Europace (2020) **0**, 1–11 European Society doi:10.1093/europace/euaa218 **EHRA SURVEY**

Knowledge gaps, lack of confidence, and system barriers to guideline implementation among European physicians managing patients with CIED lead or infection complications: a **European Heart Rhythm Association/European** Society of Cardiology educational needs assessment survey

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As the number of patients with cardiac implantable electronic devices (CIEDs) grows, they are likely to present with issues to diverse groups of physicians. Guideline-adherent management is associated with improved prognosis in patients with CIED infection or lead problems but is insufficiently implemented in practice. The European Heart Rhythm Association (EHRA) with the support of the European Society of Cardiology (ESC) Working Group on Cardiovascular Surgery, performed a multinational educational needs assessment study in ESC member countries, directed at physicians who might be confronted with CIED patients with complications. A total of 336 physicians from 43 countries, reached through the ESC mailing list, participated. They included a mix of electrophysiologists, cardiologists general physicians and cardiac surgeons .One hundred and twenty-nine (38%) of the respondents performed lead extraction. The survey included eight clinical cases and a self-evaluation question of knowledge and skills to apply that knowledge. The survey looked at 14 areas of care across five stages of the patient journey. Of the non-extracting physicians over 50% felt they lacked the knowledge and skills to make the diagnosis and refer for lead extraction and over 75% felt they lacked knowledge and skills to manage aspects of extraction and postextraction care. Barriers to correct referral were logistic and attitudinal. Extracting physicians reported significantly higher rates of adequate skills and knowledge across all five stages of the patient journey (P < 0.05). We identified major gaps in physicians' knowledge and skills across all stages of CIED care. These gaps should be addressed by targeted educational activities and streamlining referral pathways.

Keywords

Educational needs assessment • Cardiac implantable electronic devices management • Lead extraction • Infection • Complication • EHRA survey

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Introduction

The number of patients benefiting from implantation of cardiac implantable electrical devices (CIEDs) is increasing, but as a result, so is the prevalence of device infection. In addition to this, the increased uptake of larger and more complex devices, such as cardiac resynchronization therapy (CRT) and implantable cardiac-defibrillators (ICDs) in an increasingly older and comorbid population has resulted in an increase in device and lead complications. ²

Device-related infection is associated with significant morbidity, mortality, and financial healthcare burden.³ The precise burden of CIED infections is difficult to estimate because of divergent definitions and varied populations. The Danish registry reported a combined incidence of infection during the device lifetime of 1.19% for pacemaker, 1.91% for ICD, 2.18% for CRT-P, and 3.35% for CRT-D.⁴ The more recent cross-over cluster PADIT⁵ and randomized WRAP-IT trials⁶ reported lower infection rates of 0.6–1.3%, but follow-up was relatively short.

In non-infected cases, the decision to abandon or extract a lead is complex and careful consideration and discussion with the patient is recommended prior to decision. In the context of device upgrade or requirement of an additional lead, venous access maybe an issue. Management options include contralateral lead implantation with tunnelling across the chest, extraction of a redundant lead, or subclavian venoplasty. An individualized approach should be taken based on operator and centre expertise. Use of extraction as an approach to device upgrades for patients with venous occlusion may be a useful strategy in experienced centres.

Transvenous lead extraction (TLE) is the gold standard for treatment of CIED infection⁹ and is defined by the European Heart Rhythm Association (EHRA) and Heart Rhythm Society (HRS) as extraction of a lead that has been implanted for more than 1 year, or removal of lead(s) that requires the use of specialized extraction tools. ^{10,11}

The overall complication rates with TLE are low, however, when they occur, they cause both significant morbidity and mortality. Good quality randomized evidence to guide treatment is lacking, but there are now large prospective real-world registries, which have shown that both clinical and radiological success can be achieved in over 96% of cases with low complication rates. ¹³

Cardiac implantable electronic device management encompasses different aspects of care including identification of the problem, interim management, and appropriate referral, decision to extract, and post-extraction care. In addition to competent lead extraction itself, appropriate and timely referral is key to improving outcomes. There are several published international documents on the diagnosis and management of CIED infection and lead management ^{10,14–17} and although ESC and EHRA have multiple activities to disseminate and implement their practice guidelines, it is well documented that guideline adherence is insufficient in daily practice ¹⁸ and that there is a need for intensified and more focused education.

To tailor such educational efforts better, ESC and EHRA set up an educational need assessment study. The management of these complex patients is multidisciplinary, with patients seen by general practitioners, internal medicine physicians, cardiologists, and indeed electrophysiologists as well as cardiac surgeons. Since collaboration

in care deployment between these specialties is essential, we opted for a survey including these different physician subgroups.

Our aim was to assess the knowledge and skills gap that physicians have with regard to CIED management. In the short term, identifying areas where knowledge could be improved will ensure that EHRA's educational programmes are appropriate, evidence based and relevant to its members. The desired outcome in the long term and beyond would be increased awareness, knowledge, and understanding of the procedure culminating in improved patient and public health outcomes.

Methods

An anonymized survey was sent out via electronic mail to members of the EHRA, European Federation of Internal Medicine and members of the ESC working group on Cardiovascular Surgery. The questionnaire was designed following a literature review and using expert opinion to explore the knowledge and skills of the respondents along five stages of the patient journey: diagnosis, management, referral, extraction, and post-extraction care.

A mixed-methods approach was used, allowing a combination of quantitative and qualitative data. The questionnaire, cases included in the survey (Supplementary material online, *Appendix S1*), interpretation of the data generated, and the development of the manuscript was the responsibility of EHRA.

Ethical approval

The survey was anonymized with no identifiable personal or patient data so specific ethical approval was not required. The study complies with the Declaration of Helsinki.

Recruitment

Participants were recruited using membership lists from the ESC. Email invitations were sent out with a link for participants to respond to an online survey. 4321 contacts were accessed (2400 EHRA members from national cardiac societies, 1782 ESC members with interest in general cardiology and members of European Federation of Internal Medicine, and 139 ESC working group members from cardiovascular surgery) of which 4033 were reached.

A reminder was sent 2 weeks later and a final reminder was sent 8 weeks after the first email.

Survey (questionnaire)

The 15–20-min survey included key background demographics to enable detailed analyses of responses. Eight clinical cases (Supplementary material online, Appendix) were embedded in the survey to obtain insights into the clinical decision-making process of the physicians in the diagnosis and management of cardiac device issues. Participants were asked to select their multiple-choice responses and also indicate (i) their level of knowledge regarding aspects of clinical practice (not acceptable, could be improved, and acceptable); (ii) their level of skill to apply that knowledge (not acceptable, could be improved, and acceptable).

A list of 14 areas of investigation across cardiac device and lead management care pathways were considered (*Figure 1*). These were grouped across five stages to follow the patient journey. The key findings in these areas were grouped into themes to explore reasons for current clinical practice. These themes were knowledge (awareness of guidelines, current practice, safety of procedure, implications of not treating

Areas of invest	igation targeted by the study grouped in	on targeted by the study grouped into key patient themes.		
Category	Area of investigation	Key findings; Knowledge (K), Skills (S), Pathways (P)		
Diagnosis	1. Identification of problem	K, S		
	2. Diagnosis	K, S		
	3. Differential Diagnosis	K, S		
Management	4. Clinical decision making	K, S		
·	5. Knowledge and use of	K, S		
	guidelines	K, S		
	6. Treatment initiation	K, S		
Referral	7. Timing	K, S, P		
	8. Pathways	Р		
Extraction	9. Method	K, S		
Extraction:	10. Anaesthetic	P		
	11. Setting	P		
Post extraction	12. Outcome	K, S, P		
1 ost extraction	13. Discharge	K, S, P		
	14. Re implant	K, S		

Figure I Five key categories of device management, and the 14 areas of investigation.

appropriately, etc), skills to apply that knowledge, and pathways (logistics of referral or management of these patients).

Data collection and analysis

Each respondent was anonymized and given a number as an identifier, which enabled alignment and analysis of the results. The researchers identified useful quotes from the free text fields, coding segments of information into broad themes. The results were categorized further by whether the respondent was a device extractor (in the last 12 months), a cardiologist, or a non-extractor/non-cardiologist. The analysis of the quantitative survey data employed frequencies, cross-tabulations, chi-squares, and analysis of variance, using SPSS 26.0 (IBM Corporation, Armonk, NY, USA).

To simplify analyses, self-reported knowledge and skill data were dichotomized: 'acceptable' and 'not acceptable' or 'could be improved' were grouped as 'needing improvement'.

Results

There were 336 completed questionnaires from the 4033 invites; a response rate of 8%. This included respondents from 43 countries with the greatest number of responses coming from Italy, Germany, and Spain (15%, 8%, and 7%, respectively) (*Table 1*). The majority of participants were electrophysiologists (47%), 20% were internal medicine consultants, 17% general cardiologists, and 2% cardiac surgeons. The other specialties included interventional cardiologists, heart failure specialists, cardiology trainees, and infectious diseases

physicians. The respondents were experienced clinicians with over 45% having had 10 or more years in clinical practice since qualification and 71% regularly undertaking device implantation. There were also a high proportion of lead extractors with 38% having undertaken TLE in the last 12 months. Of those who described performing lead extractions, 74% reported that cardiac surgery was available on site.

In those clinicians who were not primary extractors, 45% reported referring an average of 3.7 patients per year for consideration of TLE (range 0–50, total 947 patients). See results in *Table 1*.

The presentation of patients with cardiac device issues was variable; 47% of respondents reported presentation in emergency department, 44% to implanting cardiologists, 23% reported to general cardiologists, and 12% to primary care. This is likely a reflection of the variable healthcare delivery across Europe.

Assessing gaps in knowledge with clinical problem solving

Diagnosis

Three clinical cases were presented assessing the investigation and diagnosis of potential cardiac device issues. There were 306 responses to these initial clinical questions (91%).

Case 1 described a patient with a cardiac device in situ presenting with recurrent fever- the correct management plan would include blood cultures, wound check, chest X-ray, and echocardiogram. Seventy-five percent of respondents matched the correct

Table I Study group demographics and results

	Total respondent (n = 336)
Role	
Electrophysiologists	159 (47.3%)
Internal medicine	68 (20.2%)
General cardiologists	56 (16.7%)
Cardiac surgeon	7 (2.1%)
Heart failure specialist	16 (4.8%)
Interventional cardiologists	15 (4.5%)
Other	15 (4.4%)
Country of practice	
Italy	52 (15.4%)
Germany	26 (7.7%)
Spain	24 (7.1%)
France	14 (4.2%)
UK	14 (4.2%)
Russia	13 (3.9%)
Romania	13 (3.9%)
Netherlands	11 (3.3%)
Other	169 (50.3%)
Number of years since completing residency of	, ,
0–5	98 (29.2%)
5–10	79 (23.5%)
10–20	86 (25.6%)
>20	73 (19.9%)
Device operator experience	(,-)
Number of regular device implanters	238 (71.1%)
Number of device extractors	129 (38.3%)
High volume (>30 per year)	33 (25.6%)
Moderate volume (15–30 per year)	23 (17.8%)
Low volume (<15 per year)	73 (56.6%)
Facilities and/or onward referral	. 5 (50.070)
Lead extraction facilities available on site	200 (59.5%)
Cardiac surgery available on site	95/129 (73.6%)
(extractors)	73/127 (73.0%)
HCP who had referred patients for TLE	154 (45.5%)
	157 (45.5%)
in last year 1–5 referrals	115 (74 7%)
5–10 referrals	115 (74.7%)
	22 (14.3%)
>10	17 (11.0%)
Total number of referrals reported/year	947 (average 3.7;
	range 0–50)

HCP, healthcare practitioner; TLE, transvenous lead extraction.

management plan with a further 14% requesting a blood culture but no other investigations.

Case 2 was a more subtle case of chronic pain around a device.

Case 2 was a more subtle case of chronic pain around a device. The management of this is less prescriptive and would include attempts to exclude infection prior to reassurance. Around 50% of the responses focused on the possibility of further investigation for a device complication but half would re-assure or refer for pain management only. We analysed the responses between cardiologists and

non-cardiologists and nearly half of cardiologists and extracting physicians would adopt a conservative approach in this situation (Figure 2A).

EHRA survey

Case 3 included an image of device erosion in a clinically stable afebrile patient. Guideline directed management would be a full system extraction. In total, 75% of participants opted for full system extraction. The remaining quarter opted for a more conservative approach or partial device removal/reburial. There was a divergence in the responses here with the majority of extractors and cardiologists opting for complete system extraction (95% and 85%, respectively). There were a significantly higher number of extractors offering extraction in this setting then non-extractors (P < 0.05) but still 15% of non-extracting cardiologists would offer either revision or partial removal (generator only).

Non-cardiologists were more split in their responses between partial removal (generator only) and generator reposition (Figure 2B).

Management of lead and device issues

This section focused around three clinical cases but offered alternative test results to assess how the respondents' clinical decision-making would change in response to changing clinical scenarios.

Two hundred and sixty-eight (80%) participants answered this series of questions.

Case 1 described a patient with a CRT-D device, recurrent fever, positive cultures for *Staphylococcus aureus*, and a vegetation on the lead on transoesophageal echocardiogram (TOE). About 92% reported intending to treat the patient with antibiotics and refer for device extraction. In the same patient without echocardiographic evidence of vegetation, this number falls drastically and only 57% would consider lead extraction. If the patient had *Escherichia coli* in the blood stream only 30% would refer for lead extraction.

Case 2 described a 40-year-old patient with a failing ICD lead that had been *in situ* for 9 years, with no signs of infection and not pacing dependent. In this setting, 42% of participants would extract the old lead, with 30% adding a new lead and leaving the old lead *in situ*. Around 20% felt a subcutaneous ICD (S-ICD) might be appropriate.

The patient is then found to have an occluded left subclavian vein, which increases the number favouring S-ICD to 32%. Thirty percent felt lead extraction would allow a new lead to be implanted and 17% would implant a new system on the right-hand side, with extractors significantly more likely to recommend lead extraction than non-extractors (P < 0.05) (Figure 2C).

Case 3 showed a picture of a pocket infection. Participants were asked to choose their preferred management strategy and 74% chose to extract the system, with 20% opting for a more conservative pocket washout or partial device removal. When we analysed the responses here by speciality, 63% of cardiologists would appropriately opt to extract the device in the presence of a *S. aureus* bacteraemia [without echo evidence of infective endocarditis (IE)] but a third would not. A higher proportion of extractors would offer extraction (73%) in this situation but again over a quarter would not routinely offer this (*Figure 2D*). In the presence of confirmed pocket infection, 10% of cardiologists would also still only perform a partial system extraction, with only 4% of extractors opting for this approach (*Figure 2E*).

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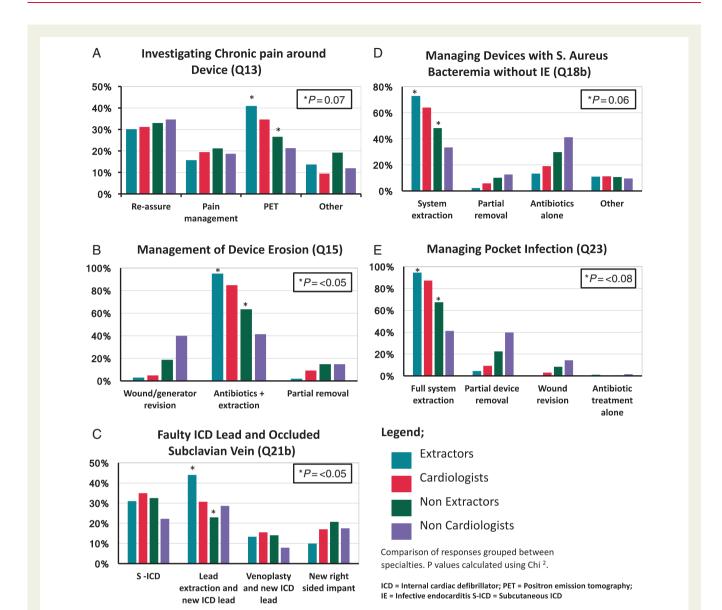


Figure 2 Five key areas of knowledge gaps in managing device extraction. ICD, implantable cardiac-defibrillator; IE, infective endocarditis; PET, positron emission tomography; S-ICD, subcutaneous ICD.

Referral for lead extraction

This was a single question which aimed to explore barriers to referring patients for consideration of TLE. Two hundred and sixty (77%) respondents answered this question describing a confirmed pocket infection with positive blood cultures. Only 50% did not perceive any barriers to referral. Eighteen percent cited the proximity to the tertiary centre as a factor, with a further 18% wanting to complete further investigations such as echo or positron emission tomography (PET). Bed constraints, cost, and the perceived lack of a diagnosis were also factors that may delay onward referral.

Extraction

EHRA survey

This section was completed by 239 (71%) respondents. When asked about which factors affect the decision to perform extraction, the

patient's co-morbidity had the largest effect, with 92% reporting this impacted their choice. Eighty-three percent reported the age of the patient and 73% the age of lead as strongly influencing the decision to undertake (and presumably refer) lead extraction.

Thirty-seven percent felt the ease of access to an extraction centre was an important consideration, and 14% did not want to refer the patient to an extracting physician for fear of losing them to follow-up.

Respondents were also asked what factors may limit patients from being considered for TLE. High risk of procedural mortality was the most common reason given, cited by 77%. Interestingly, the perceived difficulty or complexity of TLE is still high, with 43% reporting this as a limiting factor, but perhaps more strikingly almost 40% of respondents had reservations about the ability of the extractor to achieve good outcome in lead extraction procedures. Fifteen percent of these reported they were themselves extracting devices and three

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quarters were cardiologists. Whilst there is no published data on radiation exposure during TLE, 11% felt that the radiation exposure would influence their clinical decision-making.

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The survey asked extractors to list what tools were available and accessible to them when performing TLE. Locking stylets which were the most commonly used (50%) followed by non-powered mechanical sheaths (45%). Thirty-five percent had access to powered mechanical sheaths but only 19% had LASER extraction tools available. Forty-one percent had femoral snares and surgical extraction was an option for 47% of the respondents. Training had the greatest influence on which tools were selected (82%), with device and lead characteristics a factor for 51%. Twenty-eight percent felt the patient profile influenced the choice of equipment, with the evidence base less of a consideration, only regarded important by 20% of those surveyed.

The majority of extractions were performed under general anaesthetic with or without local anaesthetic (78%) and the remaining 22% favoured just local anaesthetic. Facilities available to extracting physicians varied, with 49% utilizing a catheter lab and 29% operating theatre, with 42% having access to hybrid labs. There was some overlap in the responses implying that these facilities were used variably.

Post-extraction care

The final section consisted of 5 questions around the management of patients post-extraction. Two hundred and thirty-six (70%) respondents completed this section. The first two questions aimed to assess duration of antibiotics prescribed post-extraction; the first, a case of confirmed pocket infection with negative blood cultures, and the second, a case with positive blood cultures (not specified) but negative TOE.

With a confirmed pocket infection and negative blood cultures, just over half of physicians (55%) were practising in line with the guidelines and administering 2 weeks of IV antibiotics. Twenty percent recommended 10 days with a further 20% recommending 72 h or less. When the patient had positive blood cultures the majority (58%) would offer at least 4 weeks of IV antibiotic therapy. Thirtyfour percent of respondents would offer a 2-week course with 5% willing to consider a 4-week course of oral antibiotics.

When considering device re-implantation after successful extraction 97% of respondents would review the original indication for the device, with only 1% choosing a strategy based on patient choice alone.

A common challenging scenario encountered in clinical practice is extracting devices from patients who are pacing-dependent. Respondents were asked which methods were available in their centres of practice and the most common mode was standard transvenous temporary pacing (62%). Fifty-five percent had the option of a 'semi-permanent' system using an active fixation lead with an externalized generator. Twenty-seven percent had access to epicardial pacing and 17% leadless pacing technology.

Timing of re-implantation is an area where good quality data is lacking and participants were also asked to consider the optimum time to implant a new device. The majority (60%) would re-implant when clinically stable on the contralateral side, 22% would re-implant as soon as possible on the contralateral side, with 6% considering an epicardial system and only 4% considering re-implanting as soon as

possible on the ipsilateral side. The results were grouped according to areas of investigation are listed in *Table 2*.

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Self-reported knowledge and skill assessment

After each clinical scenario, the participants were asked to self-report their knowledge and skill levels with regard to each area. The results are presented in *Figure 3*. The results were separated between respondents who were performing extractions (in the last 12 months) and those who were not, as we felt extractors were more likely to feel confident about managing these patients.

Over half of the non-extractors felt that the skills and knowledge were needing improvement when diagnosing and referring on patients needing device extraction, with a higher proportion again reporting needing improvement with the management of device-related complications. The most challenging area, however, was knowledge of the extraction process and the post-extraction care. The results show that three quarters of non- extractors felt that they were not adequately skilled or informed to manage these patients.

The extractors reported significantly higher levels of confidence at all stages of the process (P < 0.05) but still a quarter of these experienced clinicians self-reported their knowledge and skills as needing improvement, particularly with post-extraction care where over 30% felt there was further development required.

Discussion

Survey responses

The purpose of this survey was to gain insights into disparities in practices in diagnosis and management of CIED complications as well as compliance with published recommendations and guidelines across various physician groups. This knowledge would be used to guide educational activity and focus on areas that require more attention.

The survey represents a broad range of replies from varying physician groups. It included physicians (and surgeons) with diverse backgrounds as well as different length of time in practice, trying to mirror as accurately as possible current realities of health care provision for patients presenting with cardiac device issues.

The clinical scenarios and questions were designed to highlight 14 areas of investigation and clinical images were included to reflect real-world presentation rather than simple descriptions. Some clinical scenarios were straightforward with clear guideline recommendation for diagnosis and management, and others less straightforward.

Chronic pain around the device site is is a Class 2a indication for system extraction in the absence of an alternative explanation. ¹⁰ We found variable responses to this clinical scenario. One-third of respondents reassured the patient and one-third recommended a PET scan to assess occult infection, but overall half did not pursue any further investigation and only a minority considered referral for system extraction. This is clearly an area where there is lack of consensus despite guideline recommendations.

A recent worldwide survey looking at clinical practice and implementation of guidelines for the prevention, diagnosis, and management of cardiac implantable electronic device infections reported

Table 2 Areas of investigation and key knowledge gaps revealed by this study

Area of investigation **Key findings** Good knowledge of investigation, awareness of importance of blood culture testing 1. Investigation of suspected CIED infection 2. Investigation for chronic pain around cardiac device Sub optimal, half would re-assure or not investigate further 3. Recognizing device erosion as CIED infection 25% would consider conservative management or partial extraction 4. Management of confirmed CIED infection High percentage of responders considered extraction when IE was present but 30% still opted for antibiotic treatment only or partial removal if TOE was negative 5. Management and extraction strategy for failing leads Wide variation in practice but less than half would consider extraction in the first instance 6. Recognizing pocket infection and need for extraction 20% of respondents would offer conservative treatment 7. Barriers to referral 50% perceived barriers to onward referral. Proximity is a concern for 18% with bed constraints and cost also a cause for concern. 14% were concerned about losing a patient to another caregiver. 8. Factors which influence decision to extract The age and frailty of the patient appear to have the biggest influence, 37% feel ease of access to extraction service is a limitation 9. Factors which would limit TLE being offered 75% feel the procedural risk would be a limiting factor, with around 40% feeling the difficulty of the procedure also being a factor. Concerning 40% did not have confidence in the extractors ability to obtain a satisfactory outcome. 10. Tools available for extraction Locking stylets were the most commonly used, followed by powered and non-powered mechanical sheaths, surgical extraction, femoral snares and LASER. 11. Factors which influence equipment selection Training was the most important factor when deciding on which tools were used (82%). 12. Antibiotic duration post-CIED removal Variation in practice with just over half using guideline approved antibiotic duration 13. Options for temporary pacing Transvenous temporary pacing or an externalized permanent system were the most commonly used 14. Timing of re-implantation Approximately 80% would implant on the contralateral side with the majority waiting until clinically stable. Only 4% would implant on the ipsilateral side and 6% would consider an epicardial system.

 ${\sf CIED, cardiac\ implantable\ electronic\ devices;\ TLE,\ transvenous\ lead\ extraction.}$

that guidelines and recommendations were not commonly adhered to in clinical practice and that there was significant regional variation. This survey focused on CIED infection prevention and management and included members of arrhythmia societies worldwide. It suggested that in cases of pocket infection without systemic involvement complete hardware removal was applied by under two-thirds of responding physicians. This compares unfavourably with the response rate in our survey where nearly 75% advocated complete system removal. This discrepancy in the response rates for extraction is possibly explained by economic issues and limited access to extraction centres in other regions (Asia/Pacific, Latin America, and Middle East/North Africa).

The question of systemic infection with positive blood cultures for S. Aureus elicited an interesting response. Almost 92% responders considered extraction when IE was present (TOE positive vegetation) but if TOE was negative almost 40% of cardiologists and around 60% of other physicians would opt for only antibiotics or partial system removal in contravention of the guidelines. Cardiac implantable electronic device infection has an in-hospital or 30-day mortality of 5–8%^{19,20} including mortality from lead extraction, usually reported as 0.5%, ¹³ but mortality is principally related to the complications of

ongoing sepsis. The reported mortality is higher for patients who do not undergo complete removal of CIED hardware 21 and for those who incur delays in device removal. 22

The recently published EHRA consensus document²³ recommends that the timing of an extraction procedure should be without time delay after diagnosis of CIED infection, since if performed within 3 days after hospitalization it results in significantly lower in-hospital mortality and shorter length of stay.

Malfunctioning leads are another challenging area and the responses included a leadless device, addition of leads, and lead extraction (42%) reflecting a balanced view despite the Class 2a recommendation for lead extraction in the guidelines. Interestingly when the scenario was modified to that of an occluded vessel precluding vascular access, the recommendation for extraction dropped to 32% and those in favour of right-sided implants increased (1–17%) and S-ICDs increased from 18% to 32%. This is surprising and perhaps reflects the perception that lead extraction in an occluded vein carries a higher risk of complication.

The decision to consider extraction in this survey was heavily influenced by clinical factors including the patient's co-morbidity (92%), age of the patient (83%), and the age of lead (73%). However, 50% of

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Α D Diagnosis Extraction 100% 100% ** *P*<0.01 ** P<0.01 ** P<0.01 ** *P*<0.01 75% 75% 50% 50% 46% 25% 25% 21% 0% 0% Extractors Non extractors Extractors Non extractors Extractors Non extractors Extractors Non extractors Skills Skills Knowledge Knowledge В E Managament Post extraction 100% 100% ** P<0.01 ** P<0.01 ** P<0.01 ** P<0.01 75% 75% 68% 64% 50% 50% 25% 25% 0% 0% Extractors Non extractors Extractors Non extractors Extractors Non extractors Extractors Non extractors Knowledge Skills Knowledge Skills Legend; С Referral 100% ** *P*<0.01 ** *P*<0.01 Self assessed "Acceptable" 75% 76% 50% 44% 25% 0% Extractors Non extractors Extractors Non extractors

respondents perceived barriers to onward referral including the availability of beds, distance from specialist centre, and need for further investigations. Forty-three percent felt the ease of access to extraction centre would influence their decision to refer the patient. It is not clear if they are referring to geographical access or streamlined referral pathways and communication but these are areas in which access to TLE need to be improved. The questionnaire further explored barriers to lead extraction and highlighted the fact that a number of respondents perceived lead extraction as a complex procedure (44%) with a high risk of mortality (77%). This belies evidence from the ELECTRA registry which confirmed the safety and efficacy of the current practice of TLE with clinical success rates of 96.7% and mortality of 0.5%. 13

Knowledge

Figure 3 Results of self-assessment across the five key themes.

Of the respondents who undertook lead extraction, fewer operators reported using locking stylets than previously documented in the published registry data (50% vs. 71%) and a higher proportion used manual traction only (47% vs. 27%). Use of LASER was similar in this survey as in ELECTRA, and participants cited the training they had received as having the biggest influence on what tools were used. Industry and EHRA have an important role in providing this training as currently there are too few training opportunities elsewhere.

Lead extraction in our survey was performed mainly under general anaesthetic (78%) but it was concerning that nearly a quarter of extractors did not have cardiac surgery backup. The guidelines recommend facilities to perform emergent sternotomy or thoracotomy within 5–10 min and these guidelines have been in place since 2009.

Questions on post-extraction care focused around antibiotic use and timing of re-implantation. With a confirmed pocket infection and negative blood cultures just over half of physicians (55%) were practicing in line with the guidelines and administering 2 weeks of IV

antibiotics. Twenty percent recommended 10 days with a further 20% recommending 72 h or less.

There is some variation in the published Guidelines on the recommended duration of antibiotics and the most recent EHRA consensus document suggests 10–14 days post-extraction if cultures are negative. Almost three quarters of our respondents were within the recommendation guidelines, however, in a culture positive CIED infection, the guidelines recommend 4 weeks of IV antibiotics. Only 58% of respondents followed the guideline recommendations here. A minority of respondents would opt for oral antibiotics which although has shown promise in native valve endocarditis, has not yet been assessed in the setting of CIED infection. The HRS guidelines for antibiotic duration are described in *Table 3*.

The decision to re-implant post-extraction is complex, which EHRA identified as an area requiring further research. ¹² Evaluation of the patient's clinical status and patient choice should be taken into account prior to re-implant. ¹⁰ The responses in the survey reflected this and 56% of respondents felt a combination of these factors would influence the decision to re-implant.

The timing of re-implant depends on the indication for extraction. In an infected CIED extraction guidelines recommend contralateral implants, when the patient is clinically stable. Only 60% of the survey respondents went with the guideline recommendation.

Interim pacing in pacing-dependent patients undergoing extraction is complex and requires some forethought. Fifty-five percent of respondents selected a semi-permanent system with a screw-in lead and externalized generator. Almost a third suggested an epicardial system and about 17% selected a leadless pacemaker (LPM).

All these options are reasonable, although the most recent EHRA consensus suggests ipsilateral semi-permanent system as a reasonable strategy to delay re-implant.^{25,26} Epicardial systems are a reliable way of providing pacing in patients at very high risk of infection, but in the past have been associated with higher mortality.²⁷

Emerging data suggests that in selected high-risk patients, the risk of infection with LPM appears low²⁸ and the device appears safe and feasible in patients with pre-existing CIED infection and after extraction of infected leads.²⁹

Self-assessment

The self-evaluation question at each stage of the questionnaire provides insight into the physicians' comfort level in dealing with clinical scenarios involving CIEDs and yielded perhaps the most alarming responses. Despite being a cohort comprising a large number of cardiologists and extracting physicians there was a high percentage of respondents who felt uncomfortable in dealing with all aspects of CIED care. This underscores the importance of managing these patients in a multidisciplinary setting with involvement of cardiologists, electrophysiologists, and microbiologists.

In the diagnosis and referral sections <50% of respondents felt their knowledge and skill were acceptable. A quarter of extractors felt they needed improvement and over 60% of non-extractors reporting their knowledge and skills in this area needed improvement.

This is an important finding as patients with CIEDs rely on diagnosis and referral in order to access appropriate treatment in a timely manner.

Table 3 Guidelines for antibiotic therapy post-CIED removal

Negative blood	Pathogen-directed antimicrobial therapy for	
cultures	2 weeks	
Positive blood	Staphylococcus aureus—4 weeks	
cultures	Other pathogens—2 weeks	
Positive blood cul-	 Pathogen directed therapy for 4–6 weeks 	
tures and positive	 Four weeks for native valve endocarditis 	
TOE	 Six weeks advised for prosthetic valve 	
	staphylococcus infection	
Start date is considered the date of CIED extraction		
CIED, cardiac implantable electronic devices; TOE, transoesophageal echo.		

The survey clearly showed that the areas which were perceived to be the most complex and challenging were the extraction procedure itself and the post-extraction care. Almost 75% of respondents felt their knowledge and skill needed improvement and a third of participants, who regularly undertake extraction work, still felt improvement was required. This level of uncertainty is striking and gives a clear mandate that more needs to be done to educate clinicians on all aspects of CIED management.

Limitations

This survey was reliant on voluntary participation and self-reporting to achieve its endpoints and achieved a response rate of 8% across three main groups of respondents i.e. cardiologists, internal medicine physicians, and cardiac surgeons. Physician surveys are an important tool in health services and policy research, providing cost-effective sources of information and physicians attitudes, knowledge, and practice related to care delivery and training. Despite their importance, however, physician surveys are hampered by low response rates, raising concerns about their validity, and generalizability of their findings. In the survey of the survey of the survey of their findings.

Specifically, low response rates raise concerns about non-response bias or the likelihood that non-responding physicians will be systematically different from the population under study. A response rate of 8% in this survey response rate was low, however, compared favourably with a response rate of 7% across a similar undertaking by EHRA on needs assessment in atrial fibrillation (AF). This is despite the fact that the prevalence of AF is substantially higher than that of CIED complications and cardiologists and physicians are much more likely to encounter patients with AF.

This is only a single survey with no follow-on questionnaire, so it is impossible to determine whether practice is changing over time.

Conclusions

This survey was undertaken to explore the prevalent knowledge and understanding of CIED management and lead extraction and help guide future educational strategies in this area.

The majority of respondents felt extraction was very high risk and nearly half perceived this to be a limitation to referring the patient for the procedure. When referring patients for extraction, half of

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respondents perceived barriers to access to extraction centres. The perception of extraction risk, diagnostic pathways, and referral streams will need to be addressed in order to improve referral across diverse healthcare settings.

There was also poor guideline adherence, particularly with respect to post-extraction care and antibiotic duration. This was reflected in low confidence in the self-assessments and may reflect the lack of clear recommendations as well as unfamiliarity with the existing guidelines. This is an area which would benefit from targeted educational activity to improve patient outcomes and address some of the misconceptions about the safety of transvenous lead extraction.

The survey highlighted discrepencies between the real world management and guideline recommendations. Given, a large proprtion of respondents were insightful enough to rate their knowledge as requiring improvement across all stages of the patient journey, an accessible and focused educational strategy will need to be implemented to improve patient outcomes.

Supplementary material

Supplementary material is available at Europace online.

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Data availability

The data of ESC surveys are stored by ESC in the association files. The data is kept at ESC for no more than 5 years. No data is stored or accessible elsewhere online. Only the authors coordinating the survey and Chair of the EHRA Scientific Initiatives Committee get access to the data through the EHRA/ESC.

References

- Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT et al. 16-year trends in the infection burden for pacemakers and implantable cardioverterdefibrillators in the United States 1993 to. J Am Coll Car- Diol 2011;58:1001–6.
- Dai M, Cai C, Vaibhav V, Rizwan Sohail M, Hayes DL, David OH et al. Trends of cardiovascular implantable electronic device infection in 3 decades: a populationbased study. JACC Clin Electrophysiol 2019;5:1071–80.

3. Deshmukh A, Patel N, Noseworthy PA, Patel AA, Patel N, Arora S *et al.* Trends in use and adverse outcomes associated with transvenous lead removal in the United States. *Circulation* 2015;**132**:2363–71.

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- Olsen T, Jørgensen OD, Nielsen JC, Thøgersen AM, Philbert BT, Johansen JB. Incidence of device-related infection in 97 750 patients: clinical data from the complete Danish device-cohort (1982–2018. Eur Heart J 2019;40:1862–9.
- Krahn AD, Longtin Y, Philippon F, Birnie DH, Manlucu J, Angaran P et al. Prevention of arrhythmia device infection trial: the PADIT trial. J Am Coll Cardiol 2018;72:3098–109.
- Tarakji KG, Mittal S, Kennergren C, Corey R, Poole JE, Schloss E et al. Antibacterial envelope to prevent cardiac implantable device infection. N Engl J Med 2019;380:1895–905.
- Sohal M, Williams S, Akhtar M, Shah A, Chen Z, Wright M et al. Laser lead extraction to facilitate cardiac implantable electronic device upgrade and revision in the presence of central venous obstruction. Europace 2014;16:81–7.
- Gula LJ, Ames A, Woodburn A, Matkins J, McCormick M, Bell J et al. Central venous occlusion is not an obstacle to device upgrade with the assistance of laser extraction. Pacing Clin Electrophysiol 2005;28:661–6.
- Diemberger I, Mazzotti A, Giulia MB, Cristian M, Matteo M, Letizia ZM et al. From lead management to implanted patient management: systematic review and meta-analysis of the last 15 years of experience in lead extraction. Expert Rev Med Devices 2013;10:551–73.
- Kusumoto FM, Schoenfeld MH, Wilkoff BL, Berul C, Birgersdotter-Green UM, Wazni O et al. 2017 HRS expert consensus statement on cardiovascular implantable electronic device lead management and extraction. Heart Rhythm 2017;14: e503–51.
- Deharo JC, Bongiorni MG, Rozkovec A, Bracke F, Defaye P, Fernandez-Lozano I et al.; Authors (EHRA Task Force Members). Pathways for training and accreditation for transvenous lead extraction: a European Heart Rhythm Association position paper. Europace 2012;14:124–34.
- Bongiorni MG, Burri H, Deharo JC, Starck C, Kennergren C, Saghy L et al.; ESC Scientific Document Group. 2018 EHRA expert consensus statement on lead extraction: recommendations on definitions, endpoints, research trial design, and data collection requirements for clinical scientific studies and registries: endorsed by APHRS/HARS. Europace 2018;20:1217.
- 13. Bongiorni MG, Kennergren C, Butter C, Deharo JC, Kutarski A, Rinaldi CA et al.; ELECTRa Investigators. The European Lead Extraction ConTRolled (ELECTRa) study: a European Heart Rhythm Association (EHRA) registry of transvenous lead extraction outcomes. Eur Heart J 2017;38:2995–3005.
- 14. Sandoe JA, Barlow G, Chambers JB, Gammage M, Guleri A, Howard P et al. Guidelines for the diagnosis, prevention and management of implantable cardiac electronic device infection. Report of a joint Working Party project on behalf of the British Society for Antimicrobial Chemotherapy (BSAC, host organization), British Heart Rhythm Society (BHRS), British Cardiovascular Society (BCS), British Heart Valve Society (BHVS) and British Society for Echocardiography (BSE). J Antimicrob Chemother 2015;70:325–59.
- 15. Habib G, Lancellotti P, Antunes MJ, Bongiorni MG, Casalta JP, Del Zotti F et al. 2015 ESC Guidelines for the management of infective endocarditis: the Task Force for the Management of Infective Endocarditis of the European Society of Cardiology (ESC). Endorsed by: European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Nuclear Medicine (EANM). Eur Heart J 2015;36:3075–128.
- Wilkoff BL, Love CJ, Byrd CL, Bongiorni MG, Carrillo RG, Crossley GH, 3rd et al. Transvenous lead extraction: heart Rhythm Society expert consensus on facilities, training, indications, and patient management: this document was endorsed by the American Heart Association (AHA). Heart Rhythm 2009;6: 1085–104.
- 17. Baddour LM, Epstein AE, Erickson CC, Knight BP, Levison ME, Lockhart PB et al.; Council on Cardiovascular Surgery and Anesthesia. Update on cardiovascular implantable electronic device infections and their management: a scientific statement from the American Heart Association. Circulation 2010;121:458–77.
- 18. Traykov V, Bongiorni MG, Boriani G, Burri H, Costa R, Dagres N et al. Clinical practice and implementation of guidelines for the prevention, diagnosis and management of cardiac implantable electronic device infections: results of a worldwide survey under the auspices of the European Heart Rhythm Association. Europace 2019;21:1270–9.
- Sohail MR, Henrikson CA, Braid-Forbes MJ, Forbes KF, Lerner DJ. Increased long-term mortality in patients with cardiovascular implantable electronic device infections. *Pacing Clin Electrophysiol* 2015;38:231–9.
- Sohail MR, Henrikson CA, Braid-Forbes MJ, Forbes KF, Lerner DJ. Mortality and cost associated with cardiovascular implantable electronic device infections. Arch Intern Med 2011:171:1821–8.
- 21. Tan EM, DeSimone DC, Sohail MR, Baddour LM, Wilson WR, Steckelberg JM et al. Outcomes in patients with cardiovascular implantable electronic device infection managed with chronic antibiotic suppression. Clin Infect Dis 2017;64: 1516–21.

- Viganego F, O'Donoghue S, Eldadah Z, Shah MH, Rastogi M, Mazel JA et al. Effect
 of early diagnosis and treatment with percutaneous lead extraction on survival in
 patients with cardiac device infections. Am J Cardiol 2012;109:1466–71.
- 23. Blomström-Lundqvist C, Traykov V, Erba PA, Burri H, Nielsen JC, Bongiorni MG et al.; ESC Scientific Document Group. European Heart Rhythm Association (EHRA) international consensus document on how to prevent, diagnose, and treat cardiac implantable electronic device infections-endorsed by the Heart Rhythm Society (HRS), the Asia Pacific Heart Rhythm Society (APHRS), the Latin American Heart Rhythm Society (LAHRS), International Society for Cardiovascular Infectious Diseases (ISCVID) and the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS. Europace 2020;22:515–49.
- 24. Iversen K, Ihlemann N, Gill S, Madsen T, Elming H, Klein CF et al. Partial oral versus intravenous antibiotic treatment of endocarditis. N Engl | Med 2019;380:415–24.
- Kornberger A, Schmid E, Kalender G, Stock UA, Doernberger V, Khalil M et al. Bridge to recovery or permanent system implantation: an eight-year single-centre experience in transvenous semi-permanent pacing. Pacing Clin Electrophysiol 2013;36:1096–103.
- Kawata H, Pretorius V, Phan H, Mulpuru S, Gadiyaram V, Patel J et al. Utility and safety of temporary pacing using active fixation leads and externalized reusable permanent pacemakers after lead extraction. Europace 2013;15:1287–91.

- Deharo JC, Quatre A, Mancini J, Khairy P, Le Dolley Y, Csalta JP et al. Long-term outcomes following infection of cardiac implantable electronic devices: a prospective matched cohort study. Heart 2012;98:724

 31.
- Beurskens NEG, Tjong FVY, Dasselaar KJ, Kuijt WJ, Wilde AAM, Knops RE. Leadless pacemaker implantation after explantation of infected conventional pacemaker systems: a viable solution? Heart Rhythm 2019;16:66–71. EHRA position paper 33.
- 29. El-Chami MF, Johansen JB, Zaidi A, Faerestrand S, Reynolds D, Garcia-Seara J et al. Leadless pacemaker implant in patients with pre-existing infections: results from the Micra post approval registry. J Cardiovasc Electrophysiol 2019;30: 569–74.
- Mosca L, Linfante AH, Benjamin EJ, Berra K, Hayes SN, Walsh BW et al. National study of physician awareness and adherence to cardiovascular disease prevention guidelines. Circulation 2005;111:499–510.
- Kellerman SE, Herold J. Physician response to surveys: a review of the literature.
 Am J Prev Med 2001;20:61–7.
- Heidbuchel H, Dagres N, Antz M, Kuck KH, Lazure P, Murray S et al. Major knowledge gaps and system barriers to guideline implementation among European physicians treating patients with atrial fibrillation: a European Society of Cardiology international educational needs assessment. Europace 2018;20: 1919–28.