

Prophylactic implantable cardioverter–defibrillators increased life expectancy with an acceptable cost-effectiveness ratio

Sanders GD, Hlatky MA, Owens DK. Cost-effectiveness of implantable cardioverter-defibrillators. *N Engl J Med*. 2005;353:1471-80.

Clinical impact ratings: Cardiology ★★★★★☆☆

QUESTION

In patients at risk for sudden death because of left ventricular systolic dysfunction who have not had life-threatening ventricular arrhythmias, what is the cost-effectiveness of implantable cardioverter–defibrillators (ICDs) compared with control therapy?

METHODS

Design: Cost-effectiveness analysis from a societal perspective using a decision model based on the individual results of 8 randomized controlled trials (RCTs), with follow-up of 16 to 41 months and lifetime extrapolation.

Setting: {7 RCTs were done in the United States and 1 in Germany}*.

Patients: Patients at risk for sudden death because of left ventricular systolic dysfunction who had not had life-threatening ventricular arrhythmias. {Patients had a history of myocardial infarction, coronary artery disease, cardiomyopathy, heart failure, or coronary artery bypass graft}*.

Intervention: Prophylactic implantation of an ICD compared with control treatment {usually conventional medical therapy}*.

Outcomes: Incremental cost-effectiveness of ICD per year of life and per quality-adjusted life-year (QALY) with a utility adjustment of

0.88 in both groups. Costs, in 2005 U.S. dollars, were direct costs of medical care, extrapolated until death from any cause.

MAIN RESULTS

The cost of ICD implantation was estimated to be \$27 975, with replacement after 5 years at a cost of \$18 390. In all trials, the lifetime cost with ICD was greater than that with the control treatment (range for the difference \$55 700 to \$101 500). In 6 RCTs, ICD increased life expectancy and QALY (Table). In these trials, the incremental cost-effectiveness of ICD ranged from \$24 500 to \$50 700 per life-year gained and from \$34 000 to \$70 200 per QALY gained. In the 2 other RCTs, ICD did not increase life expectancy and thus was less effective and more expensive than control treatment. In sensitivity analyses, the cost-effectiveness of ICD improved if the efficacy was higher, the cost of the device was lower, the interval until

replacement was longer, quality of life was improved, and the benefit of ICD continued throughout life.

CONCLUSION

In patients at risk for sudden death because of left ventricular systolic dysfunction for whom a device-related reduction in mortality had been shown, prophylactic implantable cardioverter–defibrillators had a cost-effectiveness of \$34 000 to \$70 200 per quality-adjusted life-year gained.

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*Information from the original publications of the 8 trials used in this study.

Range of health and economic outcomes of implantable cardioverter-defibrillators (ICDs) vs control treatment (conventional medical therapy), extrapolated to lifetime, from 6 trials that showed efficacy of ICDs

Outcomes	ICD	Control	Discounted increment with ICD
Direct costs of medical care (US\$)	106 100 to 184 900	37 800 to 84 400	68 300 to 101 500
Life expectancy (y)	5.9 to 11.8	4.0 to 9.0	1.4 to 4.1
Quality-adjusted life-years	4.3 to 8.5	3.0 to 6.6	1.0 to 3.0

COMMENTARY

Cardiovascular medicine is at the threshold of moving from an era of scientific and technical limitations to an era of economic limitation. Prophylactic ICD therapy stands as a stark test of how scientific, political, and economic forces will resolve this threshold in the United States and elsewhere.

Sanders and colleagues accurately summarize the clinical and economic RCT data in the form of a cost-effectiveness analysis. Prophylactic ICD placement, in patients without documented ventricular arrhythmia but with significant left ventricular systolic dysfunction, increases average life expectancy by 2.1 to 6.2 undiscounted years (or 1.5 to 4.5 QALYs). The incremental increase in estimated lifetime medical costs is \$68 300 to \$101 500/person. Hence, the cost per life-year gained is estimated at \$24 500 to \$50 700 (\$34 000 to \$70 200/QALY gained). Consistent with these results, the Sudden Cardiac Death in Heart Failure Trial economic analysis estimated an incremental cost of prophylactic ICD therapy at \$33 200/life-year saved (1). Considering the eligibility criteria in these trials, 1 million Americans are potentially eligible for prophylactic ICD therapy.

Dialysis has been the acceptable standard for cost-effectiveness, now estimated at \$120 000/QALY (2). In 2005 dollars, the cost-effectiveness of coronary artery bypass graft for 2-vessel coronary disease involv-

ing the left anterior descending artery with severe angina is \$69 000/QALY (3). Thus, compared with many standard and accepted treatments, prophylactic ICD therapy is cost-effective. Given resource constraints, we will undoubtedly have to target or ration this therapy to as-yet-undefined subgroups at particularly high risk for sudden death with an overall medical prognosis and functional status that will allow them to reap the greatest benefit. Outpatient implantation of current or future devices that do not require a transvenous lead will further reduce implant cost. Device manufacturer exposure to product liability claims threatens any prospect for lower-cost devices in the United States. We should pay for life-saving prophylactic ICD therapy. The question remains whether our society can afford it.

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References

- Shah A, Patel M, Goyal A, et al. *Am Heart J*. 2005;149:240-53.
- Goldman L. *N Engl J Med*. 2005;353:1513-5.
- Kupersmith J, Holmes-Rovner M, Hogan A, Rovner D, Gardiner J. *Prog Cardiovasc Dis*. 1995;37:307-46.