

Current practice in transvenous lead extraction: a European Heart Rhythm Association EP Network Survey

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Aim	Current practice with regard to transvenous lead extraction among European implanting centres was analysed by this survey.
Methods and results	Among all contacted centres, 164, from 30 countries, declared that they perform transvenous lead extraction and answered 58 questions with a compliance rate of 99.9%. Data from the survey show that there seems to be an overall increasing experience of managing various techniques of lead extraction and a widespread involvement of cardiac centres in this treatment. Results and complication rates seem comparable with those of main international registries.
Conclusion	This survey gives an interesting snapshot of lead extraction in Europe today and gives some clues for future research and prospective European registries.
Keywords	Cardiac implantable electronic device • Complications • Infection • Lead extraction

Introduction

With the continuously expanding number of cardiac implantable electronic devices (CIEDs) implanted in Europe over recent years and patients' longer life expectancy, the need to perform lead extraction due to systemic or local infection is expected to grow.¹ Moreover the leads are clearly the weakest link in CIED treatment and, especially in the light of recent recalls, physicians have to take care of these lead complications requiring abandonment or extraction.

Lead extraction is today a specialized procedure with well-defined indications, excellent results, and few possible complications as described in several studies, guidelines, and scientific documents on pathways for training and accreditation.^{2,3}

Few centres in Europe have historically performed and reported on lead extraction; the majority have only recently faced this procedure but objective data on their activity are lacking.

The purpose of this survey is to give a reliable snapshot of today's practice in lead extraction in Europe.

Methods and results

In the first quarter of the current year, EHRA submitted to European device implanting centres two electronic questionnaires on daily practice in transvenous lead extraction (TLE) using the 2010 directory of EHRA of National Societies Coordinators, its own centre research network database (EHRA EP Wire), and databases previously used for atrial fibrillation (AF) and cardiac resynchronization therapy (CRT) surveys.

Among all contacted centres, answers were obtained from 182 centres. Transvenous lead extraction was performed in 164 centres. Among the extracting centres, 139 answered the first questionnaire, 81 answered the second, and 56 answered both.

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Sixty-one per cent of the centres performing lead extraction declared that they have a database for all procedures.

In the first questionnaire, we mainly asked for technical data regarding TLE procedure (activity start date, tools and venous approaches, rooms and personnel involved), posing 30 questions and obtaining answers for more than 99.9%.

In the second questionnaire, we asked for clinical data concerning TLE (indications, results, and complications), physicians practice on patient management and their perceptions of the risks associated with the procedure. There were 28 questions of which only 0.01% were unanswered.

Participant countries

The extracting centres were from 30 countries: Italy (38), Germany (20), Spain (16), France (12), Belgium (9), Poland (9), Finland (7), United Kingdom (7), Hungary (6), Greece (5), the Netherlands (4), Denmark (3), Switzerland (3), Sweden (3), Israel (3), Estonia (2), Lithuania (2), Romania (2), Norway (2), and single centres from another 11 countries (Azerbaijan, Croatia, Czech Republic, Georgia, Ireland, Luxembourg, Macedonia, Montenegro, Slovenia, Russia, and Tunisia).

Characteristics of centres

A Cardiac Surgery Department (CSD) was available in 86% of the extracting centres and in 27% of non-extracting centres, while an Intensive Care Unit (ICU) was available in all centres.

Of the extracting centres, 81% implanted more than 150 new pacemakers (PM) and 56% more than 100 new implantable defibrillators (ICD) per year including cardiac resynchronization systems, while the corresponding numbers for non-extracting centres was 39% for PM and 11% for ICD.

Very few centres started TLE activity before 1988 (5%), whereas from 1988 up to 2011 there was a continuous increase in the number of centres starting to perform TLE. The year of start up of TLE activity ranged from 2000 to 2011 in 60% of centres.

The total number of leads extracted throughout all years (reported in the first questionnaire) was 34 449 with a mean of 248 leads per centre: 84% of centres declared that they had extracted <500 leads (34% <50), 11.5% between 500 and 999 and 4.5% of centres \geq 1000 leads.

Operating room

The second survey reported that the catheterization lab was used for TLE in 60% of the centres (23% with an identified cardiac surgeon on stand-by, 31% without a specific surgeon identified, and 6% in a hospital without cardiac surgery), a hybrid room in 14% and an operating room in 26% of centres.

Personnel

Personnel involved in the TLE procedures were reported by 139 centres with a mean involvement of 2.6 cardiologists, 1.8 surgeons, and 3.6 nurses per centre. A cardiologist was the first operator in 88% of centres and a cardiac surgeon in 12%.

Tools and venous approaches for transvenous lead extraction

The first questionnaire revealed large differences in the use of extraction tools: manual traction was used by 44% of centres, locking stylets by 88%, mechanical sheaths by 79%, and laser and electro-surgical dissection sheaths by 28% and 26% of centres, respectively.

Regarding alternative transvenous approaches, 65% of centres declared that they use the femoral approach and 37% the jugular venous approach when necessary.

Volume of activity/centre/year

The mean number of patients treated/year/centre was 35 during 2010 and 38 during 2011, with 31% of centres performing TLE in > 40 patients, 46% in 10–40 patients, and 23% in < 10 patients annually.

Thirty-seven per cent of centres treated < 15 patients/year, 26% treated 15–30 patients, and 37% of centres > 30 patients (5% more than 100 patients/year). In 2011, 81 centres treated 3081 patients with TLE: 49% PM pts, 30% ICD pts and 21% with CRT devices. A total of 5299 leads has been removed: 73% pacing leads (32.5 ventricular, 31 atrial, and 9.5 CS leads), 24.5% ICD leads and 2.5% free floating leads (Table 1).

Indications to transvenous lead extraction

Indication to lead extraction was more often infection (70%: 28% systemic and 42% local) than other conditions (30% of patients). In the case of systemic infection, a transoesophageal echocardiogram (TEE) was routinely performed in 88% of centres. If vegetations were present, 83% of centres considered performing TLE and they proceeded with the procedure if the diameter of the vegetation was at most 2 cm (48%), 3 cm (31.5%), 4 cm (15%), and 5 cm (4.5%). In cases of redundant non-infected leads, 39% of centres always tried to remove them with manual traction before abandonment, whereas 32% and 7% of centres only did it if leads were implanted for less than 12 and 6 months, respectively. In 43% of the centres, patients were sometimes, but rarely (4.5%), referred for surgery as a first option due to large vegetations (60%), concomitant cardiac surgery (30%), or old leads (10%).

Clinical experience

Twenty-seven per cent and 41% of centres reported having experience in paediatric patients and in congenital heart disease

Table 1 Leads extracted in 2012 EHRA Survey (year 2011: 81 centres, 3081 patients, 5299 leads)

Leads	Percentage
Pacing leads	73
Right atrium	(32.5)
Right ventricle	(31.0)
Left ventricle (CS)	(9.5)
Implantable defibrillator leads	24.5
Free floating leads	2.5

patients, respectively. Sixty-nine of the responding centres reported a mean complete (radiological) success rate in 88% of patients (31 centres >95%), partial success in 7%, and failure in 5% of patients. Twelve per cent of centres performed extraction of fingers and subcutaneous ICD leads.

All 81 centres reported major complications in their experience: 63% of centres in <1% of patients, 27% in between 1 and 2%, 7.5% in between 2 and 5%, and 2.5% of centres in >5% of patients. Absence of death was stated by 54% of centres; 36% answered death in <0.5% and 10% of centres experienced an incidence of death in between 0.5 and 2% of patients.

Physician perceptions

The perception of easiness and risk of the procedure with respect to lead type was also addressed in the survey. For atrial leads, 80% of physicians thought that active fixation was easier to extract than passive, and 52% thought that active fixation was less risky than passive leads. For ventricular leads, 57% of respondents thought that pacing leads were easier to extract than ICD leads and 60% less risky than ICD leads.

Ninety-five per cent of physicians considered LV leads easier to extract and 67% thought that LV leads were less risky than ICD leads. The easiness and risks level of extraction procedures were felt by the majority of respondents to be independent of whether there were infective or non infective indications.

For ICD leads, among the characteristics facilitating the extraction procedure, 81% of respondents considered single coil, 72% active fixation, and 53% the presence of goretex around the shock coil. Only 28% considered smaller diameter leads easier than bigger ones.

Reimplantation after transvenous lead extraction

Some PM patients after TLE are not reimplanted: 12% of centres did not reimplant >16% of patients; 20% did not reimplant 6–15%, while 68% of centres did reimplant in at least 95% of patients. For ICD patients, 40% of centres always reimplanted all patients after TLE, while the remaining 60% did reimplant in at least 97% of patients.

Before reimplantation, when systemic infection was the indication in a PM-dependent patient, 62% of centres treated with temporary lead and an external PM as a bridge to a new system, 20% with a permanent transvenous lead and an implantable PM outside the body as bridge to the new system, 12% of centres with an epicardial permanent PM system, and 5% with a permanent transvenous lead and an implantable PM as a bridge to the new system.

In case of non-infective indication and PM dependency, new implantation was performed in the same procedure of TLE in 86% of centres, before TLE in 4% of centres and between 24 h and 4 weeks following TLE in the remaining 10%. In cases of non-infective indication and non-PM dependency, new implantation was performed in the same procedure of TLE in 73% of centres and between 24 h and 4 weeks following TLE in the remaining 27%.

In cases of infective indications there is quite a large variability regarding the timing of reimplantation after lead extraction: 68% of centres reimplant PM-dependent patients between 72 h and 2

weeks in case of systemic infection and 59% between 48 h and 1 week in cases of local infection. Seventy-seven per cent of centres reimplant non-PM-dependent patients between 2 and 4 weeks and 69% from 1 to 4 weeks in cases of systemic or local infection respectively.

When infection is the indication for TLE, 95% of centres did not reimplant a permanent new CIED in the same pocket and chest side after complete removal of the infected system as stated by the guidelines.

Discussion

This survey should be considered the biggest one published until now about the practice of lead extraction. In fact, in comparison with the previous European⁴ and US⁵ surveys, we obtained data from 164 centres vs. 38 and 158 respondents, respectively (Figure 1). Moreover this survey is highly representative of the clinical practice across Europe (30 countries involved).

Most of the centres involved have medium to high-volume experience in CIED implantation and a good availability of all emergency facilities, ICU and a CSD.

In this scenario TLE is being performed by a steadily increasing number of centres, many of which have a long-lasting and vast experience in this kind of procedure, having extracted a really huge number of PM and ICD leads until now.

Compared with the previous European survey,⁴ the number of centres treating <10 patients/year has decreased from 40 to 23% while at the same time the number of centres treating >40 patients/year has increased from 13 to 31%, probably as a consequence of a better adherence to the guidelines recommending that patients be referred to tertiary centres with experience and facilities for TLE.

Cardiologists are involved as first operator in the vast majority of centres, 88% vs. 63% when compared with the previous European survey,⁴ even if a bias could be present because some extracting centres, where TLE is performed by cardiac surgeons, did not respond to this survey.

Interventions are performed in the catheterization lab in more than half of centres, with a cardiosurgical support available in most cases. In fact, only 6% of centres declared that they

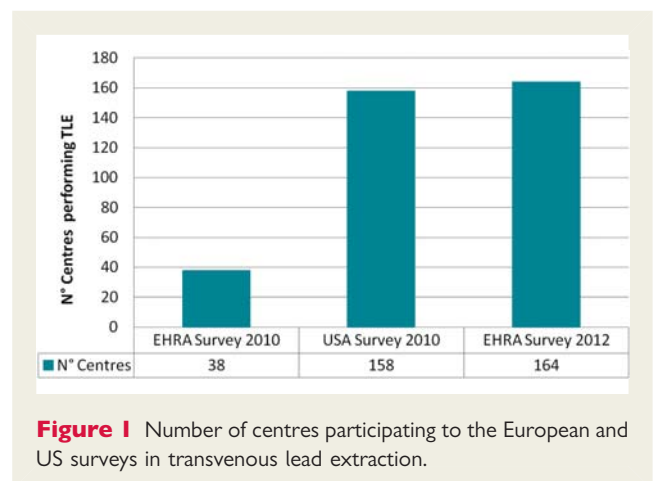


Figure 1 Number of centres participating to the European and US surveys in transvenous lead extraction.

perform lead extraction without a CSD in the hospital and the vast majority of these centres perform <15 lead extractions/year.

Survey data show that at least two physicians are trained in performing lead extraction in each centre, and cardiac surgeons and a dedicated nursing team are involved: this is in accordance with what international guidelines recommend about personnel dedicated to lead extraction.

From a technical point of view, this survey shows quite a good familiarity with all kind of TLE tools and alternative venous approaches (femoral or jugular) by the operators performing lead extraction. Furthermore, as reported in the previous European survey, non-powered sheaths are preferred to powered ones probably because of the satisfactory success rate and lower cost.

Systemic or local infections are the main indication to TLE and the survey underlines the usefulness of TEE to better evaluate vegetations in case of systemic infection. Even if most of the centres reported performing TLE when vegetations were ≤ 2 cm in diameter, a quite significant percentage of centres performed TLE even in cases with up to 5 cm vegetations. However large vegetations are the first indication to surgical extraction as the first option in 43% of centres.

We gathered interesting information regarding the perceived easiness of extraction of various kinds of leads: in general, single coil, goretex around the shock coil, and active fixation leads were perceived as easier to extract.

The data on success rate and complications are comparable with those of the main international experiences and surveys, underlining the reliability of our results as a real snapshot of today's lead extraction practices in Europe.

Conclusions

This survey gives an interesting and extensive snapshot of lead extraction in Europe today and suggests some clues for future research and a prospective European registry.

Given the limitations with a survey, a prospective European registry enrolling consecutive patients with long-term follow-up will give us a more detailed information about success rates and complication rates, which will set the stage for future educational activities.

Undoubtedly lead extraction is already a vital and necessary part of modern CIED treatment in Europe.

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