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Clinical effectiveness and cost-effectiveness of implantable cardioverter defibrillators for arrhythmias: A systematic review and economic evaluation

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Objectives: The clinical effectiveness and cost-effectiveness of implantable cardioverter defibrillators (ICD) for arrhythmias was assessed.
Methods: A systematic review of the literature of systematic reviews and randomized controlled trials that reported mortality outcomes associated with implantable cardioverter defibrillators compared with antiarrhythmic drug therapy in people at risk of sudden cardiac death due to arrhythmias was undertaken. Economic evaluations were also sought. Inclusion criteria, data extraction, and quality assessment were undertaken by standard methodology. A decision analytic model was constructed using best available evidence to determine cost-effectiveness in a UK setting.
Results: Eight randomized controlled trials, two systematic reviews, and a meta-analysis met the inclusion criteria and were of variable quality. Evidence suggests that ICDs reduce mortality in both secondary and primary prevention, although the magnitude of benefit depends on baseline risk for sudden cardiac death. Incremental cost per quality-adjusted life year ranged from £52,000 ($98,000) to over £200,000 ($379,000), depending on mortality risk and assumptions made.
Conclusions: Evidence suggests that ICDs reduce total mortality but may be cost-effective only in some subgroups of patients at high risk of ventricular arrhythmias. Further research is needed on risk stratification of patients in whom ICDs are most likely to be clinically and cost-effective.

Keywords: Arrhythmia, Heart arrest, Antiarrhythmia agents, Implantable cardioverter defibrillator

No conflict of interest is declared. J. Bryant developed the research protocol, assisted in development of the search strategy, assessed studies for inclusion in systematic review of clinical and cost-effectiveness, extracted data from and quality assessed the included studies, synthesized evidence, assisted in development of economic model, drafted and edited final report, and project managed the study. H. Brodin developed research protocol, assessed studies for inclusion in systematic review of cost-effectiveness, extracted data from and quality assessed the included studies, synthesized evidence, developed the economic model and collected data for the economic model, and drafted the report. E. Loveman

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Sudden cardiac death, usually due to ventricular arrhythmia, is a significant public health issue, occurring in approximately 75,000 to 100,000 people annually in the United Kingdom (41;33), 400,000 people in Europe (12), and up to 460,000 people in the United States (2). Most cases of sudden cardiac death occur as a consequence of a first episode of ventricular tachyarrhythmia, although increasing numbers of people are surviving a first arrhythmic event and are at high risk of further episodes. Prevention of sustained ventricular arrhythmias is either primary or secondary (preventing them from happening or recurring, respectively), and most patients are treated with antiarrhythmic drug therapy, which aims to suppress the development of arrhythmias. Some patients are treated with implantable cardioverter defibrillators (ICDs) which can actively sense and terminate life-threatening arrhythmias. Uncertainty exists about the clinical and cost-effectiveness of ICDs compared with conventional antiarrhythmic drug therapy.

Implantation rates of ICDs vary greatly between countries, with the total rate of implantation being approximately 35 per million per year (2002/2003) in England and Wales (19), 45 per million in Western Europe (43), and significantly more in the United States at approximately 184 per million per year (2000) (9). The use of ICDs in the management of arrhythmias is guided in the United Kingdom by recommendations from the National Institute for Health and Clinical Excellence (NICE) (32). We were commissioned by The National Health Service (NHS) Health Technology Assessment Program to undertake a systematic review and economic evaluation of ICDs in patients at risk of sudden cardiac death from arrhythmias to inform the process for NICE to update its guidance in 2004 in the light of new evidence and in particular to incorporate relevant newly emerging UK data. This study summarizes and updates the findings of the systematic review (7) and discusses its policy implications.

METHODS

Data Sources

Eleven electronic databases (including Medline, PubMed, Cochrane Database of Systematic Reviews, Cochrane Controlled Trials register, Embase) were searched from inception for periods up to January 2005 (search strategies available on request). Additional studies were identified through searching bibliographies of related publications and through contact with experts and manufacturers. Further details of the research methodology are available elsewhere (7).

Study Selection

Randomized controlled trials published in the English language were sought that compared ICD treatment with antiarrhythmic drug therapy (AAD); included people at risk of sudden cardiac death from arrhythmia in secondary or primary prevention categories (primary prevention including patients with a history of myocardial infarction, evidence of ventricular tachycardia, and left ventricular ejection fraction less than 35 percent; or patients with left ventricular ejection fraction less than equal to 30 percent and myocardial infarction or dilated cardiomyopathy); and used the primary patient-based outcome of mortality and the secondary outcome of quality of life. Systematic reviews of individual randomized trials were included. Published economic evaluations were also sought.

Quality Assessment and Data Extraction

The quality of systematic reviews and randomized controlled trials was assessed using criteria developed by the Center for Reviews and Dissemination (34) and by Jadad and colleagues (18), respectively. Published economic evaluations were assessed for internal (13) and external (37) validity. Inclusion criteria were applied independently by two reviewers. Decisions about quality criteria and data extraction were made by one reviewer and checked by a second, with any differences in opinion resolved through discussion.

Data Synthesis

Studies of clinical effectiveness were combined through narrative synthesis with full tabulation of included studies. Meta-analysis was not appropriate due to heterogeneity in patient characteristics, comparative interventions, and duration of trials.

Economic Evaluation

A decision analytic model with a 5-year time horizon was developed to examine the benefits and costs of ICDs compared with AAD. The model was constructed to show the cost-effectiveness of the two optional treatment arms (ICD or AAD therapy), based on probabilities of patients experiencing particular health states or treatment options during the period of the evaluation, and the consequences in terms of benefits to patients (survival and quality of life) and costs incurred. The economic evaluation adopted a UK NHS perspective for costs and benefits. It focused on hospital-based costs that were thought to represent the most significant component in the provision of the service. One generic base case

Table 1. Clinical effectiveness studies: secondary and primary prevention

Name of study/author	Study type and quality assessment	Intervention	Participant group
Secondary research			
Ezekowitz et al. (14)	Systematic review Quality assessment: CRD 4/5	ICD vs. placebo or AAD	Secondary and primary prevention
Lee et al. (26)	Systematic review Quality assessment: CRD 4/5	ICD vs. medical therapy	Secondary prevention
Connolly et al. (11)	Meta-analysis of individual patient data Quality assessment: n/a	ICD vs. amiodarone	Secondary prevention
Primary research			
AVID (1)	RCT Quality assessment: Jadad 1/5	ICD vs. AAD	Secondary prevention in cardiac arrest survivors LVEF $\leq$ 40%
CIDS (10)	RCT Quality assessment: Jadad 2/5	ICD vs. amiodarone	Secondary prevention in cardiac arrest survivors LVEF $<$ 35%
CASH (21)	RCT Quality assessment: Jadad 1/5	ICD vs. AAD	Secondary prevention in cardiac arrest survivors
MUSTT (8)	RCT Quality assessment: Jadad 1/5	EGT (inc ICD) vs. no therapy	Primary prevention post MI LVEF $\leq$ 40%
MADIT I (28)	RCT Quality assessment: Jadad 2/5	ICD vs. AAD	Primary prevention post MI LVEF $\leq$ 35%
MADIT II (29)	RCT Quality assessment: Jadad 2/5	ICD vs. AAD	Primary prevention post MI LVEF $\leq$ 30%
CABG-Patch (5)	RCT Quality assessment: Jadad 1/5	ICD vs. no ICD	Primary prevention in CABG patients LVEF $\leq$ 35%
CAT (3)	RCT Quality assessment: Jadad 1/5	ICD vs. usual care	Primary prevention DCM LVEF $\leq$ 30%

Note. Jadad 1/5 study described as randomized; Jadad 2/5 study described as randomized and with withdrawals/dropouts described.
ICD, implantable cardioverter defibrillators (ICD); AAD, antiarrhythmic drug therapy; CABG, coronary artery bypass graft; CRD, Centre for Reviews and Dissemination; DCM, dilated cardiomyopathy; EGT, electrophysiologically guided therapy; LVEF, left ventricular ejection fraction; MI, myocardial infarction; RCT, randomized controlled trial; MI, myocardial infarction.

model was specified for both secondary and primary prevention, as there are limited differences in treatment pathways.

The model was populated with data from a UK study (9) commissioned by the NHS HTA Programme to inform the ICD appraisal process supplemented with some trial data. Survival data, resource use, and costs for the ICD group were obtained from a representative sample of patients attending two UK NHS hospital trusts. Data for the AAD group were based on comparable Canadian patient-based data (10). The base case relative risk strategy for the model was derived from a synthesis of data from the two compatible sources (9;10) to give relative risk of death for UK patients. Quality of life utilities were obtained from a survey of the UK ICD patients using a generic health related quality of life measure, the EuroQol EQ5D, and used for both groups in the absence of conclusive evidence from the published literature to suggest any difference in quality of life between ICD and AAD patients. Costs were for 2001/2002, with costs and savings discounted at 6 percent and quality-adjusted life years (QALYs) at 1.5 percent.

A series of one-way sensitivity analyses were undertaken to determine the robustness of the base case model to several different scenarios, including the following: differences in survival by considering alternative relative risks of mortality for subgroups of patients, derived from clinical effectiveness data in the literature; variations in the assumptions about quality of life; and the impact of reduced device costs.

RESULTS

Quantity and Quality of Research

Clinical Effectiveness. Two systematic reviews (14;26), one meta-analysis (11), and eight randomized controlled trials (RCTs) met the inclusion criteria (Tables 1 and 2) (1;3;5;8;10;21;28;29). Three RCTs were secondary prevention trials (1;10;21), and five RCTs were primary prevention trials (3;5;8;28;29).

When judged using standard criteria for assessing methodological quality, the systematic reviews were found to be of good quality, clearly stating the research question, the search strategy, the inclusion/exclusion criteria, details of included studies, and appropriately summarizing the data, but neither provide details of the assessment of the validity of the included studies. The meta-analysis (11) pooled raw data from the same three secondary prevention trials (1;10;21) as did one of the systematic reviews (14).

All the RCTs were described as randomized, but none were double blind due to the nature of the intervention. Participants of the three secondary prevention trials were survivors of cardiac arrest, although details differed slightly between the studies, for example, in the degree of left ventricular dysfunction. Sample sizes were 1,016 (1) patients, 191 patients (21) and 659 patients (10), and length of follow-up ranged from 18 months (1) to 3 years (10). Participants in the primary prevention trials differed substantially from one

Table 2. Mortality in secondary and primary prevention

Study	All-cause mortality	Cardiac mortality
Secondary prevention		
Ezekowitz et al. (14)	RR, .76 (95% CI, .65–.89)	RR, .50 (95% CI, .38–.66)
Lee et al, (26)	RR, .75 (95% CI, .64–.87)	RR, .50 (95% CI, .34–.62)
Connolly et al, (11)	RR, .72 (95% CI, .60–.87)	RR, .50 (95% CI, .37–.67)
AVID (1)	HR, .62 (95% CI, .45–.85)	
CIDS (10)	RRR, 19.7 (95% CI, –7.7–40.0)	RRR, 32.8% (95% CI, –7.2–57.8)
CASH (21)	HR, .77 (97.5% CI, upper bound 1.112)	HR, .43 (97.5% CI, upper bound .721)
Primary prevention		
Ezekowitz et al. (14)	RR, .72 (95% CI, .63–.84)	RR, .37 (95% CI, .27–.50)
Lee et al. (26)	RR, .66 (95% CI, .46–.96)	RR, .34 (95% CI, .23–.50)
MUSTT (8)	RR, .42 (95% CI, .29–.61)	RR, .24 (95% CI, .13–.43)
MADIT I (28)	HR, .46 (95% CI, .26–.82) HR, .20 for 3 risk factors (EF < .26, QRS ≥ .12 seconds, history congestive heart failure requiring treatment)	
MADIT II (29)	HR, .69 (95% CI, .51–.93)	
CABG-Patch (5)	HR, 1.07 (95% CI, .81–1.42)	
CAT (29)	2 deaths at 1 year in the control group	4 deaths at 1 year in the ICD group

RR, relative risk; HR, hazard ratio; RRR, relative risk reduction; CI, confidence interval.

trial to another. Two of the primary prevention trials included patients who had had a myocardial infarction with left ventricular ejection fraction equal to or less than either 35 percent (28) or 40 percent (2). Patients undergoing coronary artery bypass graft (CABG) surgery with left ventricular ejection fraction less than 35 percent were enrolled in one trial (5), whereas people with a history of previous myocardial infarction and left ventricular ejection fraction equal to or less than 30 percent were enrolled in another (29). Patients with dilated cardiomyopathy and left ventricular ejection fraction equal to or less than 30 percent were included in one (3). Follow-up ranged from 20 months (29) to 39 months (28).

Cost-Effectiveness. Eleven economic evaluations, published in twelve papers, were identified, none of which had both high internal and external validity (22–25;30;35;36;38–40;44;45). Few of the studies used patient data, and in most studies, numerous assumptions had to be made about outcomes and costs.

Assessment of Clinical Effectiveness

Mortality in Secondary Prevention. The evidence suggests that ICDs reduce mortality in patients with previous ventricular arrest or symptomatic sustained ventricular arrhythmias. Results suggest a 25 percent to 28 percent (11;14;26) reduction in relative risk of death with ICD that is due to a 50 percent reduction in arrhythmic death (Table 2). A significant reduction in total mortality with ICDs is reported as 39 percent at 1 year, 27 percent at 2 years, and 31 percent at 3 years, with an average additional life associated with ICDs of 2.7 months at 3 years (1). ICD is associated with a 23 percent nonsignificant risk reduction in all-cause mortality compared with AAD therapy in one trial (21) and a 19 percent in another (10).

Mortality in Primary Prevention. The evidence suggests that ICDs reduce mortality in patients who have not had a previous sudden cardiac death episode or previous ventricular arrhythmia but who have reduced left ventricular function due to coronary artery disease with asymptomatic nonsustained ventricular arrhythmia and sustained tachycardia that could be induced electrophysiologically; and in some patients with severe left ventricular dysfunction (ejection fraction ≤30 percent) after myocardial infarction (Table 2). Two systematic reviews report results favoring ICDs, with relative risks of .72 (95 percent confidence interval [CI], .63–.84) (14) and .66 (95 percent CI, .46–.96) (26) for all-cause mortality and .37 (95 percent CI, .27–.50) and .34 (95 percent CI, .23–.50), respectively, for arrhythmic death (Table 2). Three trials report survival benefits due to ICD use in cardiac arrest patients, with a reported 54 percent reduction in total mortality (28) and overall 5-year mortality rates of 24 percent in patients who received a defibrillator compared with 55 percent among those who did not (8). A 31 percent reduction in risk of death from any cause was reported in patients with a prior myocardial infarction and advanced left ventricular dysfunction who had prophylactic implantation of an ICD, with mortality rates of 14.2 percent in the ICD group and 19.8 percent in the AAD group (29). Mortality rates by 4 years of follow-up were 27 percent in people receiving an ICD and 24 percent in those who did not, in the trial in which patients received ICD at the time of CABG (5). The hazard ratio for death from any cause was 1.07 (95 percent CI, .81–1.42) (5). All cause mortality rates were not different between the ICD group or the usual care

Table 3. Base case discounted results of economic model

Group	Cost	Incremental cost	Effectiveness	Incremental effectiveness	Cost-effectiveness	Incremental Cost-effectiveness ratio
AAD	£25,816		2.690 LYG		£9,596	
ICD	£48,339	£22,523	2.810 LYG	.119 LYG	£17,205 per LYG	£188,859/LYG
AAD	£25,816		2.10 QALYs		£12,283	
ICD	£48,339	£22,523	2.19 QALYs	.09 QALY	£22,022 per QALY	£241,739/QALY

Note. Model uses a relative mortality risk of .85, calculated from UK study (32) and CIDS study (10); quality of life utility of .75, from UK study of ICD patients and evidence from the literature of no difference between ICD patients and AAD patients; costs and saving discounted at 6% and benefits at 1.5%). AAD, antiarrhythmic drug therapy; LYG, life years gained; QALYs, quality-adjusted life years; ICD, implantable cardioverter defibrillators.

group in the trial considering the prophylactic use of ICDs in patients with recent onset dilated cardiomyopathy (3).

One primary prevention study (28) reported subgroup analyses which showed that the magnitude of survival benefit from ICD was directly related to severity of cardiac dysfunction, where defibrillator use was associated with a significant reduction in mortality rate in subsets of patients with three risk factors (ejection fraction less than 26 percent, QRS $\geq$.12 second, and a history of heart failure requiring treatment) (44).

Quality of Life. The two secondary prevention trials (1;10) reporting quality of life have inconsistent findings using a range of measures. One reports that ICD and AAD therapy are associated with similar self-perceived quality of life (27). The development of adverse symptoms is associated with significant impairment in quality of life in both groups, and the occurrence of sporadic shocks in ICD recipients (27). The other reports better quality of life with ICD therapy than AAD therapy, although this finding is not evident in patients who receive numerous shocks from their device (42). The one primary prevention trial that reported quality of life found that ICD patients had significantly lower levels of psychological well-being, perceptions of health and emotional role functioning compared with patients receiving conventional medical therapy (17;31).

Adverse Effects. Generally serious adverse events due to ICDs are infrequent. Complications that are reported include infection, hematomas and bleeding, lead dislodgement and migration, cardiac perforation, pleural effusion and pneumothorax, and device dysfunction/malfunction of generator. Adverse events associated with AAD therapy include pulmonary toxicity, thyroid dysfunction, insomnia, tremor, ataxia, and visual symptoms, and have lead to withdrawal from treatment for up to 25 percent of patients.

Assessment of Cost-Effectiveness

Cost-Effectiveness from the Literature. The published economic evaluations report a variation in the cost per life year gained (LYG) and cost per QALY associated with ICD use. In the nine studies of secondary prevention, the cost per LYG ranged from $17,100 (23) to C$213,500 (36) and the cost per QALY from $37,000 to $76,800 (38). Three studies assessing primary prevention report incremental cost-effectiveness ratios. Incremental cost per LYG ranged from $27,000 (30) to $36,700 (44) and incremental cost per QALY from $50,900 (44) to $558,000 (40). Although there is variation in the cost per QALY or LYG, generally costs appear to have increased between 1990 and 2004.

Cost-Effectiveness from the Economic Evaluation. As searches revealed that the cost-effectiveness evidence was lacking in internal validity and of limited relevance to the United Kingdom, a new economic evaluation was conducted. The discounted results of this current economic model, using the base case relative risk strategy, are shown in Table 3. Results of sensitivity analyses using different assumptions are shown in Table 4. Results show that an improved survival can be achieved with ICDs compared with drug therapy, but with high additional cost. The incremental cost-effectiveness is in several cases higher than £100,000 ($189,000) per QALY if the quality of life is assumed to be the same in both treatment groups, and more than £200,000 ($379,000) per QALY under the main base case, which assumes a relative mortality risk of .85. When assessing secondary prevention, the incremental cost per QALY ranged from £88,000 ($167,000) to £165,000 ($312,000), depending on mortality risk. For primary prevention, the incremental cost per QALY was £139,000 ($263,000), and for high risk patients with relative mortality risk of .46, the incremental cost per QALY was £52,000 ($98,000). The incremental cost per QALY for patients with a previous myocardial infarction and depressed left ventricular function was estimated at £123,900 ($233,000).

DISCUSSION

This review, guided by an expert advisory panel, considered systematically the evidence on the clinical and cost-effectiveness of ICDs for arrhythmias, and developed an economic evaluation. Eight RCTs, two systematic reviews, and a meta-analysis, plus twelve economic evaluations, were found that met the inclusion criteria of the review.

The RCTs are of variable quality when judged using Jadad quality score, and there are some methodological

Table 4. Sensitivity analysis of incremental cost-effectiveness using different strategies (with different relative risk of death, quality of life utility, and device cost)

Strategy	Cost	Incremental cost	Effectiveness QALYs	Incremental QALYs	Cost/QALY	Incremental Cost-effectiveness ratio £/QALY
Secondary prevention						
RR = .76 (14)	£25,816 AAD		1.971 AAD		£13,100 AAD	
	£48,339 ICD	£22,523	2.107 ICD	.137	£22,940 ICD	£164,931
RR = .60 (1)	£25,816 AAD		1.852 AAD		£13,940 AAD	
	£48,339 ICD	£22,523	2.107 ICD	.255	£22,940 ICD	£88,248
Primary prevention						
RR = .72 (14)	£25,816 AAD		1.946 AAD		£13,267 AAD	
	£48,339 ICD	£22,523	2.107 ICD	.161	£22,940 ICD	£139,650
RR = .46 (28)	£25,816 AAD		1.680 AAD		£15,363 AAD	
(high risk patients)	£48,339 ICD	£22,523	2.107 ICD	.427	£22,940 ICD	£52,776
RR = 1.07 (5)	£25,816 AAD		2.10 AAD		£12,296 AAD	
(low risk patients)	£48,339 ICD	£22,523	2.107 ICD	.008	£22,940 ICD	£2,948,593
RR = .69 (29)	£25,816 AAD		1.925 AAD		£13,408 AAD	
(previous MI)	£48,339 ICD	£22,523	2.107 ICD	.182	£22,940 ICD	£123,955
Base case RR = .85						
AAD QoL = .50	£25,816 AAD		1.345 AAD		£19,192 AAD	
ICD QoL = .75	£48,339 ICD	£22,523	2.107 ICD	.762	£22,940 ICD	£29,556
Device cost	£25,816 AAD		2.018 AAD		£12,795 AAD	
reduced 50%	£36,535 ICD	£10,719	2.107 ICD	.089	£17,338 ICD	£119,838

AAD, antiarrhythmic drug therapy; ICD, implantable cardioverter defibrillators; MI, myocardial infarction, QALY, quality-adjusted life year; RR, relative risk of death; QoL, quality of life.

concerns that may impact on results. These concerns include factors such as the impossibility of double-blinding, due to the comparison of a device with drug therapy; randomization of patients being at the discretion of the surgeon at the time of surgery; crossovers of patients from one treatment group to the other, which may have compromised the intention to treat analysis; the fact that many ICD patients receive antiarrhythmic drug therapy to suppress tachyarrhythmias and treat underlying heart disease; patients serving as controls may not have received maximal medical therapy; and generalizability of trials to other settings. The systematic reviews and meta-analysis, although of good quality when judged using standard criteria, showed significant heterogeneity between studies, suggesting that results obtained by pooling data should be treated with caution.

Despite the limitations of the trials, the results of the studies meeting this review's criteria suggest that ICDs offer survival benefit for patients in both secondary and primary prevention categories. Prophylactic use of ICD is of benefit in some patients with severe left ventricular dysfunction after myocardial infarction, but does not appear to benefit patients with recent onset dilated cardiomyopathy and impaired left ventricular function.

Several other recent studies were identified that do not meet the inclusion criteria for the review. These report no statistically significant benefit from ICD (20) in the populations considered and unanticipated subgroup results (4). Another study suggests a benefit resulting in the use of cardiac resynchronization therapy combined with ICDs in some people with chronic heart failure (6). Such studies highlight the need to stratify patients and identify subgroups of patients who may derive benefit from prophylactic ICD.

The identified economic literature uses a range of methodologies, with different strengths and weaknesses, and reports a range of results. Despite the differences in the assumptions used in the different economic models, the results generated by the model in this review are in broad agreement with recent studies in that there are modest benefits due to ICDs at high cost. In general, results from the literature and the economic evaluation developed in this review show increasing incremental cost-effectiveness ratios over time as more data become available. The costs associated with ICDs are greater than previously thought and the benefits in terms of LYG are probably lower than previously estimated.

Despite previous research recommendations (32) and a UK NHS funded project (9) to collect data for an economic evaluation, data on quality of life and costs associated with ICDs and antiarrhythmic drug therapy remains limited. The economic model developed in this review therefore incorporated UK data for ICD patients and comparable data from a Canadian study for drug therapy patients and took a 5-year perspective. Although there are limitations with such an approach, it can be justified in that it uses the most up to date and relevant information available and takes a realistic time frame. Possible uncertainties have been explored through sensitivity analyses, which have focused on the key variables thought to be influential, namely quality of life utilities, the cost of the ICD, and the relative risk of mortality. These

have shown that only when quality of life in the drug therapy group drops to .50 will the incremental cost-effectiveness be at a level at which technologies are usually regarded as being cost-effective. If device cost is reduced by 50 percent, the incremental cost-effectiveness is still in excess of £100,000 ($189,000). The results suggest that, for certain subgroups of patients, ICDs may be cost-effective. Only patients with any two or more risk factors including left ventricular function less than .26, QRS width ≥.12 seconds, and a history of heart failure requiring treatment, are likely to have a relative risk of mortality that will result in favorable cost-effectiveness.

CONCLUSIONS

The findings of this review suggest that ICDs offer some benefit to people at risk of arrhythmias and that the degree of survival benefit is related to the severity of cardiac dysfunction. Results of economic modeling suggest that the ICDs are unlikely to be cost-effective except for certain subgroups of patients at high risk of arrhythmias.

Such results pose a dilemma for policy makers who have to reconcile the needs of the individual patient with those of society when providing guidance on the use of ICDs, and highlight the importance of defining in which patient groups there may be survival benefit from ICD therapy. Information gaps relating to quality of life and cost-effectiveness associated with ICD use may cause uncertainty for those developing guidance and lead to delays in the decision-making process. After much deliberation, NICE issued its final appraisal determination in 2005 additionally recommending ICDs for patients in the primary prevention category who have a history of myocardial infarction and left ventricular ejection fraction of less than 30 percent and QRS duration ≥.12 seconds (16).

It is essential that further research is conducted to identify those patients for whom ICDs are most likely to be clinically and cost-effective. This must take into account developments in ICD and other cardiac technology such as resynchronization therapy, to inform future evidence-based policy and to ensure the appropriate use of ICDs and other devices and procedures (15).

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