Implantable Defibrillator

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Summary and Conclusions

TECHNOLOGY AND TARGET GROUP Cardiac arrhythmias (disruptions in heart rhythm) are common. While some arrhythmias are harmless (eg, extra beats), others such as ventricular tachycardia and ventricular fibrillation are serious disorders that can lead to sudden death. An implantable cardioverter defibrillator (ICD) can continuously monitor the user's cardiac rhythm to detect and treat serious arrhythmias in the ventricles of the heart. Treatment involving an ICD may be appropriate in patients who have already experienced a symptomatic ventricular arrhythmia (cardiac arrest) or have life threatening ventricular arrhythmias associated with decreased function in the left ventricle and/or experience fainting. In these cases, the aim of using an ICD is to prevent recurrence, ie, treatment aims at secondary prevention, which has been the most common area of application for the method in Sweden. Treatment can also aim at primary prevention. This includes patients at higher risk for life threatening ventricular arrhythmias, eg, following myocardial infarction or cases of heart failure and severely impaired left ventricular function, but who have not yet presented with serious cardiac dysrhythmias. Furthermore, the expected survival with ICD treatment should be at least about 2 years.

Information is insufficient to accurately predict the number of patients who would be appropriate candidates for ICD treatment. Based on current practice, the target group for ICD treatment aimed at secondary prevention would be approximately 400 to 500 patients per year (4.4 to 5.6 per 100 000 population). The size of the target group for ICD treatment aimed at primary prevention is difficult to estimate since the indications for treatment involve assessing the increased risk for ventricular arrhythmias and weighing in the life expectancy of the patient. A rough estimate would be 1000 to 1500 patients per year (11.1 to 16.7 per 100 000 population).

PRIMARY QUESTION What effect does ICD treatment have on survival when used for purposes of secondary and primary prevention, and what are the costs associated with the method? This assessment updates an earlier report (published February 19, 2003).

PATENT BENEFIT Three randomized controlled trials including nearly 2000 patients compared pharmacotherapy against ICD treatment aimed at secondary prevention. The combined results of these studies show a mortality rate of 8.8% in the ICD group compared to 12.3% in the pharmacotherapy group. This indicates that 29 patients would need to be treated with ICD for one year to avoid one additional death.

As regards ICD treatment aimed at primary prevention, 10 randomized trials including slightly over 8600 patients were identified. Of these trials, 4 addressed treatment following myocardial infarction, 1 addressed treatment in conjunction with coronary artery surgery, and 5 included an assessment of ICD treatment in heart failure. A meta-analysis synthesized the results from studies on ICD treatment in primary prevention. It showed that mortality was 8% lower in the group that received ICD treatment. The risks associated with ICD treatment include perioperative death, infections, thromboembolytic complications, cardiac perforation, and the possibility that the defibrillator could incorrectly interpret the heart rate, leading to delivery of inadequate shocks.

ETHICAL ASPECTS Patients at higher risk for sudden death are naturally worried about their situation. It is important for patients to receive factual and appropriate information adapted to the needs of each individual. Currently, most hospitals that provide ICD treatment also have local support groups for these patients.

ECONOMIC ASPECTS An ICD costs between 90 000 and 180 000 Swedish kronor (SEK). In addition, there are the costs for surgery, surgery-related care, and followup visits, totaling approximately 40 000 SEK. Studies estimate that the cost per life year gained for ICD in secondary prevention is between 500 000 SEK and 1.8 million SEK. Cost-effectiveness analyses have shown that the cost per life year gained for ICD aimed at primary prevention in patients who have had myocardial infarction is between 200 000 and 800 000 SEK. Regarding primary prevention in heart failure patients, the cost per life year gained is around 400 000 to 800 000 SEK. Due to the capital investment costs associated with implantation, the cost effectiveness of ICD treatment depends on the survival time of patients who respond to treatment.

SBU's appraisal of the evidence

There is strong scientific evidence that ICD treatment aimed at secondary prevention leads to lower mortality (Evidence Grade 1)*. There is moderately strong scientific evidence that ICD treatment aimed at primary prevention leads to lower mortality (Evidence Grade 2)*.

Criteria for Evidence Grading SBU's Conclusions, see page 2

Criteria for Evidence Grading SBU's Conclusions

Evidence Grade 1 – Strong Scientific Evidence. The conclusion is corroborated by at least two independent studies with high quality and internal validity, or a good systematic overview.

Evidence Grade 2 – Moderately Strong Scientific Evidence. The conclusion is corroborated by one study with high quality and internal validity, and at least two studies with medium quality and internal validity.

Evidence Grade 3 – Limited Scientific Evidence. The conclusion is corroborated by at least two studies with medium quality and internal validity.

Insufficient Scientific Evidence. No conclusions can be drawn when there are not any studies that meet the criteria for quality and internal validity.

Contradictory Scientific Evidence. No conclusions can be drawn when there are studies with the same quality and internal validity whose findings contradict each other.

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The complete report is available only in Swedish.