

# Standards for device implantation and follow-up: personnel, equipment, and facilities: results of the European Heart Rhythm Association Survey

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Received 29 June 2014; accepted after revision 8 July 2014

Cardiac device implantation is the most common of all invasive cardiac electrophysiological procedures. Over 250 000 devices are implanted each year in Europe. The purpose of this European Heart Rhythm Association (EHRA) survey was to assess the facilities, personnel, and protocols of members of the EHRA electrophysiology (EP) research network involved in device implantation. There were 68 responses to the questionnaire. The survey responses were mainly (84%) from medium- to high-volume device implanting centres, performing >200 implants per year, with over 50% performing >400 implants per year. Most consultants are male (85%), half of all centres had no female consultants, and only one in six had more than one female consultant. There is trend towards specialization in device implantation. The combination of device implantation and EP is still common (76% of all centres) but only 34% of centres have consultants performing device implantation and coronary intervention. Moreover, 23% of centres have all device implantation performed by consultants who do not perform any other types of procedure. Cardiac device implantation as a day case is the planned admission for routine elective device implantation in 30% of hospitals, 47% of hospitals have a single night stay, and 23% of hospitals have admission durations of two or more nights. Device implantation is available as a 24 h service, 365 days a year in 38% of hospitals. The commonest other model was as a daytime service on weekdays in 45% of hospitals.

**Keywords** Pacemaker • Implantable cardiac defibrillator • Personnel • Equipment • Facilities • EHRA survey • EP wire

## Introduction

The most common interventional procedure performed by heart rhythm specialists in Europe, with over 250 000 procedures annually, is cardiac device implantation.<sup>1</sup> Worldwide over 1.25 million pacemakers and 400 000 implantable cardiac defibrillators (ICDs) are implanted each year.<sup>2</sup> There are clear international guidelines on the indications for pacing and cardiac resynchronization therapy<sup>3</sup> but little in the way of practical advice within those guidelines on the process of the pacing procedure, which is generally learnt by a proctoring process during training. Although some national standards exist,<sup>4</sup> there is little international consensus on standards for the implant procedure, peri-procedural anticoagulation, staffing, and follow-up. The purpose of this European Heart Rhythm Association (EHRA) survey was to assess the practice of hospitals within the EHRA electrophysiology (EP) research network.

## Methods and results

### Participating centres

This survey is based on a questionnaire sent via the internet to the EHRA EP research network centres. Overall, 68 institutions responded. There was a wide geographical distribution from 19 countries (28 centres in the UK; 7 in Italy; 6 in Spain; 5 in Germany; 3 in Austria and Denmark; 2 in Belgium, France, and Georgia; and 1 centre in each of Argentina, Estonia, Greece, Lithuania, Norway, Romania, Serbia, Slovenia, Sweden, and Turkey). Forty-seven of the centres (69%) were university hospitals, 5 private hospitals (7%), and 16 (24%) other type of hospitals. Hospital procedure numbers are shown in Table 1. Most centres were medium- (200–399, 32%) or high-volume (>400, 52%) implanting centres. Only two centres implanted <99 devices per year.

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**Table 1** Total device implant numbers per centre (n = 65)

Implant numbers	0	1–99	100–199	200–399	>400
All devices	1	2	7	21	34
ICD	7	20	27	8	3
CRT	8	29	21	7	0

ICD, implantable cardiac defibrillator; CRT, cardiac resynchronization therapy.

Within these centres, ICD implant numbers were >100 per annum in 59%, <99 per year in 30%, and 11% performed no ICD implants. For CRT, 12% of hospitals did not implant, with 46% implanting <99 per year and 44% >100 per year.

## Device implanting personnel/staffing structure

The device implantation department was mainly part of cardiology (47 of 62 centres; 76%) and in only 2 centres (3%) was the device implantation service independent of both cardiology and EP. A heart rhythm specialist was the head of the cardiology department in 12 of 62 (19%) institutions.

Most consultants and trainees are male physicians. At the 60 centres which completed the staffing questions on the survey, there were 268 male consultants and 49 female consultants. The majority of centres had between 2 and 4 male consultants (55%), but 8% had 10 or more. Half of all centres had no female consultants, 33% had one female consultant and only one in six had more than one female consultant. The imbalance between males and females was less pronounced in trainees with 134 males and 70 females. Most centres had 1–3 male trainees and 0–2 female trainees. Part-time working is still not common in device work, with only 5% of female consultants and 18% of male consultants working part-time. Part-time jobs are well distributed throughout the European countries responding to the survey.

In the questionnaire, hospitals were asked to state what percentage of the device-implanting consultants performed other procedures in addition to device implantation. The most common combination was that of interventional EP and device implantation in 76% of hospitals. None of the device consultants performed coronary intervention (PCI) in 66% of hospitals. In only two large volume centres, there were >50% of consultants who also performed PCI (one in UK and one in Germany). Consultants specializing exclusively in device implantation are becoming increasingly common with 27 of 60 centres (45%) reporting at least one such consultant at their centre. All except 1 of the 27 centres with a specialist device consultant implant >200 devices per year and most >400. In 11 of 60 (18%) hospitals, device implantation is exclusively performed by device specialists. The model of a device specialist appears to be more common in the larger centres.

## Device implant procedures

Most devices are now implanted by Cardiologists but there remain a few centres where surgeons perform significant proportions of

transvenous device implants. Only one centre reported that 100% of device implants were performed by a surgeon with two others reporting that >50% of implants were by a surgeon. The majority (81%) of centres reported that Cardiologists performed 100% of all transvenous implants (this question excluded epicardial lead implants). Within cardiology, there was a good balance between the proportions of implants performed by physicians in training as the first operator vs. consultants. Of the 61 centres answering this part of the questionnaire, 34 (56%) indicated that a consultant was the first operator in >70% of cases. There appears to be good training opportunities in most centres with physicians in training performing implants as the first operator in between 10 and 80% of cases.

Sixty-one centres responded to the question on the location of device implants. Some centres have more than one device implanting facility. Device implants are most commonly performed (76% of centres) in a catheter laboratory that also performs EP procedures. A dedicated pacemaker operating theatre is used in 28%, a hybrid lab in 11%, and an operating theatre in 18% of centres.

During the implant procedure, assessment of lead parameters is generally well supported. Every centre apart from two has support from a cardiac physiologist, specially trained nurse, or an industry representative during implant procedures.

The choice of device manufacturer is most commonly (63%) from two to three suppliers from a previously tendered contract. In 30% of centres it is entirely at the discretion of the implanting consultant, but in 7% of hospitals it is determined by the hospital/insurance company.

There was significant variation on the presence of a radiographer to aid in the device implant procedure. The split is approximately that half of the centres 'never' have a radiographer but the other half 'always' have a radiographer. This variation in practice occurs both within countries and between European countries.

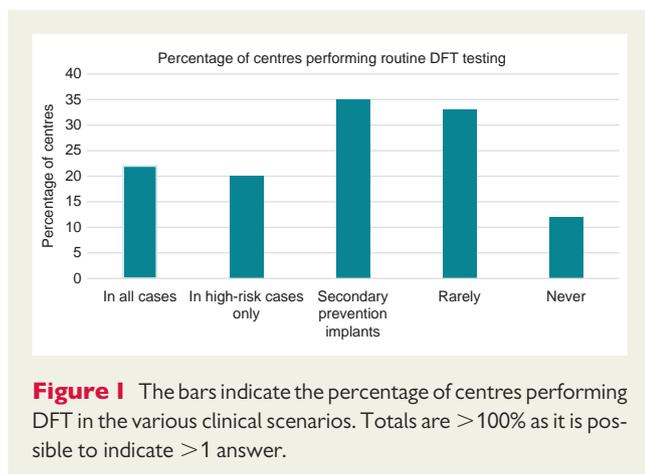
Peri-procedural antibiotics are used in all centres, with most centres using intravenous cephalosporins (54%) or a combination of other intravenous antibiotics (41%). Only 5% of centres put antibiotics into the pacemaker pocket.

The EP wire was performed at the same time as the results of the SIMPLE study<sup>5</sup> were presented at the Heart Rhythm Society. We assessed contemporary practice in defibrillation threshold testing (DFT). While some centres performed DFT on either all cases or no cases, within centres that performed DFT testing on only a proportion of cases the commonest combination of practice was to perform testing in secondary prevention cases and cases judged to be high risk for an elevated DFT (e.g. right sided implants, heart failure) (Figure 1).

## Procedural planning/admission

We recognized that policies for stopping anticoagulants and antiplatelet agents prior to elective device implantation would vary significantly, even within the same centre, dependent on the indication for the treatment. The results of the survey, therefore, only give a broad overview of practice and do not cover every clinical situation. There is clear evidence now that the continuation of oral anticoagulants, especially vitamin K antagonists (VKA), is safe at the time of device implant.<sup>6</sup>

For VKA anticoagulation, it was clear that centres varied practice depending on the anticoagulant indication. In the survey, 27% of centres had an even spread of VKA discontinuation with no single



**Figure 1** The bars indicate the percentage of centres performing DFT in the various clinical scenarios. Totals are > 100% as it is possible to indicate > 1 answer.

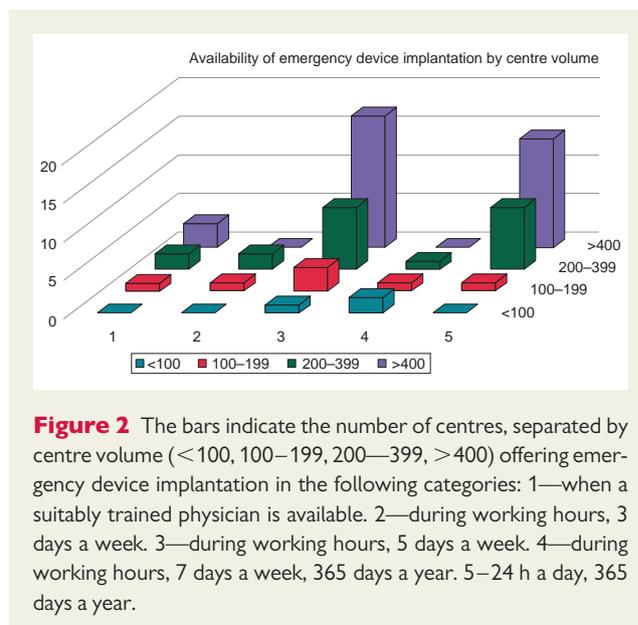
pattern predominating. Most centres preferred one particular regime for > 50% of cases as follows. Patients discontinued VKA 5 days prior to the procedure in 15% of centres, 3 days prior to the procedure in 25%, omitting only one dose of VKA in 5% or on continuous VKA in 28%. A small number (13%) of centres perform all device implants on continuous VKA, but 23% of centres indicated that they always discontinue VKA for at least a short period prior to implant. The maximum international normalized ratio (INR) accepted for a device implant was 1.5 in 4 (7%), 2.0 in 14 (23%), 2.5 in 14 (23%), 3.0 in 21 (35%), and 3.5 in 7 (12%). There was no clear relationship between centre procedure volume and maximum accepted INR.

For the new oral anticoagulant drugs (NOACs), > 90% of centres indicated that in most cases they discontinued these drugs 1–2 days prior to the procedure. Four centres indicated that they performed implants with continued NOAC use in > 50% of patients taking these drugs, and a larger number (9 of 39 who answered this part) indicated that they performed between 10 and 20% of implants in NOAC-treated patients on continued treatment.

The discontinuation of antiplatelet drugs (aspirin, clopidogrel, and prasugrel) varied greatly. There were 75% of centres that were happy to implant on continuing antiplatelet therapy, although for one-third of these centres this only occurred for patients with recent (< 1 year) drug-eluting stent implantation. The commonest other policy (15% of centres) was to continue aspirin but stop other antiplatelets 5 days prior to device implant.

## Device implant service delivery

Perhaps, the most interesting part of this survey was to understand the variation in service delivery for urgent cases and the length of patient stay for elective cases. Despite the majority (84%) of centres being of medium to high volume (> 200 implants per annum), only a proportion provided a full on-call service for device implantation (Figure 2). Of the 60 centres which answered this part, 23 (38%) provided a 24 h/365 days a year service. Most other centres (27, 45%) were restricted to a daytime, weekday implants service. The remainder mainly answered ‘only when a suitably trained physician is available’ and this likely reflects an on-call rota where non-PCI work is shared among Cardiologists of various specialities.



**Figure 2** The bars indicate the number of centres, separated by centre volume (< 100, 100–199, 200–399, > 400) offering emergency device implantation in the following categories: 1—when a suitably trained physician is available. 2—during working hours, 3 days a week. 3—during working hours, 5 days a week. 4—during working hours, 7 days a week, 365 days a year. 5—24 h a day, 365 days a year.

The planned duration of admission for elective device implantation is variable. A number of centres (18, 30%) do planned cases as day-case admissions. The most common pattern was a single overnight stay in 28 (47%) centres, with a smaller number (8, 13%) having two night admissions and 6 (10%) greater than two nights. There is a very limited literature on the safety of day-case implantation despite this first being described 25 years ago,<sup>7</sup> and the centres performing day-case implants are widely distributed geographically within Europe. In addition, some lower volume centres as well as the high-volume centres perform day-case procedures.

## Follow-up

In general, follow-up is performed by a trained nurse/cardiac physiologist with a physician available but not always present. Remote follow-up is not yet universal. A small number of centres, eight (13%), do not perform any remote follow-up. Implantable cardiac defibrillator remote follow-up is the standard of care in 35 (58%) implanting centres, with 8 (13%) also following pacemaker patients remotely. Most other centres use remote follow-up selectively, although interestingly the distance between the patient’s home and the centre did not appear to be a strong determinant in this decision-making process.

## Discussion

The EP wire shows a considerable variation in some areas of the process and staffing for cardiac device implantation. Further studies on day-case implantation seem warranted to determine whether this policy could be adopted more widely throughout Europe. It is also interesting that despite including a large proportion of high-volume implanting centres, that urgent/emergent device implantation is still only available immediately in 38% of centres. While it is not clear that there is a mortality benefit from urgent pacemaker

implantation compared with semi-elective implantation, fewer trainees are now skilled in temporary transvenous pacing which is a cause for concern if patients are waiting. Although transcutaneous pacing can be used, it is difficult for the patient to tolerate for anything longer than a short period.

There are more women training in device implantation, compared with the current consultant numbers, which are male dominated. This is almost certainly partly due to the increased numbers of female physicians, but may also indicate that EHRA initiatives to encourage women are having a positive effect. There are now a significant number of device specialists who focus exclusively on this area and this is good for future practice.

Performing device implants while anticoagulated with VKA is widespread throughout Europe; however, there is considerable variability on the highest accepted INR for the procedure. A previous EP wire<sup>8</sup> in 2012 assessed peri-procedural anticoagulation related to device procedures and reported that 40–45% of centres used bridging heparin, the median highest INR accepted for implant was 2.5 and that the commonest policy was to stop VKA 3 days prior to implant. Despite the subsequent publication of the BRUISE CONTROL<sup>6</sup> study in 2013 showing good safety for implant procedures with INRs up to 3.0 in most patients and 3.5 in patients with mechanical heart valves, variability in practice is still significant. It appears that many centres could allow a higher INR at the time of device implantation.

The testing of DFT at the time of ICD implant was also recently assessed in an EP wire.<sup>9</sup> This survey reported that DFT testing was performed in <30% of cases, with 32% of centres never performing a DFT. Only 12% of centres in the current survey reported that they never performed a DFT. The difference is probably due to the different geographical distribution of the respondents with a high number of UK centres in this survey.

We hope this document will allow centres to adjust practice in areas they wish to change.

## Acknowledgements

The production of this EP wire document is under the responsibility of the Scientific Initiative Committee of the European Heart Rhythm Association: Carina Blomström-Lundqvist (chairman), Maria Grazia Bongiorni (co-chair), Jian Chen, Nikolaos Dages, Heidi Estner, Antonio Hernandez-Madrid, Melece Hocini, Torben Bjerregaard Larsen, Laurent Pison, Tatjana Potpara, Alessandro Proclemer, Elena Sciaraffia, and Derick Todd. The authors acknowledge the EHRA Research Network centres participating in this EP Wire. A list of the Research Network can be found on the EHRA website.

**Conflict of interest:** none declared.

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