Acta Cardiologica

ISSN: 0001-5385 (Print) 0373-7934 (Online) Journal homepage: https://www.tandfonline.com/loi/tacd20

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To cite this article: Pieter-Jan Geselle, Ruben Poesen, Filip Rega, Pieter Koopman, Dieter Nuyens, Hein Heidbuchel & Rik Willems (2012) Transvenous extraction of pacing and defi brillator leads - a single-centre experience, Acta Cardiologica, 67:6, 641-648, DOI: 10.1080/AC.67.6.2184666

To link to this article: https://doi.org/10.1080/AC.67.6.2184666

Published online: 23 May 2017.

Transvenous extraction of pacing and defibrillator leads - a single-centre experience

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Purpose Worldwide, the number of transvenous extractions of chronically implanted endocardial leads rapidly increases. Despite great technical progress, lead extraction remains a challenging procedure with possible life-threatening complications. We present the success and complication rate of lead extractions in the University Hospitals Leuven, and investigated a possible relationship between the use of powered sheaths and lead type, fixation, location and implantation time.

Methods We present an observational retrospective cohort study of 157 patients admitted to the University Hospitals Leuven between January 2005 and December 2010, for the transvenous removal of a total of 259 endocardial leads.

Results Complete procedural success was achieved in 92% of patients (n = 144). Of all leads, 94% (n = 243) were completely extracted. Only in 5 patients (3%), lead extraction failed. Leads that could not be removed were significantly older (134.1 ± 90.7 months vs. 73.1 ± 61.9 months; *P* = 0.02). In the other 8 patients the leads were partially removed with a remaining major retained lead fragment in 2 and a minor fragment in 6 patients. Major procedural complication rate was 2.5% (n = 4). There were no procedure-related deaths. Powered sheaths were used significantly more for the extraction of defibrillator leads (51%) (vs. pacing leads (33%; *P* = 0.015)) and right ventricular located leads (43%) (vs. other location (28%; *P* = 0.011)). However, when comparing the need of powered sheaths for the extraction of right ventricular defibrillator leads vs. right ventricular pacing leads, only a trend to higher use was noticed (51 vs. 39%; *P* = 0.146). Powered sheath use was not related to fixation type. Leads that required the use of a powered sheath were implanted significantly longer (112 ± 69.5 months vs. 41.7 ± 33.7 months; *P* = 0.001).

Conclusions Chronically implanted endocardial leads can be transvenously extracted in a high number of cases and with a low risk of procedural complications. Powered sheaths proved to be a helpful tool to extract leads that could not be removed by manual traction. Powered sheaths are necessary for leads with longer implantation duration and are more often used for the extraction of defibrillator leads.

Keywords *Lead extraction – laser – outcome – pacemaker – implantable cardioverter/defibrillator.*

INTRODUCTION

The number of extractions of chronically implanted endocardial leads performed worldwide, increases in direct relationship with the growing number of cardiovascular implantable electronic devices (CIEDs) implanted. As the patients and the CIEDs age, there is an increasing risk of device problems, leading to the necessity of removal of some device components for a variety of reasons including lead malfunction, venous occlusion, infection, and perforation.

After implantation, endocardial leads undergo fibrotic encapsulation, complicating trans-venous lead extraction due to associated risks[1,2]. In the late 1980s the development of advanced tools and techniques such as the use of locking stylets and powered sheaths led to an important progress in the safety and effectiveness of transvenous lead extraction. The increasing experience of physicians and the intensive training programmes, including simulator-training programmes, have also contributed to better outcomes[3].

Transvenous lead extraction, however, remains a technically challenging procedure with a risk of life-

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Received 22 February 2012; revision accepted for publication 30 August 2012.

threatening complications. Consequently it is of high importance that physicians and hospitals offering lead extraction evaluate their experience on a regularly base, through clinical outcome measurement. In this paper we present our single-centre experience of pacemaker and implantable cardioverter/defibrillator (ICD) lead extraction using a variety of methods, including powered sheath-assisted extraction (Spectranetics® laser-assisted and Cook® Evolution sheaths). We report the success and complication rate of all extraction procedures in the University Hospitals of Leuven. We wanted to identify clinical variables predicting the necessity to use a powered sheath during extraction.

METHODS

We present an observational retrospective cohort study of 157 patients admitted to the University Hospitals Leuven between January 2005 and December 2010, for the transvenous removal of a total of 259 CIED leads. After removal of the device the leads were freed up and a purse-string suture was placed. A standard PM stylet was inserted and in case of an active fixation mechanism the screw was retracted. Thereafter gentile traction was performed. If it was clear that this traction was performed on the lead tip it was maintained up to a minute. If traction was not performed on the lead tip due to adhesions or because the lead could not be removed after a minute of gentile traction, a locking stylet was inserted and traction was maintained up to 15 minutes. If with a locking stylet traction was not performed on the lead tip or the lead could not be removed after 15 minutes a powered sheath was chosen. Data were collected from patient files, entered into a computerized database and retrospectively analysed.

1. Definitions

Indications and complications were classified according to the Heart Rhythm Society (HRS) expert consensus[3]. Complete procedural success was defined as the complete removal of all device parts in one patient. There was partial procedural success with minor retained lead fragment when only – one or more – lead tips could not be extracted; partial procedural success with major retained lead fragment was when one or more inner coils were left in situ. When at least one transvenous lead could not be removed, the procedure was categorized as a failed procedure. Clinical success was defined as the removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead that did not negatively impact on the outcome goals of the procedure. This may be the tip of the lead or a small part of the lead (conductor coil, insulation, or the latter two combined) when the residual part did not increase the risk of perforation, embolic events, perpetuation of infection or cause any undesired outcome.

2. Statistics

Continuous variables were compared using the Students *T*-test. For proportional variables the chi-square test was used. All *P* values were two-tailed, and $P < 0.05$ was considered to be statistically significant.

RESULTS

1. Subjects

Patient demographics and indications for lead extraction are shown in table 1. Main primary indications for cardiac pacing were sick sinus syndrome (SSS) and 3rd degree atrioventricular (AV) block, whereas almost half of the ICDs had been implanted for secondary prevention after malignant ventricular tachycardia or sudden cardiac arrest (SCA) survival. Patients with ICDs were significantly younger than patients with pacemakers (58.2 ±14.6 y, range 19-84 y vs. 67 ± 16.6 y, range 15-89 y; $P < 0.001$). The indications for extraction in our experience were mainly lead dysfunction and CIED-related infection. Almost half of the patients (n = 69 (44%)) were referred from other hospitals. Of all procedures, 87 (55%) were performed in the operating room, the remaining in the cath-lab.

Of a total number of 259 leads, 99 (38%) were extracted with the use of a pacemaker (PM) stylet. In 4 (2%) the combination of a PM stylet and outer sheath was used. In 60 (23%) leads only a locking stylet was used. In 95 (36.5%) leads a powered sheath was used (91 Spectranetics SLS® laser-assisted sheaths, 4 Cook Evolution® sheaths). Of all leads, 55 (21.2%) were defibrillator leads. More lead characteristics are shown in table 2.

Leads approached with a powered sheath (Spectranetics SLS® laser sheath + Cook Evolution® sheath) were significantly longer implanted (112 ± 69.5 vs. 26.4 ± 32 months; $P < 0.001$). We performed an additional analysis where we excluded all leads that had been implanted less than one year before removal and were removed only by manual traction, since these procedures are considered to be "lead removals" rather than "lead extractions" in the expert consensus statement[3]. The implantation duration remained significantly longer in leads extracted with a powered sheath (112 ± 69.5 vs. 41.7 ± 33.7 months; $P < 0.001$) (table 3).

Table 1 Patient characteristics

Patients (n, %)		
Sex	Men	100 (68%)
Age (mean, median, IQR, range; years)		63.4 (67, 24, 15-89)
History of cardiovascular disease	Hypertension	37 (24%)
	Coronary heart disease	48 (31%)
	Valvular heart disease	25 (16%)
	Congestive heart failure	46 (29%)
	Congenital heart disease	5 (3%)
	Arrhythmogenic heart disease	13 (8%)
History of cardiac intervention	PCI	20 (13%)
	Coronary artery bypass surgery	15 (10%)
	Valvular surgery	15 (10%)
	Heart transplantation	3 (2%)
	Correction congenital heart disease	6 (4%)
History of other comorbidity	NIDDM	10 (6%)
	IDDM	11 (7%)
	Rheumatoid arthritis	3 (2%)
	COPD	8 (5%)
	Dementia	1 (0.5%)
	Renal dialysis	3 (2%)
	Renal transplant	2 (1%)
	Inflammatory bowel disease	1 (0.5%)
Indication for ICD (n, % ICD)	VT/VF arrest survival	27 (42%)
	1° prevention ischaemic CMP	15 (23%)
	1° prevention non-ischaemic CMP	12 (19%)
	1° prevention arrhythmogenic heart disease	10 (16%)
	Total ICD = 64 (41% of all CIEDs)	
Indication for PM (n, % PM)	Sick sinus syndrome	40 (43%)
	2nd degree AV block	8 (9%)
	3rd degree AV block	28 (30%)
	AF with pauses	10 (11%)
	Other	9 (10%)
	Total PM = 93 (59% of all CIEDs)	
Indication for extraction	Lead dysfunction	66 (42%)
	Local infection	56 (35.5%)
	Systemic infection	28 (18%)
	Upgrade to CRT	6 (4%)
	Perforation	1 (0.5%)
Total number of leads to be extracted (mean ± SD, range)		1.6 ± 0.7 (1-5)
Total procedure time (mean ± SD, median, IQR, range; minutes)¶	All	109 ± 49 (95, 45, 30-260)
	ICD	109 ± 46 (98, 40, 30-240)
	Pacemaker	109 ± 51 (95, 55, 50-260)
Complete procedural success		144 (92%)
Major rest		2 (1%)
Minor rest		6 (4%)
Failure		5 (3%)
		Total patients = 157 (100%)

IQR: interquartile range, PCI: percutaneous coronary intervention, (N)IDDM: (non) insulin-dependent diabetes mellitus, COPD: chronic obstructive pulmonary disease, ICD: implantable cardioverter-defibrillator, VT: ventricular tachycardia, VF: ventricular fibrillation, CMP: cardiomyopathy, CIED: cardiac implantable electronic device, PM: pacemaker, AV: atrioventricular, AF: atrial fibrillation, CRT: cardiac resynchronization therapy, SD: standard deviation.

¶ In 36 patients (23%) procedure time had not been registered.

Table 2 Lead characteristics

Approach	Subclavian vein (n, %)	256 (99%)
Lead implantation time (mean ± SD, median, IQR, range; months)		58 ± 64 (33.7, 79, 0.1-317.4)
Atrial pacemaker	92 (36%)	81 (88%) active fixation 11 (12%) passive fixation
Ventricular pacemaker	98 (38%)	6 (6%) active fixation 92 (94%) passive fixation
Ventricular ICD	55 (21%)	55 (100%) active fixation
LV lead (coronary sinus)	14 (5%)	14 (100%) passive fixation
	Total leads = 259 (100%)	

LV: left ventricular.

Table 3 Statistical analysis on the use of powered sheaths

	Powered sheath (n = 95)	Non-powered sheath (n = 163)	*p* value
Total procedure time (median, IQR, range; minutes) ¶	129.6 ± 48.3 (120, 77.5, 50-260)	94.9 ± 42.5 (90, 60, 30-240)	< 0.001 §
Lead implantation time (median, IQR, range; months)	112 ± 69.5 (101.8, 90, 16.2-317.4)	26.4 ± 32 (15.9, 30.4, 0.1-175.7)	< 0.001 §
Lead implantation time* (median, IQR, range; months)	112 ± 69.5 (101.8, 90, 16.2-317.4)	41.7 ± 33.7 (29.7, 32, 4-175.7)	< 0.001 §
ICD lead vs. PM lead	51% vs. 33%	49% vs. 66%	0.015 [a]
Ventricular ICD vs. Right ventricular PM	51% vs. 39%	49% vs. 61%	0.146 [a]
Right ventricular vs. other location	43% vs. 28%	57% vs. 72%	0.011 [a]
Active vs. passive fixation	38% vs. 36%	62% vs. 64%	0.779 [a]

¶ In 36 (13 powered sheath, 23 non-powered sheath) patients, the procedure time had not been registered.
* Corrected for leads that were implanted < 1 y and manually extracted with PM stylet ("lead removal") (3).
§ Student t test.

Table 4 Success rate

	Extraction tool	Complete removal
Atrial PM	Powered sheath ¥	26/29 (90%)*
	Locking stylet	16/16 (100%)
	PM stylet + outer sheath	1/1 (100%)
	PM stylet	45/45 (100%)
	None	0/1 (0%)
Ventricular PM	Powered sheath £	31/38 (83%)*
	Locking stylet	30/32 (94%)
	PM stylet + outer sheath	1/1 (100%)
	PM stylet	27/27 (100%)
Ventricular ICD	Powered sheath ¡	27/28 (96%)
	Locking stylet	11/11 (100%)
	PM stylet + outer sheath	1/1 (100%)
	PM stylet	15/15 (100%)
LV lead (coronary sinus)	Locking stylet	1/1 (100%)
	PM stylet + outer sheath	0/1 (0%)
	PM stylet	11/12 (92%)
		Total = 243/259 (94%)

*Laser-assisted extraction of one atrial and one ventricular PM lead first failed, but was successful at the second attempt with a femoral approach.
¥28 laser sheath and 1 Evolution® sheath.
£35 laser sheath and 3 Evolution® sheath.
¡All 28 were laser sheath.

2. Success rate

Complete procedural success was achieved in 92% (n = 144) of the patients, partial success with a minor retained fragment in 4% (n = 6), partial success with a major retained fragment in less than 1% (n = 2), and extraction failed in 3% (n = 5) of all patients. The clinical success rate was 99% (n = 155).

A total of 243 (94%) leads were extracted completely. Of 8 (3%) leads, the tip could not be removed, whereas the inner coil was left behind in 2 (1%) leads. Six leads (2%) could not be removed at all. Details of incomplete extractions are shown in table 4 & 5. More than half of the incomplete lead extractions occurred in the first 60 patients. Laser-assisted extractions of one atrial and one ventricular PM lead, performed in one and the same procedure, failed at first, but the leads were successfully removed through a femoral approach in a second procedure. In one patient a single lead extraction was not attempted, since the pre-procedural radiography showed a complete fracture. The proximal part of the lead was located endovascularly, and could not be reached. Since the procedure was planned for lead dysfunction and the lead fragment was not causing arrhythmia, femoral extraction was not attempted.

Leads that were successfully removed were implanted for a shorter period than leads that could only be partially removed or failed to be removed: 54.6 ± 61.2 (median 32.9; range 0.1-317.4) vs. 90.2 ±76.1 months (median 39.6, range 32.9-175, *P* vs. successful removal = 0.075) and 134.1 ± 90.7 months (median 146.5, range 11-259, *P* vs. successful removal = 0.002), respectively. After excluding from statistical analysis all leads that had been implanted less than one year before removal and were removed only by manual traction, the implantation duration of successfully removed leads was 73.1 ± 61.9 months (median 55.4, range 4-317.4) and remained significantly shorter vs. failed extractions (*P* = 0.02). Powered sheaths were never used for leads implanted less than 16.2 months. Extraction with manual traction only was in our experience never possible in leads implanted longer than 97.2 months (figure 1).

3. Complications

There were no procedure-related deaths, however, the 30-day mortality rate was 2.5% (n = 4). The first patient who died, was known with severe ischaemic cardiomyopathy, had primarily been admitted for CIED-related sepsis, and died 2 weeks post-procedure due to

Table 5 Incomplete lead extractions

Sex	Age (y)	Referred	CIED indic	Extr. indic	Place	Lead type	LIT (mths)	Tool	Outcome	Management
M	88	Yes	AVB 3rd degree	Local infection	OR	Active atrial PM	175	Laser	Tip rest	Conservative
						Passive ventr. PM	175	Laser	Tip rest	Conservative
M	81	No	Other	Lead dysfunction	Cath	Passive ventr. PM	125	Evolution®	Tip rest	Conservative
M	79	Yes	SSS	Local infection	OR	Active atrial PM	146	Laser	Failure	Conservative
						Passive ventr. PM	146	Laser	Failure	Conservative
M	73	Yes	Other	Systemic infection	OR	Passive ventr. PM	216	Laser	Failure	Surgery
M	75	Yes	AVB 2nd degree	Local infection	OR	Active atrial PM	40	Laser	Tip rest	Conservative
						Passive ventr. PM	40	Laser	Tip rest	Conservative
M	71	Yes	AF + pauses	Local infection	Cath	Passive ventr. PM	21	Locking stylet	Tip rest	Conservative
M	72	No	VT/VF arrest	Lead dysfunction	Cath	Passive LV PM	33	PM stylet	Inner coil rest	Conservative
M	67	No	1° prev. NICMP	Lead dysfunction	Cath	Passive LV PM	11	Outer sheath	Failure	Surgery
M	44	No	VT/VF arrest	Lead dysfunction	OR	Active ventr. ICD	38	Laser	Tip rest	Conservative
F	44	Yes	AVB 3rd degree	Lead dysfunction	OR	Passive ventr. PM	259	Laser	Failure	Conservative
M	38	No	AVB 3rd degree	Local infection	OR	Passive ventr. PM	240	Laser	Inner coil rest	Conservative
M	37	No	AVB 3rd degree	Lead dysfunction	OR	Active ventr. PM	116	Locking stylet	Tip rest	Conservative
M*	79	Yes	SSS	Lead dysfunction	Cath	Active atrial PM	26	none	Failure	Conservative

Indic: indication, extr.: extraction, LIT: lead implantation time, AVB: atrioventricular block, AF: atrial fibrillation, prev.: prevention, NICMP: non-ischaemic cardiomyopathy, OR: operating room, Cath: catheterization lab.

*This was the patient with the complete lead fracture, in which case no extraction was attempted.

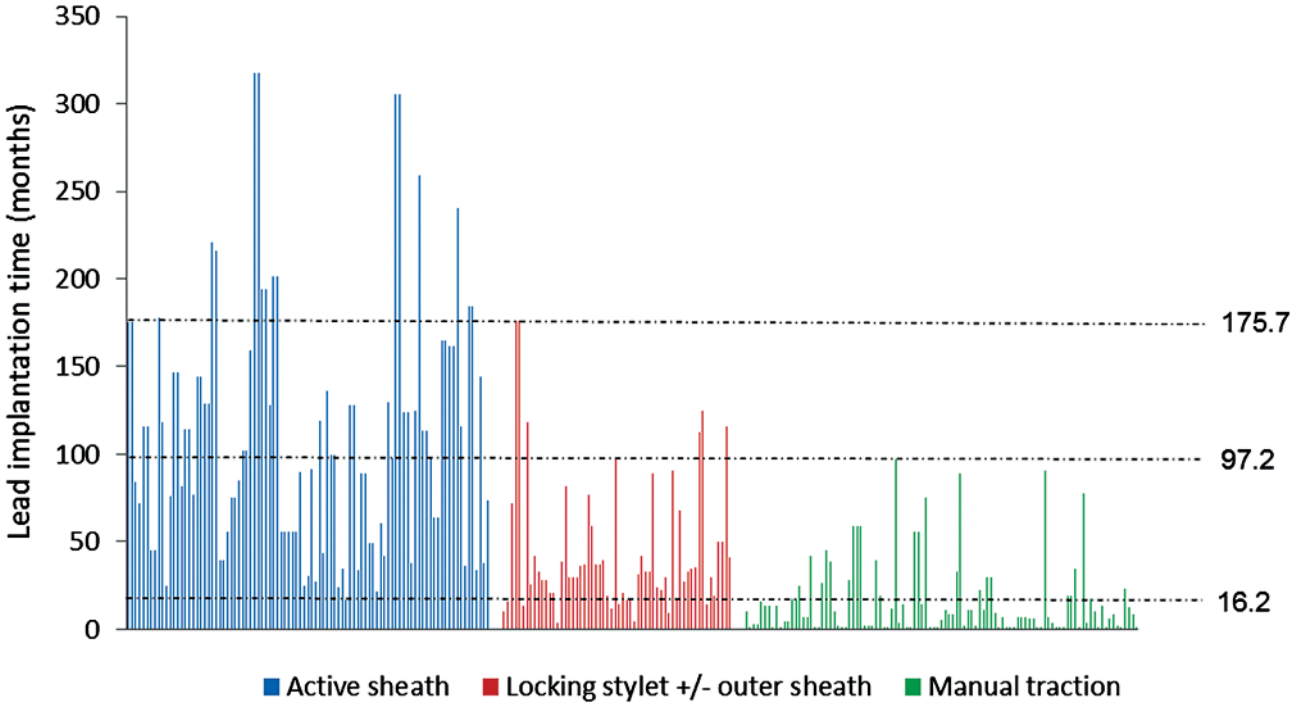

Fig. 1 Lead implantation time and extraction tool
Powered sheath use was not necessary for leads implanted < 16.2 months. Extraction through manual traction only was not possible in leads implanted > 97.2 months.

cardiogenic shock post-extraction of his cardiac resynchronization (CRT) device. The second patient was known with severe non-ischaemic heart failure, was admitted at intensive care for septic shock with multiple organ failure, and died a week after the removal of his ICD due to intracranial haemorrhage secondary to the intensive anticoagulation therapy necessary for his left ventricular assist device. The third patient was known with severe cardiomyopathy and chronic renal dialysis, had been admitted for CIED-related sepsis and died 20 days post-procedure after difficult weaning from mechanical ventilation and sudden neurologic deterioration. The fourth patient was 84 years old, had no serious medical history and had been admitted for CIED-related sepsis. She died 48 hours post-procedure due to septic shock. Major procedural complication rate not leading to death was 2.5%: one acute renal failure in need of dialysis, one septic shock, one stroke, one life-threatening arrhythmia. In the surviving patient with septic shock as major complication, the indication for extraction was severe sepsis due to CIED-related infection. The patient with stroke due to septic embolism was later diagnosed with patent foramen ovale.

There were four minor procedural complications: one deep vein thrombosis, one pulmonary embolism, one mediastinal bleeding and one haemorrhagic gastric ulcer. The patient with the gastrointestinal bleeding 10 days post-procedure was treated with low-dose acetylsalicylic acid. The pulmonary embolism and mediastinal bleeding were both considered minor, because they only caused chest pain and were limited to minor emboli and a small effusion around the subclavian vein detected on CT. Both were associated with failed lead extraction, with a lead implantation time of 124 and 146 months, respectively. Both were pacemaker patients.

4. Lead type

There was a significantly higher use of powered sheaths in the transvenous extraction of defibrillator leads when compared to pacemaker leads (51% vs. 33%, $P=0.015$). Powered sheath use was also significantly higher in the extraction of right ventricular located leads (43.1% vs. 27.6% other location, $P=0.011$). There was only a trend of higher powered sheath use in the extraction of right ventricular defibrillator leads, when compared to right ventricular PM leads (50.9% vs. 38.8%, $P=0.146$). No relationship could be demonstrated between the use of powered sheaths and lead fixation type (37.6% active vs. 35.9% passive, $P=0.779$) (table 3).

DISCUSSION

We report our single-centre experience with lead extraction. Indications for extraction in our centre were

similar to recent major studies[4-6]. The complete procedural success rate in our series was 92%. The rate of complete lead removal was 94%, which is slightly lower than 96.5-98.4% reported by other recent studies[4-7]. This can be explained by the fact that in case of an incomplete or failed procedure for lead dysfunction or limited local infection we opted only to perform additional femoral or surgical extraction attempts if clinically indicated (table 5). Our clinical success rate was actually 99%. The policy after incomplete lead extraction is determined by the extraction indication and patient characteristics. In systemic infection, all device components have to be extracted from the endovascular space. The latest HRS expert consensus puts forward to strive for complete device removal, also for local infection. However, in limited local pocket infection a minor endovascular rest is acceptable[3,8,9].

There was a clear learning curve in our experience. This is in line with former findings that the frequency of complete procedural success improves as physician experience grows, although these studies comprised mainly laser-assisted extraction[7,10,11].

Lead implantation duration was significantly higher in failed extractions and there was a trend to longer implantation duration in incompletely extracted leads. This is in accordance with other publications showing that longer implantation duration was a risk factor for incomplete extraction and failure and might be related with the extent of fibrotic encapsulation in older leads[12,13].

Other predictive variables of failure could not be demonstrated, since the number of failed extractions was too limited.

We report a 30-day mortality rate of 2.5%. Mortality was, however, not procedure-related, but due to underlying disease. The rate of major procedural complication in our series was 2.5%. This is comparable to other larger series showing 0.4-4% major complications[4-7]. Patients with CIED-related infection and vegetations larger than 2 cm were directly referred for surgical removal because of a presumably higher risk of complications performing transvenous removal.

There was a significantly higher use of powered sheaths in the extraction of ICD leads when compared to pacing leads, which is in line with the findings in a recent larger study[5]. However, there was only a trend to an increased use of powered sheaths when comparing the extraction of ICD leads vs. right ventricular PM leads. It cannot be excluded that lead location is the cause of this finding rather than lead type, since powered sheaths were significantly more used in the extraction of right ventricular located leads, when compared to other locations.

Our experience with the femoral approach for the removal of CIED leads is limited. Recent data showed similar success and complication rates of laser-assisted extractions versus femoral approach, with a longer procedure time and longer exposure to radiation in extractions through femoral approach. We had the possibility to use the femoral approach after an unsuccessful laser-assisted procedure, which might be an advantage in opting for laser-assisted extraction as first choice[14].

STUDY LIMITATIONS

This study is inherently limited by its retrospective design and relative small size.

We did not limit our analysis to the strict HRS expert consensus definition of "lead extraction", but also included "lead removals" in our lead extraction database.

CONCLUSION

Chronically implanted endocardial leads can be safely and effectively extracted using a transvenous approach, with an acceptable risk of procedural complications. Powered sheaths proved to be a helpful tool to extract leads that could not be removed by manual traction. Powered sheaths are needed for extraction of older leads. The extraction of defibrillator leads more often required the use of a powered sheath.

DISCLOSURES

RW is supported as a clinical researcher by the Fund for Scientific Research Flanders (FWO). The University of Leuven receives unconditional research funding from Boston Scientific Belgium and Medtronic Belgium. RW, DN and HH have received speakers and consultancy fees from and participated in clinical trials by different manufacturers of PMs and ICDs (Medtronic, Boston Scientific, Biotronik, St Jude Medical, Sorin).

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