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Title **The Clinical Effectiveness and Cost Effectiveness of Implantable Cardioverter Defibrillators: A Systematic Review**

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Aim

To review the clinical effectiveness and cost effectiveness of implantable cardioverter defibrillators (ICDs) for arrhythmias.

Conclusions and results

The review included 8 randomized controlled trials (RCTs), 2 systematic reviews, and 1 meta-analysis, all of which met the inclusion criteria. The RCTs varied in quality, with most trials having a Jadad quality score of 1/5 or 2/5, owing to the nature of comparing a device with drug therapy and the impossibility of double-blinding. Mortality was the outcome measure of interest, and was reported as all-cause mortality in most trials and sudden cardiac death in some trials. Eleven economic evaluations of ICDs for arrhythmias were identified. None were shown to have high internal and external validity. One unpublished study relevant to the UK was identified. The evidence suggests that ICDs reduce mortality in patients with: a) previous ventricular arrest or symptomatic sustained ventricular arrhythmias; b) no previous sudden cardiac episode or previous ventricular arrhythmia, but reduced left ventricular function due to coronary artery disease with asymptomatic nonsustained ventricular arrhythmia and sustained tachycardia that could be induced electrophysiologically; and c) severe left ventricular dysfunction (ejection fraction ≤30%) after myocardial infarction. Quality of life (QoL) data are inconsistent, but suggest that QoL is impaired in patients who received numerous shocks from implanted devices. Studies show that ICDs improve survival compared to drug treatment, but at considerably higher cost. In the published literature, incremental costs per life-year gained ranged from 27 000 US dollars (USD) to 213 543 Canadian dollars (CAD), and incremental cost per quality-adjusted life-year from USD 71 700 to USD 558 000.

Recommendations

The use of ICDs in the UK is increasing, but the technology remains underutilized compared with other developed countries. Extending the current indications to patients with prior myocardial infarction and depressed heart function would impact on costs and service provision.

Methods

A systematic review of the literature on clinical and cost effectiveness was undertaken. The Jadad criteria were used to assess the quality of selected RCTs, and criteria developed by the NHS Centre for Reviews and Dissemination were used to assess selected systematic reviews. Economic evaluations were quality assessed by their internal validity (ie, the methods used) using a series of relevant questions, and external validity (ie, generalizability of the economic study to the population of interest) by modified standard criteria. The clinical effectiveness and cost effectiveness of ICDs for arrhythmias were synthesized through a narrative review with full tabulation of results of all included studies.

Further research/reviews required

Further research is needed on the risk stratification of patients in whom ICDs are most likely to be clinically and cost effective. An evaluation of shock frequency on QoL is also required.

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