Background—We reviewed the literature pertaining to the cost-effectiveness of implantable cardioverter-defibrillator (ICD) therapy in the management of ventricular fibrillation and tachycardia. Discussed are the methodology, advantages, and limitations of economic-outcomes analyses as related to ICD therapy; the impact of new technology and physician practice patterns; and methodological recommendations for future studies.

Methods and Results—Articles published between 1990 and 1997 were screened for cost-effectiveness analyses of ICD versus antiarrhythmic drug therapy. Randomized clinical trials, prospective and retrospective studies, and economic models were included. These studies report incremental cost-effectiveness ratios ranging from cost savings of $13,975 per life-year saved (LYS) to an incremental cost of $114,917 per LYS for ICD therapy. Differences were due to study type, cost-reporting methodology, ICD technology used, and length of follow-up. Assuming current technology and physician practice patterns, we find that ICD total therapy costs may break even in 1 to 3 years.

Conclusions—Recent literature suggests that ICDs are a cost-effective therapy for management of life-threatening ventricular tachyarrhythmias. The advent of new technology and patient management practices should further improve the cost-effectiveness of ICD therapy. Future studies of ICD cost-effectiveness should address the implications of truncated follow-up periods and quality of life.

Key Words: cost-benefit analysis ▪ cardioversion ▪ defibrillation

Economic Outcomes Analysis: Key Issues
Economic outcomes analyses use a variety of methodologies but share a common objective: the comparative analysis of alternative therapies or treatment protocols based on the differences between the costs and benefits of each. This section explains the premise behind economic-outcomes analysis and the underlying differences among the methodologies used.

Much of the variability in economic-outcomes analysis stems from differences in the determination and measurement of the costs and benefits of treatment. The costs of treatment are calculated as follows: total expected costs of treatment equals initial therapy costs plus continuing therapy costs plus expected costs of treating side effects and complications. For ICDs, the implant procedure and device cost represent initial costs; battery replacement and periodic monitoring are continuing costs; and the probability of lead or perioperative complications times the cost of correction are expected costs of treating side effects and complications. For antiarrhythmic drug therapy, an electrophysiological (EP) study, drugs, and the associated hospital stay constitute initial costs. Regular prescription refills and routine patient management are continuing costs; and the probability of lead or perioperative complications times the cost of correction are expected costs of treating side effects and complications. For antiarrhythmic drug therapy, an electrophysiological (EP) study, drugs, and the associated hospital stay constitute initial costs. Regular prescription refills and routine patient management are continuing costs; and the probability of lead or perioperative complications times the cost of correction are expected costs of treating side effects and complications. For ICD therapy, including expected changes in both technology and physician practice patterns, as it might affect the economics of VT/VF management. The final section addresses pitfalls to avoid and issues to consider for future ICD economic outcomes studies.
difference between the expected total costs of treatment with ICD therapy and the expected total costs of treatment with antiarrhythmic drugs.

Defining Costs
There is no single definition of cost suitable for all analyses and decision makers. Costs of treatment based on the actual costs of the medical resources used are of greatest interest to the hospital, staff model health maintenance organizations, and others who receive a fixed payment, either capitated or based on diagnosis-related groups, for services provided. For payers and providers who accept patients on some form of fee-for-service basis, costs of treatment based on charges and reimbursement rates are most relevant. Costs of treatment that include nonmedical costs, such as the loss of income or productivity and the imputed costs of denigrations in quality of life, are most important to the patient, the patient’s family and employer, and society in general.

Another critical, and common, difference among economic-outcomes studies is the time period over which costs are tracked. This is especially problematic in evaluations of high-initial-cost interventions, such as ICDs. Because of the implant procedure and device cost, ICD therapy has a high initial cost but relatively low continuing costs. In contrast, antiarrhythmic drug therapy has much lower initial costs but higher continuing costs, reflecting the long-term cost of purchasing pharmaceuticals and the possibly higher likelihood of future events and side effects requiring costly emergency care and hospitalization. One European study examined the effects of ICD implantation on rehospitalizations in patients previously receiving a range of antiarrhythmic therapies. The results showed a reduction in frequency (from 3.23 to 0.88 per year) and total duration (from 32.94 to 9.31 days per patient per year) of rehospitalizations with the ICD.

An economic-outcomes analysis of ICD therapy that considers only a short time frame may severely overstate a relative cost disadvantage or fail to demonstrate potential cost savings because of a short follow-up period that does not capture all the continuing costs of the alternative therapy. A calculated break-even time may be reported to mitigate the problems associated with the length of the follow-up period. The break-even time is often expressed as the expected number of months or years before the initial cost disadvantage of a therapy has been offset by its lower continuing costs.

Present value is another technique commonly used to account for differences in the timing of costs and outcomes. Present value recognizes that the costs and health outcomes incurred today are more significant to the decision maker than those that may be incurred in the future. A discount rate is used to measure the present value of future costs and effects. For instance, at a 5% discount rate, costs of $100 expected to be incurred next year would be counted as a present value cost of only $95 today. The higher the discount rate is, the less significant future costs are, and the lower the economic benefit provided by a high initial-cost therapy, such as the ICD, is.
Sudden Cardiac Death; FDA, Food and Drug Administration; HCFA, Health Care Financing Administration; and MEDPAR, Medicare Provider Analysis Review.

TABLE 2. Methodological Summary of ICD Versus Antiarrhythmic Drug Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>Efficacy</th>
<th>Resource Used</th>
<th>Costs</th>
<th>Patient Population</th>
<th>Length of Follow-up or Life Expectancy, y</th>
<th>Sensitivity Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weaver et al11/1996</td>
<td>RCT</td>
<td>Actual</td>
<td>Actual records</td>
<td>Dutch private insurance charges</td>
<td>60 Postinfarct survivors</td>
<td>2.0 median follow-up overall</td>
<td>Hospital charge levels</td>
</tr>
<tr>
<td>MADIT15/1997</td>
<td>RCT</td>
<td>Actual</td>
<td>Patient report</td>
<td>Patient bills with cost to charge ratios, Medicare rates</td>
<td>181 Patients with prior MI, asymptomatic nonsustained VT, and EF &lt;35%</td>
<td>3.7 ICD, 2.8 AAD LE</td>
<td>Drop high-cost patients, drop crossovers, cost of device</td>
</tr>
<tr>
<td>Kuppermann et al19/1990</td>
<td>Markov model</td>
<td>Literature</td>
<td>Medicare data, expert opinion</td>
<td>HCFA MEDPAR charges, expert opinion</td>
<td>Meet 1985 FDA implantation guideline</td>
<td>5.1 ICD, 3.2 AAD LE</td>
<td>Mortality rates, RU</td>
</tr>
<tr>
<td>Kupersmith et al4/1995</td>
<td>Markov model</td>
<td>Literature</td>
<td>Medicare discharge abstracts</td>
<td>218 ICD implant patients</td>
<td>3.8 ICD, 2.1 AAD LE</td>
<td>Mortality rates, battery life, RU</td>
<td></td>
</tr>
<tr>
<td>Larsen et al16/1992</td>
<td>Markov model</td>
<td>Literature, expert opinion</td>
<td>Patient records reimbursed amounts</td>
<td>55 y old; recurrent sustained VT or VF</td>
<td>6.1 ICD, 3.9 AAD LE</td>
<td>AAD efficacy, battery life, age at implant</td>
<td></td>
</tr>
<tr>
<td>Owens et al17/1997</td>
<td>Markov model</td>
<td>Literature, surveys, expert opinion</td>
<td>Literature, surveys, expert opinion</td>
<td>57 y old at high or intermediate risk for SCD</td>
<td>5.6 ICD, 4.9 AAD LE</td>
<td>Battery life, survival advantage of ICD</td>
<td></td>
</tr>
<tr>
<td>AVID11/1997</td>
<td>RCT</td>
<td>Actual</td>
<td>Actual or patient records</td>
<td>Charges</td>
<td>1016 Patients with VF, VT with syncope, or sustained VT and EF &lt;40% with symptoms</td>
<td>1.5 mean follow-up overall</td>
<td>None reported</td>
</tr>
</tbody>
</table>

CIA indicates cost-identification analysis; CEA, cost-effectiveness analysis; CUA, cost-utility analysis; and CBA, cost-benefit analysis.

An example of the use of break-even times and discount rates was calculated from data presented by Kupersmith et al6 comparing the costs of ICD and antiarrhythmic drug therapy (see Figure 1). In this example, the costs are restated in 1997 dollars with the use of the medical cost component of the Consumer Price Index.7

Assuming a present-day scenario that uses an endocardial ICD without a preimplant EP study, we calculate an initial hospitalization charge of $45 584. The initial hospitalization charge for EP-guided antiarrhythmic drug therapy is $35 478. These 2 costs are shown as the year 0 costs in Figure 1. Continuing therapy costs and life expectancy are discounted at 5%. On the basis of the information reported, the average annual charges of continuing treatment are assumed to be $21 561 for endocardial ICD therapy and $31 640 for antiarrhythmic drug therapy, represented by the slopes of the lines.

TABLE 1. Types of Economic-Outcomes Analysis

<table>
<thead>
<tr>
<th>Type of Analysis</th>
<th>Benefits Measured</th>
<th>Methodology</th>
<th>Advantages and Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIA</td>
<td>Differences in the benefits of alternative therapies are not considered.</td>
<td>Accumulate costs for each therapy. The difference is equal to the incremental cost of the higher-cost therapy: cost therapyA − cost therapyB.</td>
<td>Simplest methodology, that is appropriate if there are no differences in therapeutic benefits.</td>
</tr>
<tr>
<td>CEA</td>
<td>Identifies a clinical benefit and measures differences in the realization of that benefit.</td>
<td>Calculate the incremental cost and incremental benefit of the higher-cost therapy. Express the result as the cost per unit of clinical outcome, eg, $/LYS, [(cost therapyA − cost therapyB)/benefit therapyA − benefit therapyB].</td>
<td>Considers improved clinical outcomes that require increased resource use.</td>
</tr>
<tr>
<td>CUA</td>
<td>Per CEA but explicitly considers the patient’s utility or valuation of all the benefits of a therapy.</td>
<td>Per CEA but must measure the patient’s utility or value for the clinical outcome. Result is expressed as the cost per unit of patient utility or incremental cost per quality-adjusted LYS.</td>
<td>Principal concern of patients but limited by the subjective valuation of quality of life.</td>
</tr>
<tr>
<td>CBA</td>
<td>Presumes to evaluate all therapy benefits in terms of monetary units.</td>
<td>The CBA for 1 therapy may be expressed as the costs minus the benefits: cost therapyA − benefit therapyA, or the cost per dollar of benefit: cost therapyA/benefit therapyA, or the incremental cost per dollar of incremental benefit: (cost therapyA − cost therapyB)/(benefit therapyA − benefit therapyB).</td>
<td>Principal concern of society but limited by the subjective monetary valuation of therapeutic benefits.</td>
</tr>
</tbody>
</table>

CIA indicates cost-identification analysis; CEA, cost-effectiveness analysis; CUA, cost-utility analysis; and CBA, cost-benefit analysis.
in Figure 1. The mean life expectancy after hospitalization is 3.78 and 2.06 discounted life-years for ICD and antiarrhythmic therapy, respectively. After the mean life expectancy is reached, the graphed cost curves continue as dotted lines. The distance between the 2 cost curves at any time represents the difference between the total costs of the respective therapies. The break-even time is 1.0 years, the point where the 2 cost curves cross.

Types of Economic-Outcomes Analysis
There are 4 distinct types of economic-outcomes analysis: cost-identification analysis (CIA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and cost-benefit analysis (CBA). Table 1 discusses each analysis. The primary difference among the methods is the manner in which the benefits of treatment are recognized and accounted for. A number of texts and articles provide in-depth discussions of these methods.8,9

Sensitivity Analysis
Economic-outcomes analysis should always include an evaluation of the sensitivity of reported results to changes in the cost and benefit parameters. These “what-if” scenarios allow readers to customize the analysis for their particular experience, practice, or institution. For example, the cost-effectiveness of ICDs is dependent on the life expectancy of the battery within the pulse generator. As the frequency of generator replacement is decreased as a result of technological advances, the ICD becomes more cost-effective.

Economic-Outcomes Analysis: ICD Therapy
Comparisons of ICD and antiarrhythmic drug therapy generally conclude that ICD therapy, at least as it has been practiced in the past, does not reduce total medical costs but does deliver significant reductions in mortality rate. In this section, economic-outcomes analyses of ICD and antiarrhythmic drug therapy are reviewed.

Articles for review were identified by use of MEDLINE. They were initially selected if published in English between 1990 and 1997 and if they contained the index terms “implantable cardioverter-defibrillator” or “cardioverter defibrillator” and “cost,” “economics,” or “cost-effectiveness.” In addition, abstracts reporting results of 3 recently completed, large, multicenter studies (AVID, CIDS, and CASH) were obtained from conference proceedings from US scientific meetings. Articles retrieved were then screened for CEAs of ICD compared with antiarrhythmic drug therapy. Randomized clinical trials, prospective and retrospective studies, and economic models were included. Of the 24 sources initially identified through index terms on MEDLINE and conference proceedings, 7 passed the screening criteria listed above and are analyzed in this article.

Meta-analysis and meta-regression techniques were not used in this analysis because of the lack of data provided in the studies and the limited number of studies meeting inclusion criteria for our article. Furthermore, the articles did not provide enough detailed information on SEs, CIs, or probability values to derive test-based SEs. In the absence of reliable information to perform a robust meta-analysis, we have synthesized the data in a format that presents the important findings related to economic outcomes.

A summary of the methodologies used in each of the 7 studies is presented in Table 2. This table discloses the type of study, assumptions made, follow-up, and types of sensi-
tivity analyses performed. The studies are presented in order of their findings, from most to least cost-effective for ICDs. Figure 2 depicts graphically the base case, minimum, and maximum cost-effectiveness scenarios from each of the 7 studies. All results have been restated in 1997 dollars with the use of medical cost component of the Consumer Price Index.7 Cost-effectiveness ranges are adapted from the Kupersmith et al 10 study, which examined cost-effectiveness for a variety of cardiovascular disorders and treatment options. Among the scenarios analyzed, results from AVID 11 and Wever et al 12 appear to be outliers. The AVID results may represent an outlier because of the short follow-up period. The Wever et al results fall outside the general ranges, most likely because of the high proportion of therapy changes in the EP-guided strategy group.

Figure 3 presents a summary of incremental cost-effectiveness results for the base case of each study and relevant sensitivity analyses. ICD cost-effectiveness is sensitive to battery life assumptions, use of a preimplant EP study, and relative mortality advantage of ICDs over antiarrhythmic drug therapy. Figure 4 displays incremental cost-effectiveness results for other cardiovascular interventions as determined in the Kupersmith et al10 study. With the Kupersmith et al categorization, ICD therapy appears to be cost-effective, perhaps akin to primary coronary artery stenting.

Sensitivity to Battery Life
As evident in Figure 3, the cost of ICD therapy is sensitive to battery life, which in turn depends on the type of battery and the patient’s requirements for pacing and therapeutic shocks. With current devices, patients requiring no pacing or therapeutic shocks can expect an average device longevity of ≈9 years.13 Device longevity may decrease to 5 years when continual pacing and monthly therapeutic shocks are needed.13 New technologies that allow dual-chamber pacing and shocks have comparable device longevity profiles.14

A number of published studies examine the effect of improved battery life in their sensitivity analyses.6,15–18 For example, the MADIT investigators reported cost-effectiveness of $13,311 per life-year saved (LYS) with generator replacement after the 4-year period instead of $28,751 per LYS from the base case, a savings of $15,441 per LYS.15 By extending battery life to 8 years (from 2 years in the base case), Larsen et al16 reported savings of $24,219 per LYS.

Break-Even Analyses
We calculated base case break-even periods from 6 of the 7 studies, as shown in Table 3. Reported data were insufficient in AVID11 to permit calculation of the break-even period. In 2 studies, those of Kuppermann et al19 and Wever et al12 break-even for the base case occurs within the reported life expectancy of the ICD cohort. ICD therapy would be a cost-saving therapy, saving $18,840 (Kuppermann et al19 ) and $33,733 (Wever et al12) if the average patient on antiarrhythmic drug therapy were to survive as long as the average patient receiving an ICD. Using additional data reported by Kuppermann et al, we considered an updated scenario (5-year battery life and nonthoracotomy implant) that generated a break-even at 2.93 years and total therapy life of $70,000.19

<table>
<thead>
<tr>
<th>Study</th>
<th>Battery Life</th>
<th>Break-Even Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>MADIT [15]</td>
<td>4-Year</td>
<td>4.76 years</td>
</tr>
<tr>
<td>Kuppermann [19]</td>
<td>4-Year</td>
<td>2.75 years</td>
</tr>
<tr>
<td>Kupersmith [6]</td>
<td>4-Year</td>
<td>3.25 years</td>
</tr>
<tr>
<td>Larsen [16]</td>
<td>2-Year</td>
<td>2.93 years</td>
</tr>
<tr>
<td>Owens [17]</td>
<td>4-Year</td>
<td>4.1 years</td>
</tr>
</tbody>
</table>

Figure 3. Base-case incremental cost-effectiveness and relevant sensitivity analyses (ICD vs antiarrhythmic drug therapy). Reported costs are restated in 1997 dollars with use of medical cost component of Consumer Price Index.7 Figure does not include results from Wever et al12 and AVID because no sensitivity analyses were reported in those studies. Headings at column tops report citation, device type, battery life, etc, for base case. Labels on bars indicate deviations from base case. *Relative risk ratio (RRR), antiarrhythmic drug therapy compared with ICD therapy. †Cost-effectiveness guidelines as presented by Kupersmith et al.10 ‡Assumes that there is no generator replacement within 4-year cost accumulation period.
cost savings of $54,426 if the average patient on antiarrhythmic drug therapy survived as long as the average patient implanted with an ICD. Today, patients typically receive nonthoracotomy ICDs with battery longevity $8$ years. In 2 other studies, MADIT$^{15}$ and Kupersmith et al,$^{6}$ the ICD was not expected to break even during the follow-up period or the remaining life expectancy for the base case. ICD therapy did break even in both studies within the follow-up period when new technology and updated patient management techniques, such as nonthoracotomy ICDs, improved battery life, or implantation without a preimplant EP study, were considered. In MADIT,$^{15}$ considering only endocardial ICDs and base case battery life, the break-even period is 3 years; considering a 4-year battery life, the calculated break-even period is 2.61 years. For these 2 cases, the expected cost savings with ICD implantation over the reported average follow-up period are $4910 and $8928, respectively. In the Kupersmith et al$^{6}$ study, a scenario using endocardial ICDs without a preimplant EP study yielded a 1-year break-even. This ICD treatment scenario would show total cost savings with ICD implantation of $27,991 based on the reported life expectancy of the ICD group (3.78 years).

In the remaining 2 studies, Larsen et al$^{16}$ and Owens et al,$^{17}$ ICD therapy does not break even for the base case. In both, the reported ongoing maintenance costs of ICD therapy were higher than those for the alternative. Owens et al$^{17}$ referenced published costs from the 1992 Larsen et al$^{16}$ study and a survey of hospitals in northern California as sources for estimates of annual ongoing costs used in the model. Because the annual ongoing costs were not itemized, we were unable to determine whether the ICD would break even if an alternative patient management scenario were used.

Examining the updated cases in Table 3 reveals a current range of ICD break-even periods from 1 to 3 years. Emerging patient management practices, such as elimination of the preimplant EP study, and technology improvements that increase battery life and allow nonthoracotomy implantation greatly reduce the required break-even periods from the base-case calculations, in some cases $\approx 77\%$.

The Future: ICD Technology and Patient Management

Both technology and the medical practices supporting ICD implantation have changed dramatically since the first device was implanted in 1980. Early devices were large (209 cm$^3$, 281 g), requiring a thoracotomy for implantation and typically necessitating a 7- to 24-day hospital stay. Short battery life (2 to 3 years) required frequent generator replacement. Modern ICDs are dramatically smaller (<60 cm$^3$), can be implanted pectorally with transvenous single-lead positioning in an EP or catheterization laboratory under local anesthesia, and use battery technology that extends the generator life to 9 years.$^{13}$ These changes provide the means for ICD therapy to become more cost-effective, and even cost saving, in some patients.

A 1996 retrospective analysis compared both postoperative length of stay and charges of patients who received an epicardial compared with a nonthoracotomy lead system,
with generator implantation either abdominally or pectorally. Average convalescent time was reduced from 11.6 days for epicardial/abdominal implants to 4.6 days for nonthoracotomy abdominal implants and to 2.9 days for nonthoracotomy pectoral implants. Compared with the epicardial/abdominal group, average charges were reduced by 40% in the abdominal group and by 55% in the pectoral group using the transvenous lead system. Both MADIT and Kupersmith et al also examined scenarios for technology changes from conscious sedation rather than attended general anesthesia. Elimination of the predischarge device test, and delivery of savings ranging from $4472 to $6295 per LYS, respectively.

Similar data supporting the cost advantages of the new devices and patient management practices were reported in a study that examined a hypothetical scenario including catheterization laboratory implantation and use of endocardial ICDs. The researchers found that total charges over the 27-month average follow-up were lower in the catheterization laboratory implantation scenario, $55 009, compared with either ICD implantation in the operating room under general anesthesia, $69 251, or conventional drug therapy, $77 854.

Other patient management practices that increase ICD effectiveness are elimination of a preimplant EP study, patient education, and painless high-voltage lead impedance testing, available in some newer ICDs, allows monitoring of lead integrity without arrhythmia induction procedures during patient follow-up visits.

**Economic Impact of New Technology Adoption**

As ICD use becomes more widespread, 2 issues will arise in its economic evaluation that may lead to decreased cost-effectiveness. First, inexperienced physicians may overadmit patients to the hospital for single appropriate shocks, and patients poorly educated about their devices may admit themselves, fearing their device is not working properly. A potential increase in the frequency of rehospitalization was examined in 2 studies that showed decreased cost-effectiveness ranges from an additional $3847 to $7333 per LYS. As patients and physicians become more comfortable with ICDs, this initial peak in hospitalizations could disappear. Future economic analyses should account for this learning curve through longer follow-up and scenario analysis for the post–learning curve era.

Second, the extension of use into lower-risk patient populations may not exhibit the survival differences noted in existing studies. Owens et al have shown that ICD therapy for intermediate-risk patients is less cost-effective than for high-risk patients, with incremental costs of an additional $2000 per LYS. Furthermore, as an increasing number of lower-risk patients receive ICD therapy, ICD studies should incorporate an expanded definition of costs to account for potential quality-of-life differences.

**Conclusions**

Future studies of the cost-effectiveness of ICD therapy should address 2 concerns. The first issue is follow-up time as it relates to the duration of treatment and the likelihood of battery replacement. Both MADIT and AVID were terminated prematurely after demonstrating statistically significant mortality advantages in favor of ICD therapy. Censoring the survival data, however, yields an economic-outcomes analysis of these trials that is biased against ICD therapy. To the extent possible, CEAs of ICD therapy should consider the sensitivity of the results to increases in survival time over the full course of treatment. Fitting short-term follow-up data in the context of a longer-term survival model could allow researchers to consider more fully the potential for ICD therapy to increase average survival time and reduce incremental costs. An unduly short follow-up period, however, could also bias results in favor of ICD therapy. If the cost analysis is truncated just before an expected battery replacement, the cost-effectiveness of ICD therapy would be over-

<table>
<thead>
<tr>
<th>Study</th>
<th>Case Description</th>
<th>Break-Even, y</th>
<th>ICD Cohort Life Expectancy or Follow-Up, y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wever et al12</td>
<td>Base case</td>
<td>1.0</td>
<td>2.4 Follow-up</td>
</tr>
<tr>
<td>MADIT15</td>
<td>Base case</td>
<td>4.0</td>
<td>3.7 Follow-up</td>
</tr>
<tr>
<td>MADIT15</td>
<td>Updated (endocardial ICD)</td>
<td>3.0</td>
<td>3.7 Follow-up</td>
</tr>
<tr>
<td>MADIT15</td>
<td>Updated (endocardial ICD, battery life* &gt;4 y)</td>
<td>2.6</td>
<td>3.7 Follow-up</td>
</tr>
<tr>
<td>Kupersmith et al19</td>
<td>Base case</td>
<td>4.1</td>
<td>5.1 Life expectancy</td>
</tr>
<tr>
<td>Kupersmith et al19</td>
<td>Updated (battery life of 5 y, nonthoracotomy implant)</td>
<td>2.9</td>
<td>5.1 Life expectancy</td>
</tr>
<tr>
<td>Kupersmith et al19</td>
<td>Updated (endocardial ICD, no preimplant EP study)</td>
<td>1.0</td>
<td>3.8 Life expectancy</td>
</tr>
<tr>
<td>Larsen et al16</td>
<td>Base case</td>
<td>Does not break even</td>
<td>6.1 Life expectancy</td>
</tr>
<tr>
<td>Owens et al17</td>
<td>Base case</td>
<td>Does not break even</td>
<td>5.6 Life expectancy</td>
</tr>
<tr>
<td>AVID11</td>
<td>Base case</td>
<td>Insufficient data</td>
<td>Insufficient data</td>
</tr>
</tbody>
</table>

*Assumes that within the 4-y cost accumulation period there is no generator replacement.
stated because it would not appropriately account for the significant cost of battery replacement. The most appropriate solution to this problem may be to prorate the costs of battery replacement on the basis of the likelihood of survival and the expected battery life.

The second issue is an expanded definition of costs to include other social costs, such as lost patient productivity and willingness to pay. One study assumes and assigns a quality of life of 0.75 to both antiarrhythmic drug therapy and ICD therapy cohorts but does not examine patient utilities with validated quality-of-life measurement tools. No studies have published results adjusted for actual patients’ perceived differences in quality of life under either ICD or antiarrhythmic drug therapy. Perhaps those patients receiving ICD therapy enjoy a greater sense of security, are confident in the efficacy of their device, and are less subject to lost productivity resulting from repeated attacks of arrhythmia. Alternatively, perhaps these patients are troubled by the risks and potential costs of inappropriate shocks.

Nevertheless, in the case of ICDs, the evidence to date suggests that these devices represent a cost-effective therapy for life-threatening ventricular arrhythmias; ICD therapy is in the range of other well-accepted common therapies for cardiovascular disease. Indeed, the data now strongly support the first-line use of ICDs for treatment of serious arrhythmias in patients with sustained ventricular arrhythmias (AVID, CIDS, and CASH) and those at high risk for lethal ventricular arrhythmias (MADIT). Advancing technology, such as dual-chamber ICDs that have integrated dual-chamber detection and increased specificity for patients with supraventricular tachycardias, and changes in patient management practices should lead to ongoing improvements in the cost-effectiveness of ICD therapy.

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Marshall S. Stanton and Gregory K. Bell

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