Cardiac Resynchronization Therapy (CRT) in Chronic Heart Failure

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Summary and Conclusions

TECHNOLOGY AND TARGET GROUP Various cardiac disorders, eg, myocardial infarction and heart valve disorders, may leave the heart too weak to pump the volume of blood needed by the body in a given situation. The resulting condition is called heart failure. Heart failure usually develops gradually, depending on the severity of the underlying cardiac disease. Normally, the pumping action of the right and left ventricles is well coordinated. In heart failure, the form and function of the heart can change and cause dyssynchrony, ie, deficient coordination of the contractions of the ventricles. Implantation of a biventricular pacemaker, ie, cardiac resynchronization therapy (CRT), is a new method aimed at synchronizing the action of the heart, thereby enhancing its ability to pump. Pacemaker stimulation of the right atrium and/or right ventricle is a well-established method for treating a slow pulse rate (bradycardia). In CRT, an additional electrode is placed above the left ventricle. Although pharmacotherapy has a satisfactory effect in many heart failure patients with dyssynchrony, some patients are not adequately helped by this approach, or have difficulty tolerating adequately high doses of the medication. In Sweden, the potential target group for CRT is estimated at 200 to 300 individuals per million inhabitants and year, ie, approximately 2200 patients.

PRIMARY QUESTION What are the patient benefits and costs associated with CRT in treating heart failure? This assessment updates the SBU Alert Report published November 12, 2003.

PATIENT BENEFIT Seven randomized trials compared the benefits of pharmacotherapy alone to the benefits of CRT and medication combined. Results from 5 of the trials showed that CRT yielded a 13% to 20% increase in walking ability, as measured by a 6-minute walking test. The results also showed a 20% to 30% improvement in quality of life, as measured by the Minnesota Living with Heart Failure Questionnaire. In addition, the severity level of the disease improved based on the New York Heart Association (NYHA) classification scale, on average 0.5 to 0.8 stages. Two of the randomized trials studied mortality (death from any cause). At 12-month followup the combined results showed, in a meta-analysis, the mortality risk to be 3 percentage points lower in the CRT group compared to patients receiving pharmacotherapy alone. This corresponds to a 22% reduction in relative risk. One of the studies included even longer followups. After 2 and 3 years respectively, it was shown that the differences between the groups increased with time. There is speculation concerning the extent to which the addition of implantable cardiac defibrillators (ICD) would further improve survival in patients with severe heart failure who are treated with CRT. This question, however, was not assessed in any study.

In this procedure, insertion of an electrode above the left ventricle creates a risk since the blood vessel can be damaged. Several studies reported isolated cases of death related to the surgical procedure.

ETHICAL ASPECTS An important aspect of CRT, which has ethical implications, concerns how patients are selected for treatment. Since treatment is associated with considerable costs and with some risk, it is important to thoroughly evaluate the patient's general health status and life expectancy. Furthermore, it is important for both the patient and the family to receive factual information on the benefits and risks of treatment.

ECONOMIC ASPECTS The costs associated with implanting a CRT device are estimated at just over 100 000 Swedish kronor (SEK), including hospitalization time. If the target group includes 2200 patients per year, the total healthcare cost would be around 250 million SEK. Several studies have been published on the cost effectiveness of CRT. The average additional cost per quality-adjusted life-year varies substantially among the different studies, ranging from around 180 000 to around 800 000 SEK. The variation is attributed to differences in estimating the healthcare costs and differences in the prognosis of patient survival time. Since these figures are highly uncertain, it is difficult to address the cost effectiveness of the CRT method.

SBU's appraisal of the evidence

Reduced symptoms (Evidence Grade 2)*, improved quality of life (Evidence Grade 1)*, and improvement in the severity level of disease (Evidence Grade 1)* were found in comparing CRT against pharmacotherapy alone. Furthermore, the results from 2 trials with followup after 12 months showed some reduction in the mortality risk for CRT compared to pharmacotherapy (Evidence Grade 1)*. The scientific evidence is insufficient* to determine the long-term effects and cost effectiveness of the method.

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.

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