SCIENTIFIC LETTER

An audit of the implications of implementing NICE guidance on the use of implantable cardioverter-defibrillators

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In September 2000, the National Institute for Clinical Excellence (NICE) published guidance on implantable cardioverter-defibrillator (ICD) therapy for both primary and secondary prevention of sudden cardiac death.[1] NICE anticipated that its guidance would require the implantation of approximately 50 first and replacement devices per million of the population per year, equivalent to 40/10^6/year first devices.[2] In 2000, the ICD implantation rate in the UK and Republic of Ireland was 15.4 per million first implants and 3.64 per million generator replacements,[2] little more than one third of the number recommended by NICE. We therefore audited our practice against this guidance to define the implications of its implementation and the magnitude of the current shortfall.

METHODS

A total of 1637 adult cardiac patient contacts with Freeman Hospital in January 2001 were audited against the standard published as NICE guidance.[1] The records of all patients admitted to the cardiac care unit (CCU) (144), and all adults undergoing echocardiography (737), Holter monitoring (126), exercise tolerance testing (142), open heart surgery (115), coronary angiography (205), ventricular tachycardia (VT) stimulation study (5) or ICD implantation (5) during one month, and all patients seen in one week's cardiology outpatient clinics (194) were reviewed for primary and secondary indications for ICD implantation. The number of patients seen in clinic was extrapolated to a 12th of the number of patients seen annually. Because there was no systematic screening of myocardial infarction (MI) survivors for ICD indications, extrapolations were made from published data[3 4] of the consequences of the investigations required for full screening.

RESULTS

All patients screened in whom an ICD had been implanted, either during this audit or previously, had an ICD indication in accordance with NICE guidance. In all but one case, this was a secondary prevention indication.

Twelve patients were identified who fulfilled NICE criteria for secondary prevention and did not undergo ICD implantation in January 2001. Two patients have undergone ICD implantation subsequently and a further patient had previously declined an ICD so was not included in further calculations. Three patients had ablative therapy considered by their cardiologists to be an alternative to ICD implantation, and one patient underwent VT stimulation study after a cardiac arrest where no sustained VT was induced. There was no evidence in the clinical records that ICD therapy had been considered in the remaining five patients.

Screening of patient contacts in January 2001 as recommended in the NICE guidance would have required a large number of additional investigations, shown in table 1.

Table 1 Additional screening tests and ICDs required in one month to implement NICE guidelines

Total number of patient contacts screened	1637
Additional screening tests required to identify ICD indications in one month	
Echo	30.4
Holter	74.5
EPS	18.8
Additional ICDs required in one month to implement NICE guidance	
Post-MI primary prevention	6.5
Post-MI secondary prevention	13.5
Primary arrhythmic condition	1
Total	21

EPS, electrophysiological study; ICD, implantable cardioverter-defibrillator; MI, myocardial infarction; NICE, National Institute for Clinical Excellence.

Extrapolation to include the results of full screening identified a further 10 patients with ICD indications giving a total of 21 additional ICDs in the month of January 2001. This represents a more than fourfold increase in ICD implantation from the current 29.7/10^6/year to around 125/10^6/year. This is an underestimate of the true increase as an average of only 3.7 ICDs per month were implanted during the previous year compared to the 5 ICDs implanted during the audit period.

DISCUSSION

NICE published detailed guidance on ICD usage, and stated that "NHS trusts managing cardiothoracic services should review their current clinical practice against this guidance".[1] We have done this and found a considerable shortfall in ICD implantation at our centre, our audit suggesting the need for a fourfold increase, greatly exceeding the numbers anticipated by NICE.

Three reasons were identified for this shortfall:

- *Apparent failure to consider ICD implantation*—Not all patients under the care of a cardiologist with an ICD indication detailed in the NICE guidance appeared to have been considered for ICD implantation. There is circumstantial evidence that failure of referral also occurs in other hospitals in our region as the ICD implantation rate varies from 13 to 34/10^6/year between adjacent districts (unpublished data). A similar failure of referral has been documented elsewhere in the UK.

Abbreviations: CCU, cardiac care unit; ICD, implantable cardioverter-defibrillator; MADIT, multicenter automatic defibrillator implantation trial; MI, myocardial infarction; NICE, National Institute for Clinical Excellence; NYHA, New York Heart Association; VT, ventricular tachycardia

- *Decisions against ICD implantation*—Some patients fulfilling NICE guidance for ICD implantation underwent either surgical or catheter based ablation as an alternative. Although this strategy is controversial, there are data to support it. New York Heart Association (NYHA) functional class IV heart failure or other comorbidities significantly reducing life expectancy are more conventional contraindications to ICD implantation.
- *Failure to screen post-MI patients*—This audit identified an almost complete failure to screen post-MI patients. A similar absence of screening is common in the UK.

Comparison with published data

Secondary prevention

Patients surviving a cardiac arrest in the absence of an acute MI or other transient cause have a clear cut indication for ICD implantation.[1] The Danish registry shows a first ICD implantation rate of 47/10^6 in 2000, 45/10^6 of which were for secondary prevention. This may be an underestimate of the UK incidence of ICD indications as the mortality from ischaemic heart disease, the aetiology of most ICD indications, is about 30% higher in the UK than in Denmark.

Primary prevention

Approximately 270 000 people suffer an MI each year in the UK. About half of these survive to leave hospital. Estimates from the literature suggest that about 1% of these will fulfil the MADIT[5] criteria. NICE guidance suggests that all these patients should be considered for ICD implantation, resulting in a primary prevention annual ICD indication rate of 21/10^6/year. Clearly, ICD implantation would not be appropriate in all these patients, the most common exclusion being NYHA class IV heart failure.

Total estimates

Published data suggest the new incidence of patients who should receive ICDs for secondary prevention is at least 45/10^6/year, with at least 16/10^6/year for primary prevention, giving a total of over 60/10^6/year, exceeding the NICE estimate. Our audit suggests that implementation of the NICE criteria would result in an even higher implantation rate of 125/10^6/year, four times our current rate of 29.7/10^6/year. This figure includes both the incidence of new ICD indications and a high prevalence of these indications in the population.

Conclusions

Implementation of the NICE guidance criteria for the use of ICDs for arrhythmias will have major resource implications, far exceeding those anticipated by NICE.

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