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DEVICES

The long-term outcomes of cardiac implantable electronic devices implanted via the femoral route

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Abstract

Background: Conventional superior access for cardiac implantable electronic devices (CIEDs) is not always possible and femoral CIEDs (F-CIED) are an alternative option when leadless systems are not suitable. The long-term outcomes and extraction experiences with F-CIEDs, in particular complex F-CIED (ICD/CRT devices), remain poorly understood.

Methods: Patients referred for F-CIEDs implantation between 2002 and 2019 at two tertiary centers were included. Early complications were defined as ≤30 days following implant and late complications >30 days.

Results: Thirty-one patients (66% male; age 56 ± 20 years; 35% [11] patients with congenital heart disease) were implanted with F-CIEDs (10 ICD/CRT and 21 pacemakers). Early complications were observed in 6.5% of patients: two lead displacements. Late complications at 6.8 ± 4.4 years occurred in 29.0% of patients. This was higher with complex F-CIED compared to simple F-CIED (60.0% vs. 14.3%, $p = .02$). Late complications were predominantly generator site related ($n = 8$, 25.8%) including seven infections/erosions and one generator migration. Eight femoral generators and 14 leads (median duration in situ seven [range 6–11] years) were extracted without complication.

Conclusions: Procedural success with F-CIEDs is high with clinically acceptable early complication rates. There is a notable risk of late complications, particularly involving the generator site of complex devices following repeat femoral procedures. Extraction of chronic F-CIED in experienced centers is feasible and safe.

KEYWORDS
biventricular pacing/defibrillation, cardiac implantable electronic devices, femoral vein, lead implantation/extraction, pacemaker-bradyarrhythmia's

1 | INTRODUCTION

Conventional transvenous implantation of cardiac implantable electronic devices (CIEDs) including pacemakers, implantable cardioverter defibrillators (ICD), and cardiac resynchronization therapy devices (CRT) may not be possible in patients with limited superior venous access. Despite significant developments in leadless pacing[1] and extravascular ICDs,[2] current iterations are unable to facilitate reliable atrioventricular or biventricular pacing combined with defibrillation capabilities. Surgical epicardial lead placement is limited by high procedural morbidity and high lead failure rates.[3–5]

Devices implanted via the femoral venous route (F-CIED) offer an alternative solution and the technique for simple pacemaker implantation with femoral generator positioning has been well described.[6–11] However, the experience of complex pacing devices (ICD and CRT) is limited to a small number of case reports with short follow-up duration (Table 1).[12–21] Acute implantation success, longer term follow-up of complex femoral devices, the necessity for subsequent procedures, and the feasibility and safety of chronic complex femoral device extraction has not been reported.

This study reports the experience of patients referred for CIED implantation via the femoral route from two large volume tertiary centers. Early and long-term complication rates are described, including our experience of chronic femoral lead extraction and generator removal in this unique and vulnerable cohort.

2 | METHODS

2.1 | Data source and patient selection

Patients referred for device implantation via the femoral vein between January 2002 and January 2019 at two high volume centers in United Kingdom (Royal Brompton Hospital and Barts Heart Centre) were retrospectively identified. Patients were stratified into simple femoral (single or dual chamber pacemakers) and complex F-CIED groups (single or dual chamber ICD, CRT-P and CRT-D). This study was approved by the local service evaluation review board. Patients or the public were not involved in the design, conduct, reporting, or dissemination of this study.

2.2 | Clinical variables

Procedural reports and the electronic health records yielded the following clinical characteristics: age at implant, sex, and comorbidities including hypertension, diabetes, and chronic kidney disease. Cardiac substrate was classified as ischemic heart disease, non-ischemic, congenital (e.g., structural), or inherited (e.g., channelopathy). Indication for femoral approach was recorded. Diagnostics including left ventricular (LV) ejection fraction (%), QRS duration (ms) were noted. Medications including warfarin and direct oral anticoagulant use were ascertained from electronic records.

2.3 | Femoral implant technique

F-CIED implantation and repeat procedures were performed by four highly experienced operators, each with over 10 years of device experience. Our technique of CIED implantation via the femoral route has been described previously.[15,21] All devices were implanted through the right or left femoral vein. Ultrasound guidance use as an adjunct to anatomic landmarks was dependent on implanter preference. Separate femoral punctures and normal length (13 cm) peel away sheaths were used for each lead. Standard LV delivery equipment including slittable delivery sheaths were used for coronary sinus cannulation and LV lead placement. All procedures were performed under general anesthetic. Figure 1 shows abdominal and chest X-ray images from a patient implanted with a femoral dual chamber ICD.

Active fixation atrial and right ventricular leads were used. Implant locations were selected based on lead stability, observed current of injury and acute pacing parameters. LV leads were passive fixation, −8688 in length, five were bipolar leads and one was quadripolar. Posterolateral LV positions with long QLV, acceptable thresholds, and lack of diaphragmatic stimulation were favored. Secondary positions were dependent on coronary sinus anatomy and included low posterior vein, middle cardiac vein, and anterior interventricular vein branches. Dual coil defibrillator leads were chosen in all but one patient. Defibrillation testing (DFT) was performed in all patients with high voltage devices with an initial low energy shock at 10 J below the maximum energy of the device followed by a maximum energy shock if the first was unsuccessful. Generators were positioned above the inguinal ligament in a subcutaneous pocket and wounds were closed in layers with absorbable sutures. Generators were fixated to underlying muscle or fascia in all patients. Antibacterial envelopes were not used during the initial implant as they were not routinely used at our centers at the time of initial F-CIED implantation. All patients underwent bed rest for 48 h postprocedure and had oral antibiotics for 5—7 days. Patients implanted with femoral systems following extraction of previous systems had intravenous antibiotics for 2—14 days.

2.4 | Follow-up and outcomes

Lead-related complications were defined as those requiring reintervention. A pocket hematoma was deemed present when there was a delay to patient discharge, a >2 g/dL hemoglobin loss or

TABLE 1 Published literature on simple (pacemaker) and complex (ICD and CRT) femoral devices

Study (ref. #)	Year	Number of patients		Atrial leads	RV leads	LV leads	Mean follow-up (months)	Complications
		Simple	Complex					
Case Reports								
Guidici et al.[12]	2003	0	1 ICD	1	1	0	n/a	None
Perzanowski et al.[13]	2004	0	1 ICD, 1 CRT-D	2	5	1	1	HV coil interaction requiring lead repositioning.High DFT requiring subcutaneous array
Yousef et al.[14]	2006	0	1 CRT-P	1	2	1	n/a	None
Jourdier et al.[15]	2007	0	1 CRT-D		1	1	n/a	None
Allred et al.[16]	2008	0	1 CRT-D	1	2	1	n/a	None
Shandling et al.[17]	2010	0	1 CRT-P	1	2	0	n/a	None
Agosti et al.[18]	2012	0	1 CRT-P	1	2	1	12	None
Chaggar et al.[19]	2015	0	1 CRT-P	1	2	1	24	RA and RV lead displacement
Brandão et al.[20]	2017	0	1 CRT-P	1	2	1	9	Hematoma
Marinelli et al.[21]	2020	1 PPM	0	2	0	0	n/a	None
Case Series								
Ellestad et al.[6]	1980	23	0	6	23	0	n/a	Lead perforation (13%, $n = 3$), thrombophlebitis (4%, $n = 1$), lead displacement (17%, $n = 4$)
Ellestad et al.[7]	1989	90	0	42	67	0	108	Lead displacement (13%, $n = 14$)
Mathur et al.[8]	2001	27	0	25	26	0	36.5	A lead displacement (20%, $n = 5$), pre-erosion (7%, $n = 2$), persistent pain (4%, $n = 1$)
Costa et al.[9]	2003	99	0	8	99	0	63	Infection/erosion (9%, $n = 9$), lead displacement (1%, $n = 1$), failure (3%, $n = 3$)
García Guerrero et al.[10]	2005	12	0	5	12	0	18	Infection/erosion requiring extraction (25%, $n = 3$)
García Guerrero et al.[11]	2017	50	0	22	47	4	50	Infection/erosion requiring extraction (11%, $n = 5$) Hematoma (0.5%, $n = 1$), lead failure (0.5%, $n = 1$)

Simple = pacemakers, complex = ICDs and CRTs. A, atrial; CRT-D, cardiac resynchronization therapy – defibrillator; CRT-P, cardiac resynchronization therapy – pacemaker; CS, coronary sinus; DFT, defibrillation threshold; HV, high voltage; ICD, implantable cardioverter defibrillator; LV, left ventricular; n/a, not available; RV, right ventricular; SVC, superior vena cava.

requiring pocket evacuation. Generator site-related complications were defined as those requiring intervention, including device repositioning/reburial, wound debridement/washout, and extraction. Complications were defined as early (<30 days after implant) and late (>30 days after implant).

2.5 | Statistical analysis

Cohort summary statistics were summarized with continuous data presented as mean ± standard deviation if normally distributed and median (range) for non-normal distributions. We a priori considered attempts at matched controls to be limited by likely residual confounding given the unique nature of this unusual patient cohort. Moreover, typical techniques for identifying residual confounding including falsification testing would not apply efficiently to a relatively small cohort. Thus, the proportion of successful implants, acute, and long-term complications were characterized. Comparisons were made between simple and complex femoral groups using the Students *t*-test for continuous data and Pearson's chi-squared test for categorical data with Fisher's exact test for expected values less than 5. Tests were performed two tailed with statistical significance set at $p < .05$. SPSS (IBM SPSS Statistics, Version 20 IBM Corp, Armonk, NY, USA) was used for data analysis.

3 | RESULTS

3.1 | Procedures and patient demographics

A total of 31 patients were referred for femoral device implantation, and all devices were implanted successfully. Of these, 21 were simple

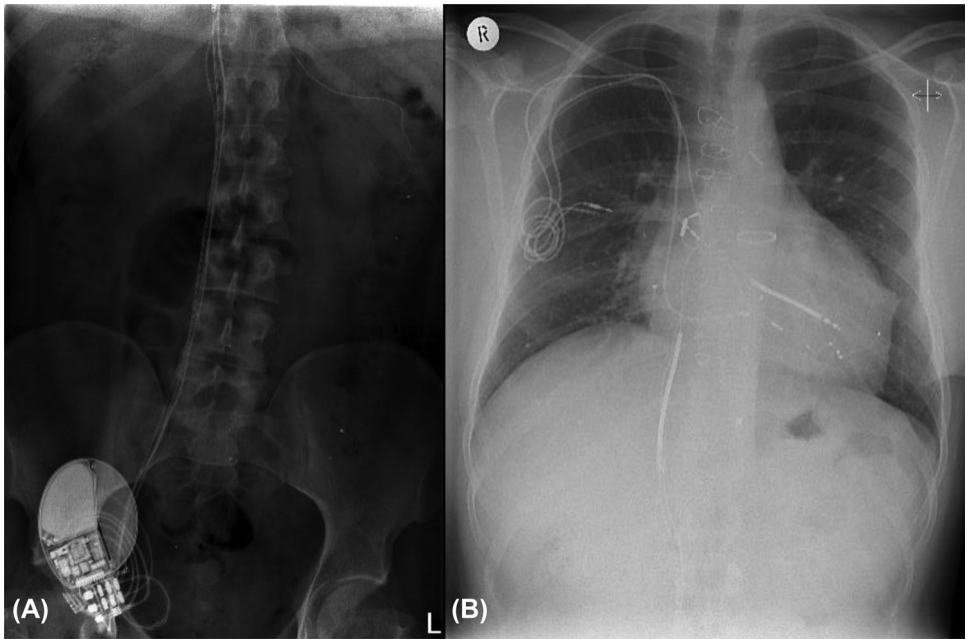

FIGURE 1 X-ray images of a femoral dual chamber ICD. A patient with double outlet right ventricle required upgrade to CRT-D but pre-procedure venography found bilateral SVC obstructions. A CRT-D was implanted from the right femoral vein (A) abdominal X-ray, (B) chest X-ray. A dual coil shock configuration including the generator resulted in successful defibrillation at implant. ICD, implantable cardioverter defibrillator; CRT-D, cardiac resynchronization therapy – defibrillator; SVC, superior vena cava

(5 AAI, 6 VVI and 10 DDD) and 10 were complex (4 CRT-D, 2 CRT-P, 3 dual chamber ICDs and 1 single chamber ICD). All patients referred for femoral CIED were successful implanted. Characteristics of the patients are summarized in Table 2. The complex F-CIED subgroup were a higher risk cohort compared to the simple F-CIED group, demonstrated by a greater degree of LV systolic dysfunction (left ventricular ejection fraction [LVEF]: 34% ± 16% vs. 52% ± 12%; $p < .01$), a higher proportion of patients in New York Heart Association class III/IV (30% vs 0%; $p = .03$) and a higher number of pacing procedures both prior to index femoral implant (4(0–6) complex vs. 0(0–4) simple, $p = .05$) and postindex femoral implant (2(0–6) vs. 0(0–7); $p = .048$). Fifty-one leads were implanted via the femoral vein: 19 right atrial (RA), 18 right ventricular (RV) pace/sense, eight RV defibrillators, and six LV leads. DFT was successful in 7/8 (88%) F-CIED patients. One patient with a failed DFT required an additional SVC coil (Transvene SVC 6937, Medtronic) implanted via the femoral route resulting in a successful DFT.

3.2 | Device and femoral access indications

The most common indication for femoral implantation was lack of superior access due to acquired superior vena cava (SVC) obstruction ($n = 16$, 52%) or prior surgical correction of congenital heart disease ($n = 8$, 26%). Other reasons included recurrent infections and erosions ($n = 6$, 19%) and recurrent pain ($n = 1$, 3%) with pectoral pacing systems. Acquired SVC obstruction was a result of central venous catheterization for renal dialysis ($n = 10$) and due to existing pacing leads ($n = 6$). SVC venoplasty/stenting was not routinely performed at our center at the time of implant and transvenous lead extraction was avoided in the six patients with existing pacing leads due to high procedural risk given multiple underlying comorbidities. In the simple F-CIED cohort devices were implanted for complete heart block ($n = 9$), sick sinus syndrome ($n = 6$), and permanent AF with symptomatic bradycardia ($n = 6$). Leadless VVI pacing was not in routine clinical use at our center at the time of initial implant in these patients with femoral implantation the only option. All six patients receiving CRT devices had severely impaired LV systolic function (LVEF < 35%). Eight patients had a device with defibrillation capabilities, three for primary prevention, and five for secondary prevention. Modern device strategies such as leadless pacing and subcutaneous ICDs were not in routine clinical use at our centers at the time of implant. One patient who received a secondary prevention VVI ICD was considered for subcutaneous ICD implantation but due to a history of ischemic heart disease and sustained ventricular tachycardia with associated syncope an endocardial VVI ICD with anti-tachycardia pacing capabilities was thought to be advantageous and the femoral route was the only viable access.

3.3 | Follow-up duration

Mean follow-up duration was 6.8 ± 4.4 years. Follow-up duration was longer in the complex F-CIED group compared to the simple F-CIED group (8.8 ± 4.2 vs. 4.8 ± 4.7 years; $p = .03$) due to the death of seven patients with simple F-CIED from heart failure ($n = 3$), lung cancer ($n = 2$), and renal failure ($n = 2$). There were 17 femoral

TABLE 2 Baseline patient demographics at the time of first femoral pacing system implantation

	Overall femoral ($n = 31$)	Simple femoral ($n = 21$)	Complex femoral ($n = 10$)	Simple vs complex p value
Demographics				
Age at implant (years)	56 ± 20	58 ± 19	52 ± 22	.48
Gender (%) female	33	36	30	.73
LVEF (%)	45 ± 16	52 ± 12	34 ± 16	<.01*
NYHA class I–II	90% (28)	100% (21)	70% (7)	<.01*
NYHA class III–IV	10% (3)	0% (0)	30% (3)	.03*
QRS duration (ms)	119 ± 30	112 ± 26	131 ± 34	.20
Etiology				
Congenital heart disease	35% (11)	38% (8)	30% (3)	1.0
Ischaemic heart disease	23% (7)	19% (4)	30% (3)	.65
Non-ischemic CM	16% (5)	4% (1)	30% (3)	.09
Inherited channelopathy	3% (1)	0% (0)	10% (1)	.32
Co-morbidities				
Hypertension	26% (8)	24% (5)	30% (3)	1.0
Diabetes	19% (6)	19% (4)	20% (2)	1.0
Chronic kidney disease	32% (10)	43% (9)	10% (1)	.10
Anticoagulation				
Warfarin	52% (16)	48% (10)	60% (6)	.02*
NOAC	6% (2)	4% (1)	0% (0)	1.0

Values are mean ± SD or % (n). Simple femoral = pacemakers, complex femoral = ICD and CRT. CM, cardiomyopathy; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; NOAC, novel oral anticoagulant; NYHA, New York Heart Association; SD, standard deviation.
*Statistically significant difference between simple and complex femoral groups at $p < .05$.

generator changes (six simple devices, 11 complex devices), two system upgrades (VVI PPM to CRT-P and ICD to CRT-D), six generator repositions and six femoral wound washouts/debridement's during the follow-up period. Eight femoral extraction procedures were subsequently required in seven patients.

3.4 | Early (within 30-day) complications

Table 3 summarizes the early and late complications. The early complication rate was 6.5% with a trend toward more complications among complex F-CIED, albeit with small numbers for comparison 4.8% versus 10%. Early F-CIED complications consisted of an RA lead displacement in a dual chamber pacemaker and both RA and RV lead displacement in a dual chamber ICD. Leads were successfully repositioned in both cases.

3.5 | Late (after 30 days) complications

The late complication rate was 29.0% with an incidence rate per 100 person-year of 5.29. There was a significantly higher complication rate with complex F-CIED versus simple F-CIED (60% vs. 14.3%; $p = .02$). The time from first device implant to first late complication was a median of 4 years (range 2—11). Lead measurements remained stable throughout follow-up.

Three patients in the simple F-CIED group had late complications. A patient with an AAI pacemaker experienced persistent erythema, skin breakdown, and oozing of serous fluid within 1 year of generator replacement and 6 years following femoral implant. Wound swabs were positive for *Enterococcus* and despite IV antibiotics and generator repositioning due to device pre-erosion, within 1 year there was repeat wound breakdown and erosion requiring whole system extraction. The second patient with a VVI pacemaker experienced wound breakdown resulting in device erosion requiring extraction 2 months following implant. The system was removed with manual traction of the lead. A third patient had RA lead failure 4 years after femoral generator box change. The eight late complications in the simple femoral group were due to two RA and six RV lead failures requiring implantation of new leads.

Six patients in the complex F-CIED group had late complications. Four were due to recurrent breakdown of the femoral wound, resulting in device ($n = 3$) and lead ($n = 1$) erosion despite antibiotic treatment. Three patients experienced wound issues following generator replacement and one was following device upgrade. A patient with a CRT-D required device repositioning 1 year after generator replacement due

TABLE 3 Device related early (<30 days) and late (>30 days) complications

	Overall femoral ($n = 31$)	Simple femoral ($n = 21$)	Complex femoral ($n = 10$)
Early complications			
% of patients	6.5	4.8	10.0
Total number of complications	2 (6.5)	1 (4.8)	1 (10.0)
RA lead displacement	1 (3.2)	1(4.8)	0
RA and RV lead displacement	1 (3.2)	0	1(10)
Late complications			
% of patients	29.0	14.3	60.0*
Total number of complications	12 (38.7)[a]	4 (19.0)[b]	8 (80.0)[c]
Wound infection/erosion	7 (22.6)	3 (14.3)	4 (40.0)
Embolic strokes	1 (3.2)	0	1 (10.0)
Infective endocarditis	2 (6.5)	0	2 (20.0)
Generator migration	1 (3.2)	0	1 (10.0)
Atrial lead failure	1 (3.2)	1 (4.8)	0

Values are *n* (%) unless stated. Simple devices = pacemakers, complex devices = ICD and CRT. CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator; RA, right atrial; RV, right ventricular.

*Statistically significant difference between complex and simple femoral groups at $p < .05$.

[a]Two late complications occurred in three patients.

[b]Two late complications occurred in one patient.

[c]Two late complications occurred in two patients.

to generator migration towards the groin crease causing persistent pain. This was followed by recurrent wound infection with wound swabs positive for proteus and anaerobes requiring intravenous antibiotics and wound debridement. Repeated infection resulted in wound breakdown and device erosion 4 months later requiring extraction.

A second patient presented with erythematous skin and recurrent breakdown of subcutaneous tissue (wound cultures grew *Staphylococcus epidermis*). A third patient presented with an open wound and protruding pacing wire from the femoral site with blood cultures positive for coagulase negative *Staphylococcus*. Both underwent two wound revisions (one had the generator placed in an antibacterial envelope) and intravenous antibiotic management but eventually required full system extraction. The fourth patient experienced recurrent wound breakdown 2 years after a femoral upgrade to CRT-P. Following a wound revision there was further wound infection (groin swabs positive for *Staphylococcus aureus*), breakdown of subcutaneous tissue and erosion of the LV lead requiring extraction of the LV lead (positive for *Pseudomonas aeuroginosa* and *Escherichia coli*). Three years later extraction of the remaining RV lead and generator was required due to infective endocarditis.

A patient with double inlet left ventricle and a defibrillation lead in a univentricular heart had repetitive systemic thrombi 10 years following femoral implant despite therapeutic anticoagulation. One patient died following infective endocarditis due to retained leads 9 years after index femoral ICD implant and 2 years after generator repositioning. There were no lead related complications or instances of IVC thrombosis/occlusion in patients with complex devices.

3.6 | Extraction of chronic femoral leads

Seven extraction procedures of chronic femoral leads were performed in six patients with the removal of 13 leads and six generators, summarized in Table 4. Whole system extractions of chronic devices were performed for one single chamber pacemaker, two dual chamber ICDs, two CRT-Ds, and one CRT-P. The extracted leads had been in situ for a median of 7 (6–11) years. All patients had undergone multiple femoral procedures prior to extraction including generator replacements, device upgrades, generator repositioning and wound debridement (median 3, range 2—4). A laser sheath (Spectranetics, Colorado Springs, CO, USA) was used for the extraction of all leads in six procedures and one LV lead was extracted by manual traction. Laser sheaths were used in a similar fashion to lead extraction performed via superior access. Operators noted the primary area of fibrosis requiring more laser sheath use was in the IVC region. Complete procedural success was obtained for each case without complications, including no retained lead fragments or requirement for vascular repair. Figure 2 shows the extraction of a dual coil ICD lead from the right femoral vein.

4 | DISCUSSION

This study reports the combined procedural and long-term experience of two referral centers with F-CIED placement. The major finding is the substantial absolute risk of long-term complications,

TABLE 4 Extraction of chronic femoral devices

Device		Years from femoral implant to extraction	Years from most recent procedure to extraction	Complication requiring extraction	Leads extracted	Leads in situ (years)	Extraction technique	Vascular repair required	Complications	Further management
ICD		10	10 [a]Index procedure	Embolic strokes due to lead thrombus	2	10	Laser sheath	No	None	Subcutaneous ICD implanted
CRT-P[b]	1	9	2 [a]Upgrade from VVI PPM	Wound infection and LV lead erosion	1	7	Manual traction	No	None	Femoral VVI system remained in place
	2	12	3 [a]Extraction of LV lead	Infective endocarditis	1	10	Laser sheath	No	None	CRT-P implanted via right pectoral route
CRT-D		7	1 [a]Generator replacement	Wound infection and generator erosion	3	7	Laser sheath	No	None	CRT-P implanted via right pectoral route
ICD		11	2 [a]Generator replacement	Wound infection and generator erosion	2	11	Laser sheath	No	None	CRT-D implanted via left pectoral route
CRT-D		6	1 [a]Generator replacement	Wound infection and generator erosion	3	6	Laser sheath	No	None	No replacement device implanted
PPM		6	1 [a]Generator replacement	Wound infection and generator erosion	1	6	Laser sheath	No	None	AAI PPM re-implanted on contralateral femoral side

AAI, single chamber atrial; CRT-D, cardiac resynchronization therapy – defibrillator; CRT-P, cardiac resynchronization therapy – pacemaker; DCM, dilated cardiomyopathy; DILV, double inlet left ventricle; ICM, ischemic cardiomyopathy; LV, left ventricular; PPM, pacemaker; VVI, single chamber ventricular.

[a]Last procedure prior to extraction.

[b]This patient had two extraction procedures.

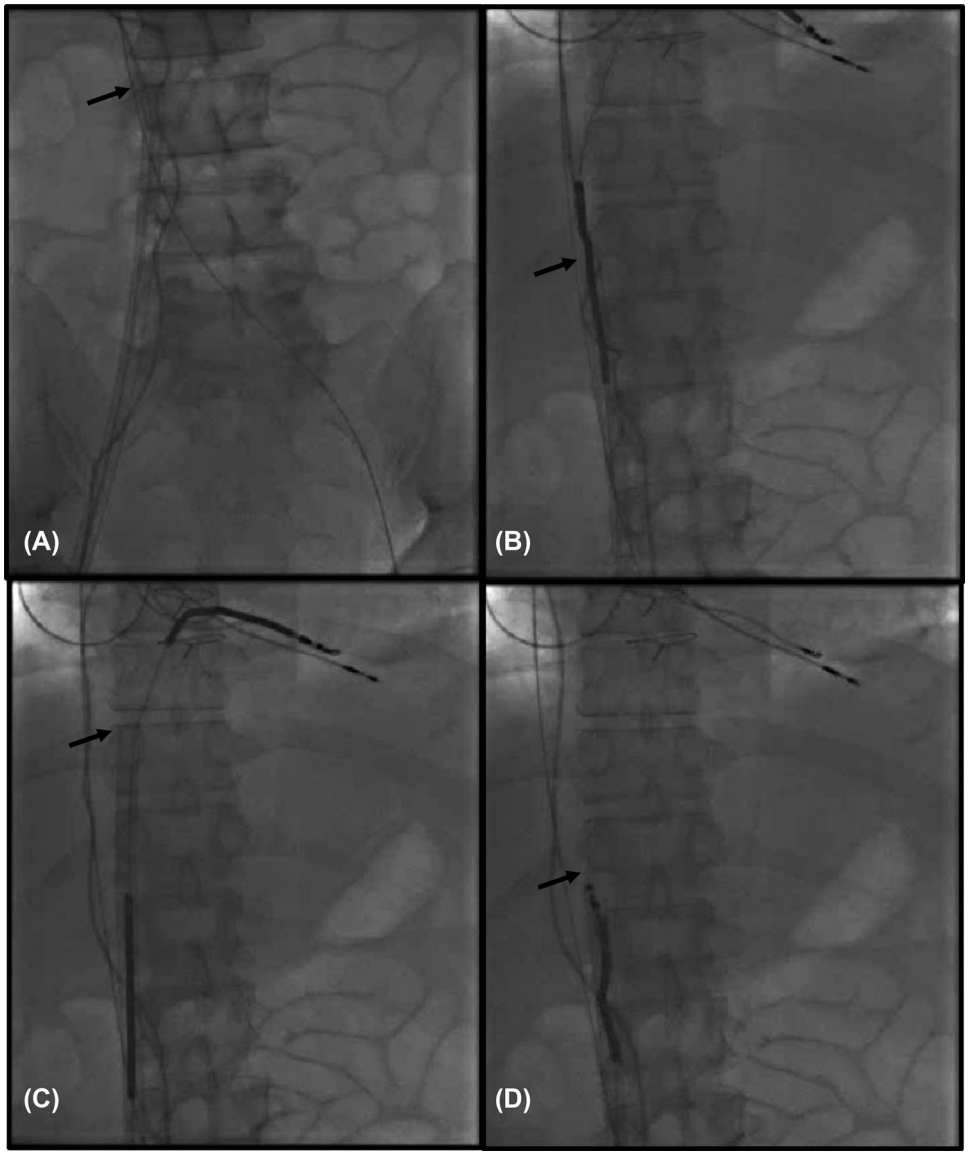

FIGURE 2 Extraction of a femoral dual coil ICD lead. Extraction of a dual coil ICD lead using a laser sheath in a patient with a femoral dual chamber ICD. (A) A 14F Spectranetics laser sheath inserted via the right femoral vein was advanced over the proximal portion of the lead. (B) The laser sheath was advanced over the proximal coil of the ICD lead. (C) Traction on the laser sheath pulled the lead tip from the RV apex. (D) Successful extraction of the lead without complication. (Arrow denotes tip of the laser sheath). ICD, implantable cardioverter defibrillator; RV, right ventricular

particularly among complex F-CIEDs, pointing towards the need for ongoing technical improvement around femoral wound management. We also note acceptable early complication rates, and the feasibility of laser-assisted extraction. Taken together, our results support continued selective use of F-CIED placement for patients ineligible for leadless or subcutaneous options. At the same time, patients should be cautioned about potential long-term risks, and followed closely post-procedure to ensure early attention to wound complications.

Pacemaker implantation via the femoral vein was first described by Ellestad et al.[6] to provide permanent pacing in patients with no superior venous access, recurrent pocket erosion/infection, or radiotherapy. In the early experience lead displacement occurred in 21% of passive fixation atrial leads[7] and recent studies with active fixation leads reported a 20% displacement rate.[8] However, a 1% displacement rate was demonstrated in 99 pediatric patients[9] and our results show a similarly low displacement rate of 6% with femoral leads. Importantly, there was no early displacement of femoral LV leads placed in the coronary sinus. This is notable as LV leads implanted via the superior route typically have a 3% displacement rate.[22] The inferior approach via the femoral route may facilitate better lead stability within the coronary sinus but requires confirmation with a larger sample utilizing modern quadripolar and/or active fixation LV leads.

Our study also builds on the limited available long-term follow-up of femoral pacemakers previously reported in both adult[11] and pediatric[9] cohorts. A 10-year follow-up of 50 adult patients with femoral pacemakers reported an 11% extraction rate due to device erosion or

infection[11] and others have reported 7%–25% extraction rates.[8–10] This is similar to the 10% femoral pacemaker extraction rate in this study.

This is the first study to provide long-term follow-up of femoral ICDs and CRTs which has previously been limited to case reports with 2 years follow-up. Our study shows over 7 years there is a significant risk of late complications, with 60% experiencing a complication. In particular, femoral wound breakdown causing device erosion occurred in 40% of patients after generator replacement or device upgrade. Despite multiple wound revisions, antibiotic management, and washout procedures all proceeded to extraction. The higher complication rate of complex femoral devices highlights the risk of femoral ICD and CRT generator positioning. The different microbial flora of the groin area compared to the chest[23] combined with the larger size of ICD and CRT generators may contribute to poorer wound healing resulting in wound breakdown leading to erosion. Particular consideration should be taken during additional femoral procedures to reduce the incidence of wound infections. This could include stringent application of standard anti-infective processes, the fixation of generators to quadriceps fascia to minimize generator movement and the routine use of bio-absorbable antibacterial envelopes for initial F-CIED implantation as well as additional procedures.

To our knowledge, this is the first paper to report the extraction of chronic femoral leads of simple and complex devices. The extraction of five femoral pacemakers has been described but with a mean duration in situ of 2 years.[11] Longer lead implant duration consistently predicts major perioperative complications from lead extraction procedures with an 8% increase per year.[24] The successful extraction without complication of 14 leads implanted for 8 years in this study therefore shows extraction of femoral leads is feasible, and appears safe, but requires validation with a larger group of patients. Laser sheaths can be used in a similar fashion to extractions via superior access, but care should be taken when applying laser energy in the IVC area. Three patients with complex devices were re-implanted with transvenous pectoral systems following extraction. The initial indications for femoral pacing were recurrent erosion and infection of pectoral-sited devices. With three years of uncomplicated follow-up of their re-implanted devices it could be that a prolonged period of recovery and healing of the pectoral region has allowed successful re-implantation.

4.1 | Limitations

Our study includes certain limitations. Patients with F-CIEDs remain a rare cohort, and large-scale randomized trials in these patients are impractical. Therefore, the strength of conclusions in this study is limited by the small sample size and retrospective design. The sample itself includes heterogeneous patients, although generic implant considerations were consistent. Advances in technology arising through our study period, such as leadless pacing, subcutaneous extravascular ICDs, conduction system pacing, and the wider adoption of standard techniques and data supporting the safety of venoplasty/stenting for patients with SVC obstruction[25,26] may influence reproduction of these data in a contemporary cohort. Our results reflect those achieved by experienced operators at referral centers, working alongside dedicated anesthesia staff and with cardiac surgical back-up as needed. Thus, these findings should be extrapolated cautiously to other settings.

5 | CONCLUSIONS

There are low rates of early complications but an increased risk of late complications following the implantation of CIEDs via the femoral route. This is more pronounced with ICDs and CRTs and manifests as poor wound healing, wound infection, and breakdown leading to generator erosion. Extraction of chronic femoral leads can be performed without complications by experienced operators.

AUTHOR CONTRIBUTIONS

Samuel Griffiths, Conception, data collection & analysis, drafting and critical revision, and responsible for overall content. Jonathan M. Behar, Conception, drafting, critical revision, and final approval of the article. Daniel B. Kramer, Drafting, critical revision, and final approval of the article. Mike T. Debney, Conception, data collection, and data analysis. Christopher Monkhouse, Alicia Y. Lefas, Martin Lowe, and Fouad Amin, Data collection and data analysis. Emily Cantor, Vennella Boyalla, and Nabeela Karim, Critical revision of the article. Jan Till, Vias Markides, and Jonathan R. Clague, Data collection and critical revision of the article. Tom Wong, Data collection, drafting, critical revision, final approval of the article, and responsible for overall content.

CONFLICT OF INTERESTS

The authors have no conflicts of interest to disclose.

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