The incidence of implantable cardioverter defibrillator indications in patients admitted to all coronary care units in a single district

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KEYWORDS
implantable cardioverter defibrillators (ICDs); guidelines; audit

Abstract
Aims Implantable cardioverter defibrillators (ICDs) have been shown to reduce all-cause mortality in groups of patients at high risk of ventricular arrhythmias. The true incidence of ICD indications is unknown but we hypothesize that it far exceeds the number actually implanted.

Methods In a one month observational audit, we reviewed the clinical records of all 336 patients admitted to coronary care units serving a district with a population of 471,000, to determine the additional screening tests required in myocardial infarction (MI) survivors and the number of additional ICDs which would be implanted for the primary and secondary prevention indications recommended in UK National Institute for Clinical Excellence (NICE) guidance. A further analysis was performed to determine the effect of extending the primary prevention indications to include the selection criteria used in the second multicentre automatic defibrillator trial, MADIT II.

Results Using NICE criteria, we found the incidence of ICD indications to be 98.4/10⁶/year. The addition of patients fulfilling MADIT II selection criteria for primary prevention would have increased this to 453/10⁶/year.

Conclusion We conclude that the implementation of national guidance on the use of ICDs for arrhythmias will require the systematic screening of MI survivors, and would identify an incidence of ICD indications at least three times that anticipated by NICE, and eight times as many as were actually implanted in the UK in 2000. If the primary prevention indications were widened to include MADIT II selection...
Introduction

Data from randomised controlled trials on the use of implantable cardioverter defibrillators (ICDs) for both primary [1–3] and secondary prevention [4–7] of sudden cardiac death have accumulated rapidly in recent years. In the United Kingdom (UK), the National Institute for Clinical Excellence (NICE) reviewed this evidence, and published guidance on the use of ICDs for arrhythmias in September 2000 [8] (Table 1). This document states that those "managing cardiothoracic services should review their current clinical practice against this guidance". As a part of this process, we audited patient contacts with cardiac services in a large ICD implanting centre [9], and showed that all ICDs implanted were in accordance with NICE recommendations. We also revealed a large number of patients who fulfilled the NICE criteria, but did not undergo ICD implantation. We could not, however, determine the true incidence of patients with indications for ICD implantation, as the size of the referral population was unknown. We addressed this limitation by auditing all patient admissions to the three coronary care units (CCUs) serving a defined district with a population of 471,000.

Since the publication of the NICE guidance, the second Multicenter Automatic Defibrillator Implantation Trial (MADIT II) has demonstrated that ICD therapy conveys a 31% reduction in all-cause mortality in patients with previous myocardial infarction and a left ventricular ejection fraction of <30% [10]. This has been recognised in the ACC/AHA/NASPE 2002 update on indications for ICD therapy [11]. These simplified selection criteria remove the requirement for a complex screening cascade to identify the high-risk post myocardial infarction patient who might benefit

<table>
<thead>
<tr>
<th>Table 1</th>
<th>NICE guidance [8] on the use of implantable cardioverter defibrillators for arrhythmias</th>
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</thead>
<tbody>
<tr>
<td>Secondary prevention</td>
<td>Patients who present, in the absence of a treatable cause, with:</td>
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<tr>
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<td>• Cardiac arrest due to ventricular tachycardia (VT) or ventricular fibrillation (VF)</td>
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<td>• Spontaneous sustained VT causing syncope or significant haemodynamic compromise</td>
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<td>• Sustained VT without syncope/cardiac arrest, and who have an associated reduction in ejection fraction (less than 35%) but are no worse than class III of the New York Heart Association functional classification of heart failure</td>
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<tr>
<td>Primary prevention</td>
<td>Patients who have not suffered a previous resuscitated sudden cardiac death nor previous VT but have:</td>
</tr>
<tr>
<td></td>
<td>• A history of previous myocardial infarction (MI) and all of the following:</td>
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<td></td>
<td>(i) non-sustained VT on Holter (24 h ECG) monitoring;</td>
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<td></td>
<td>(ii) inducible VT on electrophysiology testing;</td>
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<tr>
<td></td>
<td>(iii) left ventricular dysfunction with an ejection fraction (EF) less than 35% and no worse than class III of the New York Heart Association functional classification of heart failure.</td>
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<tr>
<td></td>
<td>• A familial cardiac condition with a high risk of sudden death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia (ARVD) and following repair of Tetralogy of Fallot.</td>
</tr>
<tr>
<td>The use of ICDs should not be routinely considered for patients in the following categories:</td>
<td>Patients with spontaneous sustained VT with minimal symptoms and good cardiac function (EF &gt; 35%).</td>
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<td>Patients presenting with syncope of unknown cause (with no previous history of MI) and who have inducible VT on electrophysiological testing (EPS) in the presence of normal cardiac function (EF &gt; 35%).</td>
</tr>
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<td></td>
<td>Patients with syncope of unknown origin, with haemodynamically significant VT or VF induced at EPS and in the presence of impaired cardiac function (i.e. EF &lt; 35%).</td>
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from ICD therapy, but would be expected to increase the number of patients with an indication for ICD therapy. We used both the NICE criteria and the MADIT II selection criteria as audit standards.

**Methods**

The records of each of the 336 patients admitted to the three CCUs in our district during one month were audited for both primary and secondary ICD indications using previously described methodology [9]. The screening cascade used is shown in Fig. 1. The date of the index event in each patient was recorded in order to differentiate between patients with new ICD indications (incidence) and the patients with pre-existing ICD indications (prevalence). The patients’ post-codes were recorded so that only those resident in the district were included in the analysis. Because there was no systematic screening for high-risk post-MI patients, extrapolations were made from published data [12,13] of the consequences of the investigations required for this (Table 2). The total number of ICDs implanted in patients resident in the district during the year preceding the audit was determined from ICD implantation records in order to calculate the district implantation rate.

**Results**

Fourteen first ICDs were implanted in patients from the district during the year preceding the audit, an implantation rate of 29.7/10^6/year. During the audit period, 145 patients were admitted to the Freeman Hospital (FH), 96 to the Royal Victoria Infirmary (RVI) and 95 to North Tyneside District Hospital (NTDH) CCUs. Of these, 45 (31%) in FH, 83 (86%) in RVI and 95 (100%) in NTDH were normally resident within the district. All ICDs implanted, both during the month of screening (detailed in Table 3) and in the previous year, were in accordance with NICE guidance. Seven patients were identified who fulfilled NICE secondary prevention criteria, but did not undergo ICD implantation (Table 3). There was no evidence in the records of four of these that ICD therapy had been considered. Three of these seven patients were resident in the district and had their index event within the qualifying month, giving an incidence of 76.4 ICDs/10^6/year for secondary prevention.
Full screening of patients would have required an extra 42 (1070/10^6/year) echocardiograms, 15.7 (401/10^6/year) Holter recordings and 2.47 (62.9/10^6/year) electrophysiology studies. This additional screening would be expected to result in an additional 0.86 (22.0/10^6/year) ICDs for primary prevention, giving a total of 98.4/10^6/year applying NICE criteria. If MADIT II criteria were adopted, screening would have identified an additional 14.8 patients (376/10^6/year) with indications for ICD implantation for primary prevention (Table 4). Adding this to our ICD implantation rate of 29.7/10^6/year gives a total incidence of 128/10^6/year for NICE indications, and 483/10^6/year if MADIT II criteria were included.

In addition to identifying patients with new indications for ICD implantation, this audit also identified patients with indications for ICDs, the index event for which was outside the qualifying month. If this were consistently repeated over a year, it would be equivalent to an additional 41.2 ICDs/10^6/year using NICE criteria, and 311 ICDs/10^6/year, using MADIT II criteria.

**Discussion**

This audit has confirmed that all ICDs implanted in patients from Newcastle and North Tyneside comply with UK national guidance. It also shows that the district ICD implantation rate of 29.7 per million in 2000/2001 was higher than the UK national average of 19.0 per million [14], although short of the NICE "target" of 40 per million (the estimate of 50 ICDs per million including 10 per million (20%) replacement devices) [8]. It has also demonstrated that the number of patients fulfilling NICE criteria for secondary prevention and not receiving ICDs was 76.4/10^6/year. If this number is added to those in the district who did receive an ICD for these indications, a total of 106 ICDs/10^6/year is required, clearly far in excess of the NICE "target".

During the audit period, no patient in the district either received or was referred to the implanting centre for consideration of ICD implantation for primary prevention of sudden cardiac death. No systematic screening programme was in place in any of the three hospitals to identify patients who fulfil the MADIT/MUSTT criteria for primary prevention. Using calculations based on published data relating to the incidence of severely impaired left ventricular function post-MI, non-sustained ventricular tachycardia on ambulatory monitoring and inducibility of ventricular tachycardia at electrophysiological study, we were able to calculate the number of patients who might be considered for ICD implantation had such a screening programme been in place. This indicated an
additional incidence of 22.0 ICDs/10^6/year, the overall incidence of first ICDs becoming 128/10^6/year.

The recently updated ACC/AHA guidelines on ICD implantation include patients fulfilling MADIT II criteria as having a class IIa indication for ICD implantation [11]. If NICE guidance were to be modified to include these patients the incidence rises to 483/10^6/year.

These figures represent the incidence of ICD indications. It is rather more difficult to calculate the prevalence of these in our population, and this audit of acute admissions to CCUs was not designed to do so. However, using NICE criteria, if these results were repeated over a year, an additional 41.2/10^6/year patients with prevalent ICD indications would be identified. Using the less strict MADIT II criteria, this rises to 311/10^6/year. This is clearly an undefined but probably large underestimate of the true prevalence in the population.

It seems reasonable to include patients with prevalent indications for ICD implantation as the majority of patients recruited to MADIT [1] and MUSTT [3], the trials providing the evidence for guidance on primary prevention, were included because of a remote myocardial infarction. The time elapsed between infarction and randomisation was at least six months in 78% of patients recruited into MADIT and 88% in MADIT II, while 83% in MUSTT were at least one month post-MI. An estimate of the total number of ICD indications would therefore be 169/10^6/year for NICE and 793/10^6/year including MADIT II primary prevention criteria (Table 4).

**Limitations of the study**

1. The audit was conducted during a single month, and therefore is only a "snapshot", which may not be representative of practice throughout the year. The results are, however, compatible with our previous audit in a single ICD implanting centre, which similarly demonstrated under-provision of ICD therapy [9]. While the exact numbers of real and hypothetical patients may vary from month to month, the conclusion that patients currently fulfilling NICE criteria are not receiving ICDs and that the numbers are far in excess of those anticipated by NICE remains valid.

2. As no systematic screening programme was in place to identify MADIT/MUSTT primary prevention ICD patients, estimates of the numbers likely to complete the screening cascade had
to be made, generating hypothetical patients (based on actual patients admitted with acute MI). We used data from contemporaneous published studies to predict the results of screening, and tended to take a conservative estimate when more than one was available (for example, in TRACE [15], 40% of consecutive MI patients had an EF of ≤35%, compared with the 16% estimate used in this study [13]). This conservative approach may obviously result in an underestimate of ICD indications.

3. We did not adjust the figures to take into account life threatening co-morbidity, which is a contraindication to ICD implantation, as there was often insufficient information available in the records to make this judgement. Thirteen percent of patients with ventricular arrhythmias screened for the AVID trial were excluded for medical reasons [16]. The proportion of post-MI patients in class IV heart failure (also a contraindication to ICD implantation) is not known.

4. We did not take age into account. Age is not a specific contraindication to ICD implantation, and is not an exclusion criterion in most of the trials (although the upper age limit for recruitment to MADIT [1] was 80). Schmitt et al. [17] screened 1436 MI survivors, and identified 248 who were considered high risk. Of these, 54 (22%) were 75 years or over, and were excluded from further risk stratification. If ICDs were limited to those under 75 in our population, our estimates fall to an incidence of 93/10^6/year under current NICE guidance, and 310/10^6/year if these were extended to include MADIT II criteria.

5. We did not take into account the high prevalence of coronary disease in our health authority. The directly age-standardised mortality rate from all circulatory diseases in persons aged 35–74 for Newcastle and North Tyneside (1996–1998) is 161.5 compared with the mean for England of 133.8 [18]. As coronary heart disease is the aetiology of the majority of ICD indications, this would suggest that the figures should be reduced by 17% before extrapolation to the rest of the country.

6. Although this study has identified patients with prevalent as well as incident ICD indications, it was not designed to define prevalence, and clearly underestimates it by a large but unknown amount. Many patients with ICD indications are not seen in CCUs and a complete audit of prevalent indications would have to include population-based screening which is beyond the scope of this study.

Conclusions

ICD implantation in the UK falls far short of rates in many European countries and in the USA. National guidance published in the UK in 2000 was broadly similar to other guidelines in Europe and the USA at that time, but now seems rather conservative as subsequently published trial data and updated guidelines in the USA have extended ICD indications. This audit suggests that if UK national criteria were fully implemented, ICD implantation would increase by a factor of seven locally, and by a factor of 10 nationally, exceeding that anticipated by NICE by a factor of four. If the guidance were modified to take into account more recent trial evidence, this increase would be larger, perhaps a factor of 19. Clearly this would have very significant implications for provision of ICD therapy in the UK and elsewhere.

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References


