Summary and Overall Assessment (ICD 20131104)

Introduction

This evaluation is based on the Swedish Dental and Pharmaceutical Benefits Agency (TLV) commission from the government to conduct health technology assessments of medical devices. An evaluation at the national level can shed light not only on the individual care providers, but also on society as a whole through the utilisation of the ethical platform. It is very important that decisions and recommendations do not rely only on the principle of cost-effectiveness, but also take into account the other prevailing principles, namely the principles of human dignity and of need and solidarity, in accordance with the Health and Medical Services Act (1982:763).

Method and target group

The method evaluated in this document is treatment with implantable cardiac defibrillator (ICD) in cases of heart failure. An ICD is an active implant that supplies the heart with a defibrillating high energy shock when a ventricular fibrillation is detected. The implant can also emit a weaker electrical stimulation in order to prevent a dysrhythmia becoming a ventricular fibrillation. The treatment is appropriate for patients with heart failure who have survived a cardiac arrest (secondary prevention) or for patients who have an established increased risk of sudden cardiac death as a result of heart failure (primary prevention).

The patients who are treated with ICD also receive medication for heart failure in accordance with the treatment guidelines. However, there is no pharmacological treatment that is as effective at combating ventricular fibrillation or resetting the heart rhythm in active ventricular fibrillation as ICD treatment.

Disease severity

Patients who have been treated in general have serious symptoms as a result of a chronic disease state and may suffer from reduced left ventricular function and/or serious disturbances to the heart rhythm. In addition, the patients have an increased risk of sudden cardiac death or have previously survived a sudden cardiac arrest. The TLV assesses the disease severity and the future risk as high with regard to both primary and secondary prevention.

Patient benefit

According to the TLV's assessment, the benefit to patients of ICD treatment is better than that of treatment with medication alone. This assessment is based on scientific studies with a low level of uncertainty and that are of a good quality.

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The results of the studies show statistically significant reductions in mortality when using ICD treatment for both primary and secondary prevention, compared to patients who have only received pharmacological treatment.

In certain cases however, the clinical benefit in general differs for certain sub-groups within the patient population in terms of primary prevention. This mainly involves differences in the risk of sudden cardiac death. This aspect should be taken into consideration on an individual bases when making treatment decisions. Otherwise there is a risk that resources are taken from other urgent healthcare measures that may be assumed to provide a greater net benefit.

The benefit to patients in cases of secondary prevention, as well as the effect in cases of imminent or ongoing ventricular fibrillation, is considered to be equal for all patients who receive the treatment. It should also be emphasised that the benefit to patients is considered to be equal for all individuals with a high risk of sudden cardiac death, regardless of their sub-group.

Cost-effectiveness
The general assessment is that ICD is a cost-effective treatment for the relevant patient population. This assessment is based on that the severity of the condition is considered to be high in cases of both primary and secondary prevention and because the treatment saves lives.

The cost per quality-adjusted life year (QALY) for primary prevention is estimated as SEK 365,000 from a healthcare perspective. For secondary prevention, the cost per QALY is about SEK 360,000 from a healthcare perspective. From the perspective of the cost to society as a whole, there is no improvement in cost-effectiveness. The cost-effectiveness ratio appears to be reasonable in relation to the severity of the disease, which is judged to be high.

The data underlying this health economic analysis is considered to have a high degree of certainty, reliability and relevance. However, there is a certain degree of uncertainty in the quality of life weighting, which means that the certainty with regard to the results from the cost-effectiveness analysis is considered to be moderate.

Follow-up and evaluation
Further studies into a number of parameters are of importance, primarily when it comes to how quality of life is affected by an ICD and how the clinical benefit varies in the patient population. The current remote monitoring requires a more extensive foundation in order to enable more definitive conclusions to be drawn concerning clinical effect, patient benefit and cost-effectiveness.

Overall assessment

Organisations responsible for healthcare may decide whether or not to introduce the method to a greater extent as it is probably the case that the treatment is currently underused. When making individual decision on priorities, consideration should be given to how the patient's quality of life will be affected by the treatment, for example, in the terminal stages of life. This should be weighed up with the patient's motivation, their risk for sudden cardiac arrest, their biological age and general health.