Use of a Screening Tool Improves Appropriate Referral to an Electrophysiologist for Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death

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Background—Despite data showing the benefits of implantable cardioverter-defibrillator (ICD) insertion for primary prevention in populations at risk for sudden death, professional society guidelines recommending primary prevention, and recognition by payers of the clinical value of ICDs in these populations, ICDs for primary prevention remain underused. We sought to determine whether implementing a screening tool would increase appropriate identification of patients showing clinical evidence of ICD benefit and prompt referral to an electrophysiologist for ICD implantation.

Methods and Results—Screening tools were affixed to medical records for patients seen in 2 outpatient cardiology offices that queried ejection fraction and whether referral to an electrophysiologist was made (N=6632). The number of appropriate referrals in the screening period were compared with analogous data collected before implementation of the screening tool (control period) through retrospective record review (n=3606). Significantly more eligible patients were offered referral during the screening period than during the control period at both sites, 80% (8/10 eligible) versus 33% (5/15) at site 1 (P<0.02) and 100% (44/44) versus 60% (21/35) at site 2 (P<0.001). Of all patients offered referral, 41% (32/78) accepted.

Conclusions—The use of a screening tool increases referral to electrophysiology for patients in whom placement of an ICD confers the benefit of sudden cardiac death primary prevention. Barriers to referral include both physician and patient factors. Verification of these findings on a larger scale as well as studies defining the foundation of these barriers may further improve use of ICDs in patients for whom their mortality benefit is well described. (Circ Cardiovasc Qual Outcomes. 2011;4:00-00.)

Key Words: implantable cardioverter-defibrillators • diagnosis • utilization • primary prevention

The benefit of implantable cardioverter-defibrillators (ICDs) for primary prophylaxis in patients at high risk of sudden cardiac death (SCD) is well established. Large trials have demonstrated that the ICD improves mortality in patients with decreased ejection fraction (EF) and congestive heart failure or a history of myocardial infarction. On the basis of these compelling studies, recent guidelines from the American College of Cardiology, American Heart Association, Heart Rhythm Society, and American Heart Failure Association recommend ICDs in patients with a depressed EF and heart failure or myocardial infarction, and the Centers for Medicare & Medicaid Services has approved reimbursement for ICD placement in patients meeting these clinical criteria.

However, despite data showing the benefits of primary prevention, professional society guidelines recommending primary prevention, and recognition by payers of the clinical value of ICDs in these populations, to what extent the use of ICDs for primary prevention has been incorporated into outpatient practice is unknown. Analyses of data from claims databases suggest that ICDs for prevention of SCD are underused. Hernandez et al analyzed more detailed data from the American Heart Association’s Get With the Guidelines Heart Failure quality improvement program, evaluating 59,965 discharges for patients with an EF <30% who had been hospitalized for heart failure, and found that of the 13,034 patients eligible for ICD placement, <40% received an ICD, confirming these previous claims-based reports of significant underutilization.

Studies of other recommended therapies, such as β-blockade in heart failure and antibiotics for endocarditis prophylaxis, have shown that the use of a clinical reminder can improve...
the implementation of guidelines into clinical practice.\textsuperscript{12,13} We sought to determine whether implementing a screening tool would increase appropriate identification of patients showing clinical evidence of ICD benefit for primary prevention of SCD and, further, prompt referral to an electrophysiologist for appropriate patients for discussion of implantation.

**WHAT IS KNOWN**
- Implantable cardioverter-defibrillators (ICDs) save lives in populations with defined clinical characteristics indicative of high risk for sudden cardiac death.
- However, research shows that ICDs are underused.

**WHAT THE STUDY ADDS**
- Use of a simple screening tool in a general cardiology office increases appropriate referral of patients to an electrophysiologist for consideration for ICD implantation.
- Patient refusal of ICD implantation is high.
- Large-scale studies of the benefits of a clinical reminder for ICD implantation in appropriate patients are needed.

**Methods**

**Study Design**
Medical records of scheduled outpatients in 2 cardiology practices were flagged with a screening tool. The screening tool queried whether EF was \( \leq 35\% \). If yes, the physician was asked whether the patient was referred to an electrophysiologist for ICD implantation. At site 1, a Yale cardiology faculty practice (New Haven, CT) outpatient site, the screening tools were used during September and October 2007. Site 2, a local private cardiology practice (N\&\O Cardiology Associates; Norwich, CT), participated from July 2009 through January 2010. All interventional and general cardiologists staffing each site were informed about the screening tool immediately before its institution and were not aware of the study until it began (with the exception of authors M. Remetz and JF). Medical record review was performed for all patients seen during the screening period to collect demographic and clinical data, to confirm the most recently measured EF, and to confirm whether a referral was made. The modalities by which EF had been clinically assessed included transthoracic echocardiography, nuclear imaging, and contrast left ventriculography. Patients eligible for referral to an electrophysiologist for primary prevention ICD implantation were defined as those with confirmed EF \( \leq 35\% \) with indications for primary prevention as outlined in the Centers for Medicare & Medicaid Services coverage decision of 2005\textsuperscript{5} who had not been previously evaluated by an electrophysiologist (with or without an ICD implanted) and were appropriate for referral. Inappropriateness for referral was defined as terminal illness, cognitive or psychiatric contraindication to a primary prevention ICD, or documented prior statement by the patient that invasive procedures were not desired. Patients undergoing appropriate work-up, such as coronary angiography or a repeat EF determination in a patient recently receiving a diagnosis of cardiomyopathy, also were considered inappropriate for referral at that time.

To determine baseline rates of referral for ICD evaluation in appropriate patients before initiation of the screening tool, a retrospective medical record review of patient visits during March and April 2007 at site 1 and August through November 2008 at site 2 (control periods) was performed to collect analogous data, including patients’ EF, and if \( \leq 35\% \), whether they were referred to an electrophysiologist, as well as demographic and clinical data. Baseline periods were chosen to avoid potential biasing of baseline rates by knowledge of the development of the study by the cardiology providers during the 2 to 3 months before its initiation.

At site 1, physician compliance with completing the screening tool also was collected. Accuracy of data entered by the physician was determined by comparison to data in the medical record.

**Statistical Analysis**
Comparison of referral and acceptance rates for electrophysiological evaluation for appropriate patients between control and screening periods was performed by Fisher exact test and for comparison of prior electrophysiological evaluation, by \( \chi^2 \) analysis. For comparison of referral and acceptance rates between men and women, data from the 2 sites and from control and screening periods were combined. Sensitivity and specificity of the screening tool for identification of patients with EF \( \leq 35\% \) compared with the medical record was determined (tools left blank were counted as a no response). Statistical analyses were performed with JMP version 5.0.1 software (SAS Institute; Cary, NC). The study was approved by the Yale Human Investigation Committee.

**Results**

**Referral for Electrophysiology Evaluation of Eligible Patients**
As shown in Table 1 among patients with EF \( \leq 35\% \), during the control period, fewer patients had been seen by an electrophysiologist for consultation before the index visit compared with the screening period at site 1 (49\% versus 71\%; \( P<0.02 \)) but not at site 2. Among eligible patients not previously evaluated by an electrophysiologist, 6\% to 14\% of patients in the control period and 8\% to 9\% in the screening period were undergoing appropriate work-up, and 5\% to 14\% and 0\% to 2\% in control and screening periods, respectively, were not appropriate for ICD implantation. Thus, at site 1, there were 15 patients in the control period and 10 in the screening period eligible for referral, and at site 2, 35 patients in the control period and 44 in the screening period were eligible for referral. Significantly more of these eligible patients were offered referral during the screening period than during the control period (site 1, 80\% versus 33\%; \( P<0.02 \); site 2, 100\% versus 60\%; \( P<0.001 \)). Overall acceptance rate for those offered referral was 41\% and did not differ based on screening tool use.

**Use and Accuracy of the Screening Tool**
At site 1, 38\% of screening tools were left blank (Table 2). Sensitivity of the tool for identification of patients with EF \( \leq 35\% \) was 58\% and specificity, 99\%. Of the 55 total patients in whom medical record review revealed an EF \( \leq 35\% \), 21 of the screening tools had been left blank, although 1 patient was referred to an electrophysiologist at the visit regardless, and on 2 screening tools, there were noted EFs >35\% when the EF was determined to be \( \leq 35\% \) on medical record review.

**Sex Rates of Electrophysiology Referral and Acceptance**
As shown in Table 3, there was no significant difference in the percentages of eligible men and women who had been evaluated previously by an electrophysiologist before the index visit. Additionally, there was no difference in the
number of eligible men and women who were offered a referral and no significant difference in the number of men and women who accepted the referral.

**Discussion**

The present study demonstrates that at 2 cardiology outpatient practices (1 academic, 1 private), use of a screening tool increased referral of patients with clinical evidence of benefit from a primary prevention ICD to an electrophysiologist for device implantation, although compliance with and accuracy in completing the tool were imperfect. Among patients offered a referral, less than one half chose to pursue the possibility of ICD implantation at either site.

Prior studies have shown that ICDs for primary prevention are underused9–11 despite definitive evidence of benefit in selected patients1–4 and guidelines recommending their use in appropriate populations.5,6 To our knowledge, the present study is the first to evaluate use of ICDs for primary prevention in the real-life setting of an outpatient cardiology office, as prior studies reporting utilization rates were based on hospital discharge databases.9–11 The offices at which the study occurred demonstrated control utilization rates of 33% and 60%, already above the averages reported in the large discharge database studies. This finding may reflect improved implementation of guidelines possibly as a result of the literature reflecting underuse. Site 2 had greater use during the control period, which was 1 year later than site 1, also suggesting dissemination of guidelines into practice. The use of a screening tool further increased appropriate referral at both sites, as has been shown for the use of other recommended therapies, such as β-blockers for patients with heart failure.13

### Possible Barriers to Appropriate Referral

That the screening tool was associated with increased referral suggests that 1 barrier to appropriate referral may be physician understanding and recollection of the importance of ICD therapy for primary prevention. Of interest, the sensitivity of the filled-out form was low, implying that the actual completion of the screening tool appears not to be the necessary step; rather, having the screening tool present as a reminder may be adequate.

Even with the screening tool, several barriers to referral at both the physician and the patient level were identified. The screening tool was not always completed accurately, and lack of physician awareness of patient EF may hinder recognition of patients who may benefit from an ICD. Another barrier to use may be patient willingness to undergo evaluation, demonstrated by the number of patients declining referral. Possible explanations for this finding may include misunderstanding of a technologically advanced intervention, media coverage of some of the recalls associated with ICDs, or fear of defibrillation, among others. Additionally, it is unknown whether these general cardiologists’ introduction of the ICD to patients maximally encouraged compliance with the recommendation. Further research is needed to delineate these barriers. Campaigns to increase awareness of the benefits of ICDs for appropriate patients aimed at both physicians and the public could perhaps increase appropriate use of this life-saving therapy.

### Potential Clinical Impact

The numbers of total patients meeting criteria for ICD benefit in any one general cardiology practice is not high, and a large

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**Table 1. Referral for ICD in Patients With EF ≤35%**

<table>
<thead>
<tr>
<th></th>
<th>Site 1</th>
<th></th>
<th>Site 2</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Period</td>
<td>Screening Period</td>
<td></td>
<td>Baseline Period</td>
</tr>
<tr>
<td>Total visits</td>
<td>846</td>
<td>646</td>
<td></td>
<td>2760</td>
</tr>
<tr>
<td>No. with EF ≤35%</td>
<td>59</td>
<td>55</td>
<td></td>
<td>183</td>
</tr>
<tr>
<td>Already seen by EP</td>
<td>28 (47)</td>
<td>39 (71)</td>
<td>&lt;0.02</td>
<td>127 (69)</td>
</tr>
<tr>
<td>Ongoing work-up*</td>
<td>8 (14)</td>
<td>5 (9)</td>
<td></td>
<td>11 (6)</td>
</tr>
<tr>
<td>Not appropriate for ICD*</td>
<td>8 (14)</td>
<td>1 (2)</td>
<td></td>
<td>10 (5)</td>
</tr>
<tr>
<td>Eligible for referral</td>
<td>15 (25)</td>
<td>10 (18)</td>
<td></td>
<td>35 (19)</td>
</tr>
<tr>
<td>Offered referral (% of eligible)</td>
<td>5 (33)</td>
<td>8 (80)</td>
<td>&lt;0.05</td>
<td>21 (60)</td>
</tr>
<tr>
<td>Accepted (% of offered)</td>
<td>3 (60)</td>
<td>3 (38)</td>
<td>0.59</td>
<td>6 (28)</td>
</tr>
</tbody>
</table>

Data are presented as no. (%), unless otherwise indicated. EP indicates electrophysiologist.

*Defined in text.

**Table 2. Screening Tool Use (Performed at Site 1)**

<table>
<thead>
<tr>
<th>Answers to “EF ≤35%?”</th>
<th>Confirmed by Medical Record Review as ≤35%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>646</td>
</tr>
<tr>
<td>Yes</td>
<td>37</td>
</tr>
<tr>
<td>No</td>
<td>346</td>
</tr>
<tr>
<td>Left blank</td>
<td>249</td>
</tr>
<tr>
<td>Unknown</td>
<td>14</td>
</tr>
</tbody>
</table>

*Not documented in medical record.

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**Table 3. Referral for ICD, Sex Breakdown (EF ≤35%)**

<table>
<thead>
<tr>
<th></th>
<th>Men</th>
<th>Women</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible for referral</td>
<td>75</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Offered referral (% of eligible)</td>
<td>56 (75)</td>
<td>22 (76)</td>
<td>1.0</td>
</tr>
<tr>
<td>Accepted (% of referred)</td>
<td>24 (43)</td>
<td>8 (36)</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Data are presented as no. (%), unless otherwise indicated.
number of patients are needed to be screened to identify those who would benefit from ICD implantation. However, as described by Myerburg et al., epidemiological studies of SCD reveal an inverse relationship between the incidence of SCD in a risk-factor-defined population and the numbers of total SCDs contributed by that group. Those at highest risk (survivors of prior arrest) make up the smallest total numbers; and the population of patients at moderate risk, such as Sudden Cardiac Death in Heart Failure Trial-type patients, is intermediate in its contribution to total SCD. Thus, targeting these moderate-risk patients, such as those seen in a general cardiology practice, by the use of a very simple reminder may have important public health implications. As seen in our data, the filling out of the form did not seem to be the crucial component; rather, the visual reminder may have improved appropriate referrals. Incorporation of more-sophisticated screening tools for practices with electronic medical records systems may further improve identification of patients at risk for SCD. Whether large-scale screening in cardiology practices using an even-simpler reminder than the form in this study may similarly improve referral of appropriate patients for ICD requires further study.

Sex and ICD Use

Previous studies have shown that women are less likely than men to receive an ICD if indicated, even after controlling for clinical differences. Studies of other cardiac procedures have suggested that physicians may be less likely to suggest invasive procedures to women. In our study, however, no difference in physician referral patterns between men and women was seen. There also were no significant differences in acceptance rates for ICD between men and women, although the numbers of women were small. One prior study has shown that women refuse cardiac catheterization more frequently than men, but the absolute difference was very small at <1%. Further investigation is needed to determine whether patient preferences underlie differences in ICD use in women as previously reported.

Limitations

Limitations of the study include its small size, and these data should be viewed as hypothesis generating. Additionally, we cannot exclude the possibility of observation bias because the knowledge of the study rather than of the screening tool itself may have altered physician behavior. Further, documentation of heart failure class or exercise tolerance was inadequate, and whether some patients not offered an ICD had class IV congestive heart failure precluding benefit cannot be determined.

Future Directions

The efficacy of a screening tool shown in our small population needs to be replicated in larger populations in multiple centers. Additionally, an unexpected finding was the number of patients declining referral to an electrophysiologist. Qualitative investigation of their reasons for declension may provide further information on barriers to implementing these life-saving guidelines. Further analysis of physician barriers also is needed.

Conclusions

The use of a screening tool increases referral to an electrophysiologist for patients in whom placement of an ICD confers the benefit of SCD primary prevention. Barriers to referral include both physician and patient factors. Verification of these findings on a larger scale as well as studies defining the foundation of these barriers may further improve use of ICDs in patients for whom their mortality benefit is well described.

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None.

Disclosures

Dr Lampert has received significant research funding from Boston Scientific, Medtronic, and St Jude Medical for an unrelated study and modest speaking fees from Medtronic and Boston Scientific on unrelated topics.

References


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