Barriers to patients eligible for screening investigations and insertion of primary prevention implantable cardioverter defibrillators

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Aims
Primary prevention (PP) implantable cardioverter defibrillator (ICD) implant rates in the UK are below national targets and barriers to this are not well known. This study was designed to identify the stages along the referral pathway from general to specialist care that eligible patients reach and what proportion eventually receive an ICD.

Methods and results
A single institution database search was performed to identify all adults with severe left ventricular systolic dysfunction (left ventricular ejection fraction, LVEF ≤ 35%), documented in the calendar year 2007. Medical records were assessed for age, heart failure aetiology, QRS duration, evidence of non-sustained ventricular tachycardia on Holter, electrophysiological study, and records of consultation with general physicians, cardiologists, and electrophysiologists (EPs) and reference to assessment of risk of sudden cardiac death and the role of ICD implantation. Three hundred twenty-six patients with LVEF ≤ 35% were identified from three electronic databases. Mean age was 72 ± 12 years. Seventy-two patients satisfied UK National Institute for Clinical Excellence guidelines for PP ICD implantation and 63 eligible for further screening. Of the 135 patients, 76 (56%) patients reviewed by a general cardiologist did not receive ICD implantation or referral for further assessment. When offered, ICD acceptance rate was high (35 vs. 3 patients who refused ICD). After seeing an EP, 8 of 47 (17%) patients were not offered ICD or further screening. The average age was 66.5 ± 6.2 years and no patient greater than 80 years had a PP ICD.

Conclusions
Failure to refer from the general physician to cardiology and from the cardiologist to EP is the principle reason for low PP ICD implant rates among eligible patients in the UK.

Keywords
Implantable cardioverter defibrillators • Primary prevention • Tertiary centre

Introduction
Randomized clinical trials have shown mortality benefit from primary prevention (PP) implantable cardioverter-defibrillators (ICDs) in patients at high risk of sudden cardiac death (SCD).1–5 Indications for PP ICD implantation in the United Kingdom were published in January 2006 by the National Institute for Clinical Excellence (NICE).6 Eligible patients require a history of previous myocardial infarction (MI) (> 4 weeks) and either, left ventricular ejection fraction (LVEF) ≤ 35%, no worse than class New York Heart Association (NYHA) class III, have non-sustained ventricular tachycardia (nsVT) on Holter monitoring and inducible ventricular tachycardia (VT) on electrophysiological (EPS) testing, or LVEF ≤ 30%, no worse than NYHA class III and have a QRS duration ≥ 120 milliseconds. Despite these well-publicized guidelines, implant rates are lower than national targets and PP ICD only account for a minority of implants in the United Kingdom.7

The reasons for low PP implant rates are likely to be multifactorial and include lack of physician knowledge (particularly non-implanting cardiologists), failure to implement guidelines, failure to screen patients and collect relevant data such as LVEF, a lack of financial resources or implanting cardiologists; age, gender or race bias or even patient refusal to accept the therapy. This study investigates whether there is a failure to refer patients with appropriate...
Patient aged ≤ 80 years

Of the 92 patients ≤ 80 years of age who were assessed by the general cardiologist, 48 of 92 (52%) had MADIT2 wide QRS (UK NICE) criteria making them eligible for ICD implant with no further testing. Of the 92 patients, 42 of 92 (46%) were referred to EP. There was no evidence in the medical records of discussion about SCD prevention and the role of an ICD in those that had not been referred onwards. Of the 42 patients referred to EP, 35 of 42 (83%) received an ICD, 4 of 42 (10%) patients were not offered ICD or further screening, 1 of 42 (2%) patient had negative EPS, and 2 of 42 (5%) patients declined ICD after consultation. Only 1 of 52 patients seen by the general cardiologist but not referred on to EP had Holter monitoring to screen for nsVT (Figure 2).

Patient aged > 80 years

There were a total of 41 patients aged > 80 years satisfying UK NICE PP ICD criteria and seen by the general cardiologist. Of these, only 5 of 41 (12%) patients were referred to EP. One was offered but declined ICD therapy. None of the other four, all who had LVEF ≤ 30% and QRS duration ≥ 120 ms, were offered ICD by the EP cardiologist. No patient > 80 years of age had implantation of a PP ICD, despite having no medical contraindication and achieving all the criteria set by the National and International guidelines (Figure 3).

Gender

The majority of patients in the study group were male (95 of 135, 70%). There was a trend towards a gender bias with 29 of 95 (31%) of eligible or potentially eligible male patients receiving an ICD compared with 6 of 40 (15%) of female patients; however, this did not reach statistical significance (P = 0.08).

Discussion

Our study identified 135 patients with ischemic cardiomyopathy and a LVEF of ≤ 35% who were eligible or potentially eligible for a PP ICD. Of the 72 (53%) patients who had a wide QRS and no co-morbidities, satisfying UK national guidelines for a PP ICD, one half progressed no further than general cardiology and were not referred
to an EP cardiologist for consideration of an ICD implant. Of the 61 (45%) patients who were eligible for screening with Holter monitors (and if positive for nsVT, EPS) all had seen a general cardiologist but 80% were not referred on to an EP for further assessment. Thus, when all the necessary information on heart failure aetiology, LVEF, and ECG QRS duration is present in the medical records, the major barrier to referral for assessment and implantation of a PP ICD occurs at the general cardiologist level.

The UK national target is 100 new ICD implants per million population per year, including an estimated 40 PP ICDs. Although this study data were collected and analysed in 2009, the UK implant rate remains static (national average ICD implant rate of 76 per million population in 2011) and the implant rates per million for Oxfordshire remain low (60 in 2008, 58 in 2009, 76 in 2010, and 52 per million in 2011) indicating a steady state in referral numbers.

In this study, only 6% of patients with all the requisite information in their records had not been seen by a cardiologist. Their presence on one of the three databases reviewed was likely to be a consequence of prior cardiology consultation. The echocardiography database was the only investigation that may have been requested directly from general medicine with cardiology review. The number of patients with undocumented LVEF \( \leq 35\% \) and ischaemic heart disease (IHD) that do not appear on the three databases and remain in primary care or general medicine is not known.

**Figure 1** Flow chart showing criteria for PP ICD implantation and referral pathway.
A recent questionnaire survey has highlighted a significant lack of knowledge of guidelines among cardiologists who do not implant ICDs. In case scenarios, non-implanters frequently failed to offer knowledge of guidelines among cardiologists who do not implant patients for Holter and EPS, suggesting that there is less knowledge patients for ICDs and only a minority of potentially eligible MADIT plexity may prevent recall of indications. In this study, general cardiologists may mistakenly believe that MADIT2 wide QRS patients are at higher risk and have more to gain, whereas in actuality, the number needed to treat to prevent one death at 3 years in the original MADIT trial was smaller than MADIT2 (4 vs. 11). Hospitals with higher implant rates appear to be better at adopting published guidelines across the spectrum of cardiology. To overcome the deficit in the UK, there either needs to be improved education and guideline awareness, or a simplification of the guidelines, broadening the criteria and bringing them in line with Europe and North America. In a survey of New Zealand cardiologists’ and general physicians’ knowledge and use of ICDs, 62% replied that they were familiar with international guidelines. Only half thought that PP ICD use was cost-effective. In our study, it is possible that some patients were not referred to EP due to a bias against device therapy based on cost rather than a lack of guideline awareness. However, even secondary prevention ICDs are underutilized even when there is a perception that they are more cost-effective than PP ICDs.

Previous trials, including MADIT2, have shown underutilization of ICD implants in women and ethnic minorities. In MADIT 2 trial, women represented only 13% of the total recruitment while Blacks 8% and Hispanics 3%. In our study, we found almost twice the proportion of women did not receive ICD or screening compared with men, although this did not reach statistical significance. In our study, no patients >80 years of age received a PP ICD. This elderly group made up 30% of all patients identified with eligible criteria and represents a more ‘real world’ population when compared with the PP trials, where 50% of patients enrolled were under the age of 60. Advanced age had less of an effect on general medicine referrals but there was a significant influence on cardiologists, who only referred 14% of the over-80s to EP, none of who were offered an ICD. In USA practice in 2004–2005, 16% were in-patients aged 80 years or more. This age bias present in UK cardiologists has been demonstrated in a previous survey.

Only 2 of 42 patients under 80 years of age referred on to EP cardiologist declined screening tests or an ICD implant. This concurs with previous studies reporting patient refusal as the cause for eligible patients not receiving ICDs in 7% of cases and non-referral was the dominant reason, occurring in 33 – 38% of patients. This suggests that selected patients will almost always accept device therapy when offered. Patients are more optimistic about the benefits of therapy than their treating physicians.

**Conclusions**

When the relevant data are available in medical records, the principle barrier to a PP ICD is the failure of general cardiologists to refer patients to EP cardiologist. Patients who already have all the criteria (IHD, LVEF < 30% and wide QRS) are more likely to be referred than those who require additional screening with Holter and, if appropriate, EPS. There is an age bias against the elderly with no patients aged >80 in this study offered an ICD. When offered, almost all patients accept the therapy. Better education of general cardiologists may help raise UK implant rates up to national target levels. When the relevant data are available in medical records, the principle barrier to a PP ICD is the failure of general cardiologists to refer
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