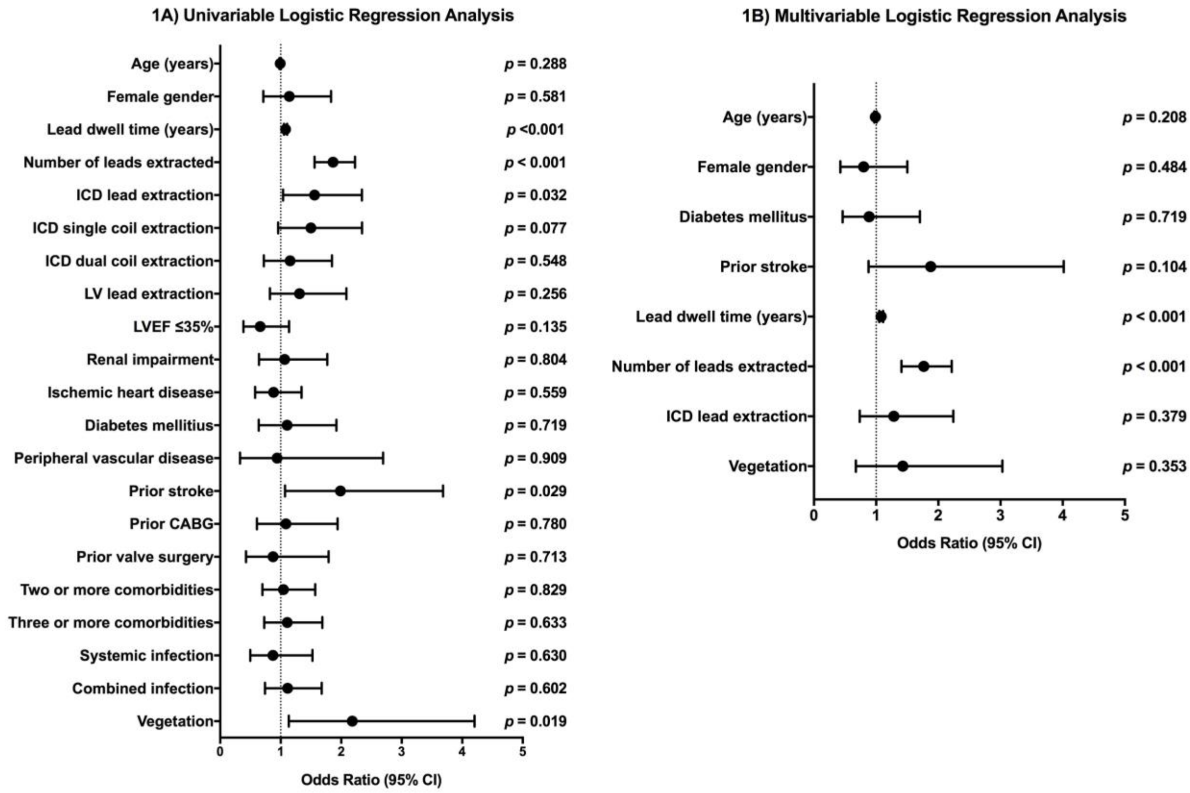

Figure 1: (A) Univariable analysis to determine variables associated with bailout transfemoral lead extraction **(B)** Multivariable analysis to determine independent predictors of bailout transfemoral lead extraction

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Tables and Figures

Table 1: Device and lead characteristics

Device Type	Femoral Group (n=118)	Non-Femoral Group (n=934)	Combined Group Totals (n=1052)
CRT-Pacemaker	11/118 (9.3%)	52/934 (5.6%)	63/1048 (6.0%)
CRT-Defibrillator	26/118 (22.0%)	190/934 (20.3%)	216/1048 (20.6%)
Single chamber pacemaker	10/118 (8.5%)	71/934 (7.6%)	81/1050 (7.7%)
Dual chamber pacemaker	38/118 (32.2%)	361/934 (38.7%)	399/1050 (38.0%)
Single & dual chamber ICDs	33/118 (28.0%)	255/934 (27.3%)	288/1048 (27.5%)
Bi-atrial pacemaker	0%	5/934 (0.5%)	5/1048 (0.5%)
Lead type	**Femoral Group (n=318)**	**Non-Femoral Group (n=1864)**	**Total (n=2182)**
Right atrial pacing leads	88/318 (27.7%)	657/1864 (35.2%)	745/2182 (34.1%)
Right ventricular pacing leads	132/318 (41.5%)	133/1864 (7.1%)	265/2182 (12.1%)
Left ventricular coronary sinus leads	31/318 (9.7%)	191/1864 (10.2%)	222/2182 (10.2%)
Single coil ICD lead	36/318 (11.3%)	188/1864 (10.1%)	224/2182 (10.2%)
Dual coil ICD lead	31/318 (9.7%)	195/1864 (10.5%)	226/2182 (10.4%)
Lead fixation mechanisms	**Femoral Group (n=318)**	**Non-Femoral Group (n=1864)**	**Total (n=2182)**
Active	227/318 (71.4%)	1264/1864 (67.8%)	1491/2182 (68.3%)
Passive	91/318 (28.6%)	600/1864 (32.2%)	691/2182 (31.7%)

Device characteristics calculated on a total of 1052 procedures. Lead characteristics calculated on a total of 2182 leads extracted.

CRT-cardiac resynchronization therapy

ICD-implantable cardioverter-defibrillator

Table 2: Patient demographics comparing femoral and non-femoral groups

Demographics	Femoral Group (n=118)	Non-Femoral Group (n=934)	Total (n=1052)	*p* value
Mean age at extraction (years) ± standard deviation	63.9±16.3	65.6±14.8	65.4±15.0	0.402
Male	89/118 (75.4%)	686/934 (73.4%)	775/1052 (73.7%)	0.739
Ischaemic heart disease	44/117 (37.6%)	356/893 (39.9%)	400/1010 (39.6%)	0.688
Prior coronary artery bypass graft surgery	16/117 (13.7%)	121/892 (13.6%)	137/1009 (13.6%)	1.000
Previous valve repair or replacement	10/117 (8.5%)	88/891 (9.9%)	98/1008 (9.7%)	0.742
Mean LVEF (%)	46.7±14.7	44.0±14.50	44.4±14.6	0.120
Severe left ventricular systolic dysfunction (LVEF ≤35%)	23/88 (26.1%)	207/632 (32.8%)	230/720 (31.9%)	0.225
Diabetes mellitus	18/117 (15.4%)	134/884 (15.2%)	152/1001 (15.2%)	1.000
Peripheral vascular disease	4/117 (3.4%)	37/884 (4.2%)	41/1001 (4.1%)	1.000
Prior stroke	14/117 (12.0%)	65/886 (7.3%)	79/1003 (7.9%)	0.098
Chronic obstructive pulmonary disease	13/117 (11.1%)	114/884 (12.9%)	127/1001 (12.7%)	0.659
Renal impairment	22/118 (18.6%)	173/902 (19.2%)	195/1020 (19.1%)	1.000
≥2 comorbidities	63/118 (53.4%)	492/933 (52.7%)	555/1051 (52.8%)	0.922
≥3 comorbidities	41/118 (34.7%)	319/933 (34.2%)	360/1051 (34.3%)	0.918

Patient demographics calculated on a total of 1052 procedures. Unknown values excluded from analysis denoted by varying denominators.

LVEF-left ventricular ejection fraction

Table 3: Procedural outcomes and clinical characteristics for femoral and non-femoral groups

Indications and Clinical features for Transvenous Lead Extraction	Femoral Group (n=118)	Non-Femoral Group (n=934)	Total (n=1052)	*p* value
Systemic infection	22/118 (18.6%)	160/927 (17.3%)	182/1045 (17.4%)	0.700
Local infection and/or erosion	49/118 (41.5%)	341/929 (36.7%)	390/1047 (37.2%)	0.314
Combined infection	71/118 (60.2%)	501/927 (54.0%)	572/1045 (54.7%)	0.239
Positive microbiology	**60/116 (51.7%)**	336/907 (37.0%)	396/1023 (38.7%)	**0.003**
Vegetation visible on transthoracic or transesophageal echocardiogram	**17/93 (18.3%)**	53/676 (7.8%)	70/769 (9.1%)	**0.003**
Mean lead dwell time (years) ± standard deviation Median lead dwell time (years) [IQR]	**11.6±9.7** **8.9 [3.9-16.3]**	6.6±6.6 4.9 [1.3-9.5]	7.2±7.2 5.4 [1.6-10.2]	**<0.001**
Mean number of leads extracted per case ± SD Median number of leads extracted per case [IQR]	**2.7±1.3** **2.0 [2.0-4.0]**	2.0±1.0 2.0 [1.0-3.0]	2.1±1.0 2.0 [1.0-3.0]	**<0.001**
Procedural characteristics				
Hybrid Theatre (including OR) Procedure Location	**33/118 (28.0%)**	5/934 (0.5%)	38/1052 (3.6%)	**<0.001**
Powered sheath extraction required	**90/118 (76.3%)**	476/910 (52.3%)	566/1028 (55.1%)	**<0.001**
Clinical failure	4/118 (3.4%)	10/921 (1.1%)	14/1039 (1.3%)	0.064
Emergency thoracotomy	**5/118 (4.2%)**	7/934 (0.7%)	12/1052 (1.1%)	**0.007**
Details of 30-day procedure related major complications and deaths				
Procedure related major complications including procedure related deaths[a]	**10/118 (8.5%)[b]**	10/934 (1.1%)	20/1052 (1.9%)	**<0.001**
Intra-procedural	**9/118 (7.6%)**	9/934 (1.0%)	18/1052 (1.7%)	**<0.001**
Post-procedural	**2/118 (1.7%)**	1/934 (0.1%)	3/1052 (0.3%)	**0.035**
Procedure related deaths	1/118 (0.8%)	2/934 (0.2%)	3/1052 (0.3%)	0.300
Intra-procedural	0%	1/934 (0.1%)	1/1052 (0.1%)	1.000
Post-procedural	1/118 (0.8%)	1/934 (0.1%)	2/1052 (0.2%)	0.212
Cardiac avulsion or tear	**6/116 (5.2%)**	4/929 (0.4%)	10/1045 (1.0%)	**<0.001**
Vascular avulsion or tear	**5/116 (4.3%)**	5/929 (0.5%)	10/1045 (1.0%)	**0.002**
Flail tricuspid valve leaflet requiring intervention or surgery	1/118 (0.8%)	0%	1/1052 (0.1%)	0.112
Disseminated intravascular coagulation	0%	1/934 (0.1%)	1/1052 (0.1%)	1.000
Stroke	**2/116 (1.7%)**	1/929 (0.1%)	3/1045 (0.3%)	**0.034**
All-cause 30-day major complications including deaths				
All-cause 30-day major complications including deaths[a]	**13/118 (11.0%)**	27/934 (2.9%)	40/1052 (3.8%)	**<0.001**
All-cause 30-day mortality	4/118 (3.4%)	19/934 (2.0%)	23/1052 (2.2%)	0.315
Details of 30-day non-procedure related major complications including deaths				
Heart failure	0%	1/934 (0.1%)	1/1052 (0.1%)	1.000
Sepsis with or without multi organ failure	1/118 (0.8%)	14/934 (1.5%)	15/1052 (1.4%)	0.716
Respiratory arrest	1/118 (0.8%)	0%	1/1052 (0.1%)	0.112
Arrhythmia	1/118 (0.8%)	2/934 (0.2%)	3/1052 (0.3%)	0.300
30-day non-procedure related deaths	3/118 (2.5%)	17/934 (1.8%)	20/1052 (1.9%)	0.483

Procedural outcomes and clinical characteristics calculated on a total of 1052 procedures. Unknown values excluded from analysis denoted by varying denominators.

[a]If >1 major complication (including death) occurred for a single transvenous lead extraction procedure, only one major complication or death was counted when calculating the 'procedure related major complication including procedure related death' rate.

[b]One patient in the Femoral group had an intra-procedural and post-procedural major complication which are recorded separately but not double counted for the overall 30-day procedure related major complication.

Table 4: Breakdown of causes of all-cause 30-day Mortality

Cause of 30-day death	Femoral Group deaths (n=4)	Non-Femoral Group deaths (n=19)	Total deaths (n=23)
Sepsis	2/4 (50.0%)	15/19 (78.9%)	17/23 (73.9%)
Arrhythmia (ventricular fibrillation)	1/4 (25.0%)	2/19 (10.5%)	3/23 (13.0%)
Superior vena cava tear	0%	1/19 (5.3%)	1/23 (4.3%)
End-stage heart failure	0%	1/19 (5.3%)	1/23 (4.3%)
Pneumonia	1/4 (25.0%)	0%	1/23 (4.3%)

Clinical records were reviewed to determine cause of death of patients who died within 30 days following lead extraction.

Table 5: Demographics of patients undergoing bailout transfemoral lead extraction

Demographics	Bailout transfemoral lead extraction (n=104)
Mean age at extraction (years) ± standard deviation	63.9±16.1
Male	79/104 (76.0%)
Ischaemic heart disease	38/103 (36.9%)
Prior coronary artery bypass graft surgery	15/103 (14.6%)
Previous valve repair or replacement	9/103 (8.7%)
Mean LVEF (%)	47.0±14.9
Severe left ventricular systolic dysfunction (LVEF ≤35%)	19/78 (24.4%)
Diabetes mellitus	17/103 (16.5%)
Peripheral vascular disease	4/103 (3.9%)
Prior stroke	14/103 (13.6%)
Chronic obstructive pulmonary disease	12/103 (11.7%)
Renal impairment	21/104 (20.2%)
≥2 comorbidities	56/104 (53.8%)
≥3 comorbidities	38/104 (36.5%)

Patient demographics calculated on a total of 104 bailout transfemoral lead extraction procedures.

Unknown values excluded from analysis denoted by varying denominators.

LVEF-left ventricular ejection fraction

Table 6: Procedural outcomes and clinical characteristics of bailout transfemoral lead extraction procedures

Indications and Clinical features for Transvenous Lead Extraction	Bailout transfemoral lead extraction (n=104)
Systemic infection	16/104 (15.4%)
Local infection and/or erosion	43/104 (41.3%)
Combined infection	59/104 (56.7%)
Positive microbiology	52/102 (51%)
Vegetation visible on transthoracic or transesophageal echocardiogram	13/82 (15.9%)
Mean lead dwell time (years) ± standard deviation Median lead dwell time (years) [IQR]	11.8±9.6 9.0 [4.3-16.4]
Mean number of leads extracted per case ± SD Median number of leads extracted per case [IQR]	**2.8±1.3** **2.0 [2.0-4.0]**
Procedural characteristics	
Hybrid Theatre (including operating room) Procedure Location	32/104 (30.8%)
Powered sheath extraction required	81/104 (77.9%)
Clinical failure	4/104 (3.8%)
Emergency thoracotomy	5/104 (4.8%)
Details of 30-day procedure related major complications and deaths	
Procedure related major complications including procedure related deaths[a]	10/104 (9.6%) [b]
Intra-procedural	9/104 (8.7%)
Post-procedural	2/104 (1.9%)
Procedure related deaths	1/104 (1.0%)
Intra-procedural	0/104 (0%)
Post-procedural	1/104 (1.0%)
Cardiac avulsion or tear	6/103 (5.8%)
Vascular avulsion or tear	5/103 (4.9%)
Flail tricuspid valve leaflet requiring intervention or surgery	1/104 (1.0%)
Stroke	2/103 (1.9%)
All-cause 30-day major complications including deaths	
All-cause 30-day major complications including deaths[a]	12/104 (11.5%)
All-cause 30-day mortality	3/104 (2.9%)
Details of 30-day non-procedure related major complications including deaths	
Sepsis with or without multi organ failure	1/104 (1.0%)
Arrhythmia	1/104 (1.0%)
30-day non-procedure related deaths	2/104 (1.9%)

Procedural outcomes and clinical characteristics calculated on a total of 104 bailout transfemoral lead extraction procedures. Unknown values excluded from the analysis denoted by varying denominators.

[a]If >1 major complication (including death) occurred for a single transvenous lead extraction procedure, only one major complication or death was counted when calculating the 'procedure related major complication including procedure related death' rate.

[b]One patient undergoing bailout transfemoral lead extraction had an intra-procedural and post-procedural major complication which are recorded separately but not double counted for the overall 30-day procedure related major complication.