Cost-Effectiveness of Catheter Ablation in Patients With Ventricular Tachycardia

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Background—This study evaluated the cost-effectiveness of catheter ablation therapy versus amiodarone for treating ventricular tachycardia (VT) in patients with structural heart disease. The analysis used a societal perspective for a hypothetical cohort of VT patients with implantable cardioverter-defibrillators, who were experiencing frequent shocks.

Methods and Results—We calculated incremental cost-effectiveness of ablation relative to amiodarone over 5 years after treatment initiation. Event probabilities were from the Chilli randomized clinical trial (Chilli Cooled Ablation System, Cardiac Pathways Corporation, Sunnyvale, Calif), the literature, and a consensus panel. Costs were from 1998 national Medicare reimbursement schedules. Quality-of-life weights (utilities) were estimated using an established preference measurement technique. In a hypothetical cohort of 10 000 patients, 5-year costs were higher for patients undergoing ablation compared with amiodarone therapy ($21,795 versus $19,075). Ablation also produced a greater increase in quality of life (2.78 versus 2.65 quality-adjusted life-years [QALYs]). This yielded a cost-effectiveness ratio of $20,923 per QALY gained for ablation compared with amiodarone. Results were relatively insensitive to assumptions about ablation success and durability. In less severe patients with good ejection fractions who suffer their first VT episode, the incremental cost-effectiveness ratio was $6028 per QALY gained. These cost-effectiveness ratios are within the range generally thought to warrant technology adoption.

Conclusions—This study demonstrates that, from a societal perspective, catheter ablation appears to be a cost-effective alternative to amiodarone for treating VT patients. (Circulation. 2000;101:280-288.)

Key Words: catheter ablation ■ tachycardia ■ cost-benefit analysis ■ tachyarrhythmias

Two recent trials have demonstrated that implantable cardioverter-defibrillators (ICD) can improve the survival of patients at increased risk of sudden death.1,2 Roughly 50 000 ICDs were implanted worldwide in 1997 for treating ventricular arrhythmias. Between 40% and 70% of these patients will experience 1 or more ICD discharges during the first 2 years after implantation,3 with a substantial subset requiring additional treatment because of frequent recurrences of ventricular tachycardia (VT). For these patients, treatment options are limited to antiarrhythmic drug therapy, usually with amiodarone, or catheter ablation. Surgical ablation of VT previously has been considered an option in this population but has largely been abandoned because of significant operative risk.4 Several investigators recently reported that catheter ablation is effective in decreasing the frequency of VT episodes when used as adjunct therapy in patients receiving frequent ICD shocks.5 However, the economic implications of catheter ablation have not been explored.

The objective of this study was to evaluate the cost-effectiveness of catheter ablation of sustained VT relative to treatment with amiodarone in patients with ICDs who experience frequent VT episodes or ICD shocks. We also examined the cost-effectiveness of catheter ablation in a less severely ill population (patients with good ejection fractions who suffer their first VT episode). Our analyses were primarily based on catheter ablation data collected during a multicenter, prospective, randomized clinical trial of the Chilli Cooled Ablation System (Cardiac Pathways Corporation, Sunnyvale, Calif). This catheter ablation system can create larger lesions than standard radiofrequency (RF) energy,6 and recently was approved by the United States Food and Drug Administration for treating mappable VT attributable to ischemic heart disease or cardiomyopathy.7 As a point of reference, the cost-effectiveness ratios of other common therapies for arrhythmias and prevention of sudden cardiac death range from $10 000 to $48 000.8–11

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Background

The current study incorporates clinical data collected during the Chilli Cooled Ablation System randomized trial, which compared the Chilli Cooled Ablation System and antiarrhythmic therapy for treating VT. Conducted between September 1995 and June 1997, the trial included 107 patients. Patients were eligible to participate in the trial if they had documented sustained monomorphic VT with 2 or more episodes during the 2 months before enrollment. The mean left ventricular ejection fraction was 31±13%, with ischemic heart disease present in 82% of patients. The study demonstrated that 71.9% of patients who underwent ablation experienced a ≥75% reduction in VT episodes or ICD shocks at 2 months. Long-term treatment success (defined as no recurrence of any VT at 6 months) was significantly higher in patients who underwent ablation than those who received antiarrhythmic therapy (55% versus 19%, P=0.001). The cumulative incidence of ablation-related major adverse events (eg, cardiac perforation, third-degree heart block, or thromboembolic event) was 6.7%. Clinical, adverse event, and quality-of-life data from the trial were made available for this cost-effectiveness analysis.

Framing the Analysis

Cost-utility analysis is a type of cost-effectiveness analysis in which outcomes are adjusted for quality of life, for example, using quality-adjusted life-years (QALYs) gained. The quality adjustment comes from utilities, numbers that reflect an individual’s preference for particular health outcomes. In this study, we developed a decision-analytic Markov model with 24 health states using DATA™ (version 3.0, TreeAge Software, Inc) to simulate the 5-year clinical, economic, and quality-of-life outcomes associated with 2 VT treatment strategies, catheter ablation or medical therapy (amiodarone), for a hypothetical cohort of patients with VT (Figure 1). A panel of 3 cardiac electrophysiologists provided the clinical framework for the model and made final decisions on data inputs. This research was performed according to the guidelines that have been established to minimize conflict of interest in pharmacoeconomic studies.

The incremental cost-effectiveness ratio of catheter ablation relative to amiodarone was calculated as the difference in costs incurred divided by the difference in QALYs accrued between catheter ablation and amiodarone. Success was defined as the proportion of patients achieving a ≥75% reduction in VT episodes or ICD shocks comparing equivalent time periods before and after treatment. Conducted from the societal perspective, the analysis considered all relevant costs and benefits regardless of who incurred or accrued them (eg, the patient, physician, or payer). Costs and health effects were discounted at a 3% annual rate. All results were expressed in 1998 US dollars. Sensitivity analyses helped to assess external validity and generalizability of our estimates.

We selected a 5-year time horizon to ensure that we included all relevant costs and benefits. Although the literature includes 5-year follow-up data on amiodarone treatment, the follow-up on catheter ablation is limited to 3 years. Several sensitivity analyses were performed to address this limitation.

Twenty-four health states reflecting the 2 treatment alternatives and associated outcomes (for example, ablation success without any adverse events) were included in the model. Each health state has an associated cost and utility. With each 1-month cycle, patients could transition from 1 health state to another and incur the corresponding cost and utility of being in that state. The 1-month time interval is long enough to capture significant events and short enough to be sensitive to utility and cost differences over time.

Transition probabilities (ie, probabilities of passing from 1 health state to another) and other parameter estimates were derived from the Chilli trial, a comprehensive literature review, and the opinion of the clinical panel (Table 1). Because certain probabilities change over time (eg, treatment success and mortality), we programmed the model to apply the appropriate cycle-specific probability for time-dependent parameters. The time-dependent probabilities appear in Figure 2.

Assumptions

Several assumptions were made to construct this cost-effectiveness model. (1) This analysis only applies to patients with ICDs who would be candidates for catheter ablation and amiodarone; (2) patients who are successfully treated with catheter ablation are not on concomitant amiodarone therapy; (3) half of the amiodarone patients initiate treatment as inpatients, whereas the other half initiate therapy as outpatients; (4) patients receive 400 mg of amiodarone daily; (5) treatment success and failure data for months 1 through 6 were from the Chilli trial. Because failures generally occur during the first 6 months after catheter ablation, we assumed a small monthly probability of failure (0.1%) to extrapolate 6-month Chilli clinical trial data to 5 years. (6) Patients who fail either treatment cross over to the alternative treatment; however, each treatment can only be attempted a maximum of 2 times (the clinical panel indicated that patients rarely would be treated with catheter ablation >2 times). (7) Patients treated with either catheter ablation or amiodarone have identical survival rates. However, patients who exhaust all possible treatments have a higher mortality rate. (8) Permanent side effects of either amiodarone or catheter ablation result in a one-time cost, as well as ongoing monthly costs for the remainder of the model. Additionally, throughout the model, patients receive the minimum utility value of either the permanent side effect or their present health state. (9) The sequence of ablation-related adverse events, specifically, mild thromboembolic events, moderate cardiac perforation, and mild or moderate heart block, resolve within 30 days of the procedure; and (10) all patients who experience severe neurological impairment, hyperthyroidism, mild/moderate pulmonary toxicity, or severe hepatic toxicity discontinue amiodarone treatment.

Eliciting Utilities

A cost-utility analysis incorporates the concept that diminishing levels of health may compromise the quality of life. This is accomplished by applying different utility weights to life expectancy according to the level of health experienced over time. The utility weights reflect the preference for a particular health outcome and range from 0, indicating death, to 1, indicating perfect health. We derived utilities from 2 sources: (1) quality-of-life data (Medical Outcomes Study 36-item Short Form Health Survey [SF-36]) at 6 months after treatment in the Chilli trial, and (2) estimates from the clinical panel using the trial data as reference points. The SF-36 scores for catheter ablation success and drug therapy success were transformed to utilities based on equations from Shmueli.

Before eliciting utility estimates from the panel, we transformed the 2 reference utilities to rating scale values using a power curve transformation and placed the values on a rating scale thermometer ranging from 0 (death) to 1 (perfect health). We provided panels with the 24 health states, specifically, 8 short-term clinical events, 13 possible long-term outcomes, brief descriptions of the 2 treatments and their associated risks, and death. The panelists ranked the health states on the rating scale thermometer by indicating a patient’s likely preference for each state. Each panelist’s values were then transformed back into utilities (scale 0 to 1) for use in the cost-effectiveness model. The resulting health state utilities are summarized in Table 2.

Medical Resource Utilization and Costs

Costs were assessed from the societal perspective. The indirect costs of lost productivity and the intangible costs of pain and suffering related to VT morbidity were not estimated directly but instead were implicitly incorporated in the utility values. To estimate 5-year direct medical costs, the panel enumerated medical resource utilization associated with the 2 therapeutic alternatives and their potential sequelae. A physician experienced in medical reimbursement assigned procedure and diagnosis codes to hospitalizations, physician office visits, laboratory tests, and professional services. After iden-
Figure 1. Simplified schematic of cost-effectiveness model. □ represents a decision to use 1 of 2 therapies for treating VT: catheter ablation or medical therapy (amiodarone). The M denotes a Markov node, indicating entry into a Markov tree; and ◯, chance nodes. Branches emanating from the catheter ablation arm are duplicated on the amiodarone arm, as symbolized by the [ ]. Once a treatment option is chosen, patients enter a Markov tree, which represents the health states in which patients may exist during each cycle (each cycle = 1 month). A patient receiving catheter ablation may be a clinical success (≥75% reduction in VT episodes or ICD shocks) or
fying codes for resource use, we derived cost estimates from 1998 national Medicare reimbursement schedules. Table 2 lists each of the treatment-specific, event-related, and outcome-related costs incorporated in the model.

We calculated hospitalization costs as the amount Medicare pays on the basis of assignment to a diagnosis related group. Professional services associated with hospitalizations and outpatient visits were assigned current procedural terminology codes. The corresponding resource-based relative-value scale relative-value units were converted to professional reimbursement payments with Medicare’s 1998 national conversion factor. Laboratory test costs were from the 1998 Clinical Laboratory Information Act Fee Schedule. Drug costs were estimated from the Drug Topics Red Book,22 a compendium of wholesale drug prices in the United States. We deducted 20% from the average wholesale price to obtain a more accurate estimate of actual drug costs.

failure (75% reduction in VT episodes or ICD shocks), suffer a permanent adverse event (AE), or die. A patient who fails ablation treatment, with or without a permanent AE, may undergo a second and final ablation procedure or may crossover to amiodarone. Patients receive no further treatment if they have previously attempted both treatment alternatives twice. A patient on amiodarone may be successful, fail, experience one-time or permanent AEs (AEs, with the exception of bradycardia, may not occur until after 6 months of therapy), or die. Some patients experiencing one-time AEs will discontinue amiodarone, whereas all patients with permanent amiodarone AEs discontinue therapy regardless of their clinical status (success or failure). Each terminal branch (\(\triangleright\)) ends in a health state to which the patient returns to begin the next monthly cycle. A patient remains in the model for 60 cycles (5 years) or until death.

### TABLE 1. Base-Case Probability Values Used in the Model

| Parameter | Probability, % | Reference No. |
|-----------|----------------|
| **Amiodarone** | | |
| Mild/moderate neurological impairment | 4.5 | 26–29 |
| Probability of discontinuing amiodarone due to mild/moderate neurological impairment | 75 | CP |
| Severe neurological impairment | 0.5 | 26–29 |
| Hyperthyroidism | 0.3 | 26–29 |
| Probability of death due to hyperthyroidism | 50 | CP |
| Hypothyroidism | 2.7 | 26–29 |
| Probability of discontinuing amiodarone due to experiencing hypothyroidism | 0 | CP |
| Mild/moderate ocular impairment | 2 | 26–28 |
| Probability of discontinuation due to mild/moderate ocular impairment | 5 | CP |
| Mild/moderate pulmonary toxicity | 1.8 | 2, 26–31 |
| Severe pulmonary toxicity (fatal) | 0.2 | 2, 26–31 |
| Mild hepatic toxicity | 0.99 | 26–29 |
| Probability of discontinuation due to mild hepatic toxicity | 50 | CP |
| Severe hepatic toxicity | 0.01 | 26–29 |
| Skin discoloration/photosensitivity | 10 | 26–28 |
| Probability of discontinuation due to skin discoloration/photosensitivity | 10 | CP |
| Impotence | 2 | CP |
| Probability of discontinuation due to impotence | 30 | CP |
| Symptomatic bradycardia | 3% in the first 6 months | 26–28 |
| Probability of discontinuation due to symptomatic bradycardia | 0 | CP |
| Amiodarone failure rate | Time-dependent | CCT, CP |
| (Figure 2A and 2C) | | |
| Amiodarone survival | Time-dependent | CCT, CP |
| (Figure 2E) | | |
| **Catheter ablation** | | |
| Mild thromboembolic event | 1.35 | CCT |
| Severe thromboembolic event | 1.35 | CCT |
| Moderate cardiac perforation | 1.17 | CCT |
| Mild or moderate heart block | 2.70 | CCT |
| Ablation failure rate | Time-dependent | CCT, CP |
| (Figure 2B and 2D) | | |
| Ablation survival | Time-dependent | CCT, CP |
| (Figure 2F) | | |

All probabilities are annual unless otherwise indicated. CP indicates clinical panel; CCT, Chilli clinical trial.7
Figure 2. A, Initial success of amiodarone, base-case and sensitivity analysis assumptions. Thick line represents the base-case success estimate, defined as a ≥75% reduction in VT episodes or ICD shocks. Solid and dotted lines represent 10% increase or decrease, respectively, in initial success estimate and were used in sensitivity analyses. B, Initial success of ablation treatment, base-case and sensitivity analysis assumptions (lines are as in A). C, Durability of amiodarone, base-case, and sensitivity analysis assumptions. Dashed line represents a change in the success rates to yield a durability of 30% at 5 years; thick line is as in A. D, Durability of ablation treatment, base-case, and sensitivity analysis assumptions. Dashed line represents a change in the success rates to yield a durability of 44% at 5 years; thick line is as in A. E, Amiodarone survival curves, base-case, and sensitivity analysis assumptions. Thick line represents the base-case estimate of all-cause mortality; solid and dotted lines represent 15% increase or decrease, respectively, in the survival rates and were used in sensitivity analyses. F, Ablation treatment survival curves, base-case, and sensitivity analysis assumptions. Lines are as in E.
Sensitivity Analysis

Sensitivity analyses were performed to determine the consequences of making alternative assumptions about the initial success (proportion successful in first month), durability (5-year treatment success), and cost of both therapies (reflecting use of generic amiodarone or performing ablation on an outpatient basis), the risk and timing of adverse events associated with both therapies, survival rates, daily dose of amiodarone, utilities associated with health states, crossover to ablation on amiodarone failure or severe adverse event, population disease severity, annual discount rate, and time horizon. The generalizability of the results was assessed using 1-way sensitivity analyses and several analyses in which multiple parameters were varied over plausible ranges.

Table 3 reports the 5-year cost, utility (expressed in QALYs), and cost-effectiveness ratio for the hypothetical cohort of VT patients. This base-case analysis (ie, the scenario that incorporates the most likely values of all model parameters) assumes a 63% 5-year durability for catheter ablation and a 44% 5-year durability for amiodarone. In a hypothetical cohort of 10 000 patients, 5-year costs were higher for patients undergoing ablation compared with amiodarone ($21 795 versus $19 075), as were 5-year utility values (2.78 versus 2.65 QALYs). This yielded a cost-effectiveness ratio
of $20,923 per QALY gained for ablation compared with amiodarone (Table 3). This cost-effectiveness ratio reflects the incremental cost of obtaining an additional QALY expectancy from ablation compared with amiodarone.

In the base-case analysis, 54% of patients who initially received amiodarone subsequently underwent at least 1 ablation procedure, whereas 23% of patients who initially received ablation subsequently crossed over to amiodarone therapy. The costs associated with adverse events were greater for amiodarone than for ablation. On average, ∼12% ($2332) of the 5-year treatment costs for amiodarone were associated either with treating amiodarone adverse events or crossing over to ablation due to treatment-related adverse events, compared with only 1% ($203) for ablation.

Sensitivity analyses demonstrated that the incremental cost-effectiveness of catheter ablation compared with amiodarone was relatively insensitive to changes in treatment success rate or durability, survival of amiodarone patients, adverse event rates or timing, amiodarone dosage or cost, health state utilities, crossover to ablation on amiodarone failure or severe adverse event, and discount rate. The results were most sensitive to assumptions about the cost of catheter ablation, the survival rate of catheter ablation patients, and the time horizon (ie, the time during which costs and QALYs were estimated). Complete results of the sensitivity analyses are available from the authors.

When the cost of the catheter ablation procedure was increased by 33% (from $14,980 to $19,973), the incremental cost-effectiveness ratio increased to $42,754 per QALY gained. However, when the ablation procedure cost was decreased by 33% (to $9987), meant to reflect outpatient treatment, then ablation dominated amiodarone therapy, ie, ablation yielded lower costs and higher utility. Reducing the survival rate of ablation patients from 46% to 41% at 5 years yielded a cost-effectiveness ratio of $46,133 per QALY gained. Decreasing the model time horizon to 2 years also yielded a cost-effectiveness ratio of $46,133 per QALY gained.

We also assessed the relative value of both treatments in a population with less severe disease (patients with good ejection fraction who suffer their first VT episode). We hypothesized that this population would have increased treatment success rates, increased survival rates, decreased ablation complication rates (which also results in a slightly decreased ablation cost), and increased utilities of both treatment and outcome health states. The analysis of this population yielded lower total costs and higher total QALYs compared with the more severe population. The cost-effectiveness ratio in this less severe population was $60,287 per QALY gained (ablation: $17,965, 3.42 QALYs; amiodarone: $16,458, 3.17 QALYs). The disproportionate crossover rates seen in the base-case analysis were even more pronounced in the less severe population. Roughly 38% of patients whose first treatment was amiodarone subsequently underwent at least 1 ablation procedure, whereas 8% of those patients who initially received ablation subsequently crossed over to amiodarone.

Discussion

To the best of our knowledge, this study is the first to evaluate the cost-effectiveness of catheter ablation in treating VT. Our study demonstrates that from a societal perspective, catheter ablation of VT appears to be a reasonable alternative to amiodarone therapy in patients with frequent VT episodes (similar to those patients enrolled in the Chilli trial) and patients with less severe disease ($20,923 per QALY and $60,287 per QALY, respectively). Laupacis and colleagues suggest that cost-effectiveness ratios <$100,000 per QALY warrant consideration for use.23 The favorable cost-effectiveness ratios appear to be due, in part, to the high crossover rate from amiodarone to ablation and the costs associated with amiodarone-related adverse events. These factors contribute toward increasing the 5-year costs and decreasing the quality of life associated with amiodarone.

The cost-effectiveness of catheter ablation relative to amiodarone compares favorably with that of other common therapies for arrhythmias and prevention of sudden cardiac death: specifically, $10,736 per QALY gained for amiodarone versus conventional medical therapy for a 55-year-old patient with recurrent sustained VT or ventricular fibrillation,8 $23,269 per QALY gained for ablation versus medical therapy in Wolff-Parkinson-White syndrome,11 $29,580 per QALY gained for ICD versus conventional medical therapy for high-risk patients with asymptomatic nonsustained VT,10 $39,769 per QALY gained for an ICD regimen versus an

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TABLE 3. Cost-Effectiveness of Catheter Ablation Compared to Amiodarone*

<table>
<thead>
<tr>
<th></th>
<th>Mean Total Costs (SD)</th>
<th>Mean Total QALYs†</th>
<th>Incremental Cost</th>
<th>Incremental QALY</th>
<th>Incremental Cost per QALY Gained‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter ablation</td>
<td>$21,795 ($9,225)</td>
<td>2.78</td>
<td>$2720</td>
<td>0.13</td>
<td>$20,923</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>$19,075 ($10,940)</td>
<td>2.65</td>
<td></td>
<td></td>
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</tbody>
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*Analyses were run on a hypothetical cohort of 10,000 ventricular tachycardia patients over 5 years.
†Maximum of 5.00 QALYs.
‡Incremental Cost = $2720 / 0.13 = $20,923.
amiodarone followed by ICD regimen in patients at high risk for sudden cardiac death, and $47 317 per QALY gained for ICD versus amiodarone for a 55-year old patient with recurrent sustained VT or ventricular fibrillation. Of particular interest, the cost-effectiveness ratios resulting from our study and that by Hogenhuis and colleagues were $20 923 and $23 269 per QALY gained, respectively, for catheter ablation relative to medical therapy in VT and Wolff-Parkinson-White syndrome, respectively. All cost-effectiveness ratios have been adjusted to 1998 US dollars using the medical care component of the Consumer Price Index.

As with any model-based analysis, the results are only as good as the underlying assumptions. Although we believe that our assumptions are reasonable, one in particular warrants further comment: the 5-year durability of catheter ablation. To inform our estimate for this value, we relied on 6-month data from a randomized trial. However, we believe that the most appropriate analysis is to examine 5-year cost-effectiveness. Only by modeling patient care for such a long period of time can one account for both the changes in clinical outcome and costs of treating patients who fail initial therapy. As such, we assumed a small monthly probability of failure to extrapolate 6-month clinical trial data to 5 years. We tested the robustness of this assumption using sensitivity analyses and found that when the 5-year catheter ablation durability was decreased from 63% to 44%, the resulting cost-effectiveness ratio increased but was still favorable ($36 191 per QALY).

Other study limitations are worth mentioning. The health state utilities were elicited from clinicians familiar with this patient population. Alternatively, we could have elicited utilities from individuals without symptoms. The literature suggests that eliciting utilities from clinicians, rather than patients, results in underestimating patients’ own preferences for their health state experiences. When we increased health state utilities by 10% to reflect potential patient valuations, the resulting cost-effectiveness ratio was even more favorable ($18 133 per QALY). Further, our health state utilities for ablation success and failure (0.89 and 0.75, respectively) are similar to the patient-based values reported by McDonald and colleagues (0.91 and 0.74, respectively; Kathryn M. McDonald, MM, unpublished data, 1998) for patients who underwent radiofrequency ablation for atrioventricular nodal reentrant tachycardia with arrhythmias.

In addition, we recognize that our base-case analysis applies primarily to patients undergoing catheter ablation procedures at experienced ablation centers similar to those that participated in the Chilli clinical trial. Initially, as the technology diffuses, success rates may be lower as cardiologists gain experience in performing this procedure. We attempted to address this limitation by decreasing the initial success rate from 85% to 75% in a sensitivity analysis. Although this analysis resulted in a higher cost-effectiveness ratio ($32 755 per QALY gained), it did not alter the overall conclusions of the study.

Lastly, our base-case analysis applies only to patients with severe VT who experience frequent ICD firings. We addressed this limitation by varying our assumptions to reflect a less severely ill population. Our results suggest that catheter ablation also may be a cost-effective alternative in a less severely ill population.

Catheter ablation has become a reasonable alternative for VT patients, having proven to be both safe and effective. Fundamentally we believe its clinical role should be based on patient and physician assessments of safety and efficacy relative to alternative treatments. In today’s environment, however, cost also plays a role in treatment selection. Our analysis shows that, from a societal perspective, catheter ablation of VT is cost-effective in patients with impaired ventricular function and frequent ICD firings. Our results also suggest that further clinical research is warranted in patients with good ejection fraction who suffer their first VT episode.

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References


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