Clinical Reminders to Providers of Patients with Reduced Left Ventricular Ejection Fraction Increase Defibrillator Referral:

A Randomized Trial

Gupta et al: Reminders to Providers of Patients with Reduced Ejection Fraction Increase Defibrillator Referral

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DOI: 10.1161/CIRCHEARTFAILURE.113.000753

Journal Subject Codes: Ethics and policy [100] Health policy and outcome research; Heart Failure: [110] Congestive
Abstract

Background—Many patients who are candidates for defibrillators (ICDs) are not referred for potential implantation. We sought to determine if a simple provider reminder would increase referrals.

Methods and Results—We identified consecutive patients from 1/2007 through 7/2010 in the VA Palo Alto Healthcare System with a left ventricular ejection fraction (LVEF) below 35% on echocardiography. Patients were excluded using available administrative data only (no chart review) if they were known to have an ICD, if they were ≥ 80 years old, or if they did not have a current primary care or cardiology provider within the system. We randomized patients to no intervention or a clinical note to the provider in the medical record. The outcomes were referral for consideration of defibrillator implantation (primary) and documented discussion (secondary). Of 330 patients with LVEF ≤ 35%, 128 patients were known to have an ICD, 85 were no longer followed in the healthcare system, and 28 were ≥ 80 years old, leaving 89 patients to be randomized. 46 patients were randomized to intervention and 43 to control. Eleven of 46 (24%) intervention patients were referred for consideration of ICD implantation during the following six months versus 1 of 43 (2%) control patients ($p=0.004$). Overall, 31 of 46 (67%) intervention patients versus 19 of 43 (44%) control patients had documentation discussing potential candidacy for defibrillators ($p=0.05$).

Conclusions—In patients with low LVEF, a simple electronic medical record-based intervention directed to their providers improved the rates of referral for ICD implantation.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01217827.

Key Words: defibrillator, sudden cardiac death, reminder systems, randomized controlled trial, guideline adherence
Randomized clinical trials have demonstrated that implantable cardioverter defibrillators (ICDs) reduce all cause mortality in select primary prevention populations.(1-4) Reduced left ventricular ejection fraction (LVEF) remains the most widely used criterion for identifying patients at high risk for sudden cardiac death in these trials and for selecting potential candidates for ICDs.(5) However, ICD therapy has been underutilized even though it has been shown to prolong survival in select patients with reduced LVEF. Specifically, implantation rates of ICDs, with or without cardiac resynchronization therapy (CRT), in eligible candidates without contraindications or documented reasons for non-referral, are estimated to be only approximately between 35% to 51%.(6-12) Optimal implementation of evidence-based, guideline-recommended ICD therapy into clinical practice may potentially translate into substantial prevention of heart failure deaths.(12)

Clinical reminders prompting health care providers to address quality of care metrics, represent one strategy for improving implementation of guideline-recommended therapies.(13-14) We have previously shown in randomized trials that clinical reminders attached to echocardiography reports lead to increased adherence to treatments known to prolong survival in individuals with heart failure, namely ACE inhibitors and beta-blockers.(15-17) The purpose of our study was to determine if a simple clinical reminder directed to the providers’ of potentially eligible patients for ICD via the electronic medical record system would increase appropriate referral for ICD implantation.
Methods

Patients

We identified all echocardiograms obtained from January 2007 through July 2010 at the VA Palo Alto Healthcare System (VAPAHCS). We identified consecutive patients with LVEF ≤ 35%. If a patient had more than one echocardiogram during this period, we used data from the most recent echocardiogram. We excluded patients if they already had a defibrillator (using local records), if they were ≥ 80 years old, or if they did not have a primary care physician or cardiologist at the VAPAHCS. We elected to employ an age cut-off in our trial to limit submission of reminders for patients who were unlikely to be ICD candidates due to competing co-morbidities or a shortened life expectancy. In addition, this age group is minimally represented in primary prevention trials establishing the benefit of ICDs.(1-4)

Study Protocol and Intervention

Patients meeting the study criteria were randomized with a computerized random-number generator to no intervention (control) or intervention (reminder), which consisted of a clinical reminder stating potential eligibility for an ICD. The reminder (Appendix A) was a standardized note that a) noted the patient’s potential eligibility for ICD; b) listed specific potential exclusion criteria for ICD therapy; and c) explicitly listed the method for patient referral for an ICD using the electronic medical record (EMR). Options suggested included referral to cardiology clinic, electrophysiology clinic, or directly to the electrophysiology laboratory. The reminder further requested (but did not require that) the physician addend their intended action, by indicating the specific reason for non-referral or planned referral action from the aforementioned list of options.

The reminder was directly incorporated into each intervention patient’s permanent EMR. In addition, notification that the reminder was inserted into the EMR was sent to the patient's
primary provider and/or cardiologist (if also followed in a facility cardiology clinic) for their signature indicating they had reviewed the reminder. Such notifications appear each time a provider opens the EMR system to access the care of any patient. Notification for co-signature is removed by either going to the reminder and co-signing the note or deleting the request for co-signature. In all cases, the reminder remained in the patient's EMR. The institutional review board at Stanford University approved the protocol. The trial was registered with clinicaltrials.gov: NCT01217827.

Baseline data were collected from records to describe the population that included prior diagnoses and VA prescriptions (non-VA prescriptions were not available).

**Outcome Data**

Six months after randomization, a trained adjudicator (PG) reviewed all patients’ EMRs to determine if defibrillator implantation was addressed. The primary outcome was referral for consideration of defibrillator implantation within six months of randomization, defined as an encounter by a cardiac electrophysiologist in which ICD consideration was documented as part of the evaluation. The secondary outcome was documentation of a discussion of ICD candidacy. We could not completely blind the outcome data abstractor to the randomization group of each patient since the reminder note was part of the medical record. For this reason, we confirmed the abstractor’s findings with a second reviewer. At a mean follow up of two years we determined survival and reviewed the patient’s medical record for cause of death (post-hoc analysis). We used the provider’s documented cause of death if death occurred in the hospital. If the death occurred elsewhere (another hospital, outpatient or unclear) we labeled it as unknown unless recent clinic notes indicated the patient was end-stage in their disease (e.g. NYHA class IV, metastatic cancer).
**Statistical Analysis**

All patients randomized to the intervention received the clinical reminder. An intention to treat analysis was used for all outcomes. Thus, all patients were included in the analysis even if they did not have a clinic visit with their provider during the six month follow-up period. We used t tests to compare continuous variables, chi-square tests (with Yates correction for continuity) to compare categorical variables with cell values > 5 and Fisher’s Exact Test to compare categorical variables with cell values ≤ 5. Survival was displayed using Kaplan-Meier graphs and the log-rank statistic was used to compare differences between the two randomized groups. The study was designed to have at least 80% power (α error=0.05) to detect a 20% absolute increase in defibrillator referral. We planned to randomize approximately 90 patients. All analyses were performed with STATA® version 10 (Statutory LP, College Station, TX). All significance tests were 2 sided. A p value of less than 0.05 was considered statistically significant.

The authors had full access to and take responsibility for the integrity of the data. All authors have read and agree to the manuscript as written. The funding sources had no role in the design, analysis or reporting of the study or in the decision to submit the manuscript for publication.

**Results**

We identified 330 patients with LVEF ≤ 35% over 3.5 years as shown in Figure 1. Patient characteristics and medication use were similar for the two randomized groups. Per our initial review, 128 patients already had an ICD, 85 were no longer followed at the VA Palo Alto
Healthcare System, and 28 were ≥ 80 years old, leaving 89 patients to be randomized. There were 46 patients randomized to the reminder and 43 to control (Figure 1).

The mean age of the patients was 65 ± 7 years, 97% were male, and the mean left ventricular ejection fraction was 27% ± 4%. Co-management with a facility cardiologist was ongoing at the time of randomization in 67% of patients and 4% of patients were co-managed by both a non-facility cardiologist and a facility cardiologist (Table 1). All differences at baseline between the reminder and the control groups were not statistically significant (p > 0.05). A prior discussion regarding an ICD was noted in 31 of 89 randomized patients (35%) following additional detailed chart review. The provider electronically acknowledged receipt of the reminder in 44 of 46 cases (96%).

Outcomes

By the end of the six months of follow-up following randomization, 11 of 46 (24%) reminder patients met the primary outcome (referral for ICD evaluation), compared to 1 of 43 (2%) control patients (p = 0.004) (Figure 2). A cardiac electrophysiologist’s evaluation was completed and an ICD implanted within six months of randomization in four reminder patients compared to no control patients. The secondary outcome, documentation of an ICD discussion, was met in 31 of 46 (67%) intervention patients versus 19 of 43 (44%) control patients (p = 0.05).

Detailed six-month outcome data are shown in Table 2. Overall, five patients died (1 reminder, 4 control) without prior ICD discussion, three patients had already been referred for an ICD despite initial screen (2 reminder, 1 control), 24 patients were deemed not to be a candidate by the provider (11 reminder, 13 control), 11 patients refused an ICD (7 reminder, 4 control), and an ICD was not addressed in 34 patients (14 reminder, 20 control). Three patients in the reminder group and 5 in the control group did not have documented contact with their provider during the
six month follow-up period. All differences in secondary outcomes between the reminder and the control groups were not statistically significant (p>0.05). In the 24 patients deemed not to be a candidate for ICD by the provider, 15 (17% of all 89 patients) were still undergoing medication optimization (8 reminder, 7 control), five (6%) had a repeat LVEF above 35% (1 reminder, 4 control), and four (4%) did not have expected survival with good functional status for at least one year (2 reminder, 2 control).

By two years following the reminder, 7 of the 12 referred for an ICD had the ICD placed (two of these outside of the VA system). For those five not implanted the reasons were development of NYHA class IV symptoms, improvement in LVEF to more than 40%, patient refusal, technical difficulties expected with implantation, and unclear in one.

Long-term survival is shown in Figure 3. During a mean follow-up of 2 years there were 26 deaths (17 in the control group and 9 in the reminder group). Patients randomized to the reminder had a slightly better survival over next 2 years than those not receiving a reminder in their medical record (p=0.03). Cause of death for the control arm was heart failure in 17, cancer in 3, other in 2, and unknown in 9 (2 at outside hospitals and 7 at unknown locations, all unexpected based on prior history). For the reminder group it was heart failure in 2, cancer in 2, other in 2 and unknown in 3 (all 3 at unknown locations and unexpected based on prior history). Two of the deaths occurred in patients with a prior ICD (both inpatient heart failure).

**Analysis Limited to Those without Known Prior ICD Discussion**

There were 15 patients (17%) where the provider reported there was a discussion regarding ICDs prior to our sending the reminder (10 reminder, 5 control). With these 15 excluded, 9 of 36 in the reminder group were referred for possible ICD implantation compared to 1 of 38 without a reminder (p=0.006).
Predictors of Referral

Sixty seven percent of patients in both the reminder and the control groups were co-managed by a cardiologist in this trial. Seventeen percent of patients were referred for ICD if co-managed with cardiologist(s) as compared to 7% of patients managed only by primary care provider \((p=0.2)\). Prior ICD discussion was associated with a non-significant trend for more referrals for ICD evaluation (19% if prior discussion versus 10% if no prior discussion; \(p=0.2\)). Age, sex and baseline ejection fraction were also not associated with referral for an ICD.

Discussion

This randomized trial demonstrated that an EMR-based clinical reminder to providers of patients with reduced LVEF improves the rates of referral for consideration of primary prevention ICD implantation.

Multiple strategies to overcome low utilization of ICDs in eligible candidates have been considered.\(^{(18)}\) Recently, participation in performance improvement registries has shown efficacy in improving adherence with guideline-recommended therapies, including ICD therapy.\(^{(19)}\) However, improving dissemination strategies for ICDs remains critical. A broad systematic review conducted by the National Institute for Health Research’s Health Technology Assessment Program in 2004 that analyzed diverse randomized trials involving healthcare guideline dissemination and implementation strategies, suggested modest benefit with reminders.\(^{(20)}\) Specifically, the authors reported a modest improvement in performance across interventions of 14.1% in 14 cluster randomized comparisons for reminders, 8.1% in 4 cluster randomized comparisons of dissemination of educational materials, 7.0% in 5 cluster randomized comparisons of audit and feedback, and 6% in 13 cluster randomized comparisons of
multifaceted interventions involving educational outreach. Our results are consistent with these estimates.

We have previously shown that clinical reminders are effective in improving heart failure care.(15-17) One trial randomized 1546 consecutive patients with reduced LVEF to a reminder of beta-blockers or no reminder. 74% of patients randomized to reminder received beta-blocker prescription compared with 66% of patients (p=0.002) not receiving the reminder.(17) The reminder was estimated to be highly cost-effective compared with other accepted medical interventions. Per a follow-up survey, the reminder was recalled by 76% of physicians and viewed favorably with a recommendation for continuation by 85%. (17) Our ICD reminder was more intensive in that a notification of the reminder was sent to a provider. This may explain the greater relative increase in management change with the ICD reminder compared to the more passive reminder placed in the echocardiography report.

Developing an effective reminder system for device-based therapies poses several unique challenges. Defibrillator therapy, as opposed to medication use, has more complex indications, is more invasive, and has more risks to the patients, including procedural risks and inappropriate shocks. (21-23). Unlike medications, ICD consideration requires most providers to whom the reminder is directed refer the patient to a specialist as opposed to initiating therapy on her own. To overcome some of these potential barriers, our reminder included directions for referral and explicit response options including reasons for non-referral. Further, it should be noted that our electronic reminder required that the provider either acknowledge that the reminder was received or delete the request for acknowledgement. This "active interaction" was associated with a 96% provider acknowledgement rate, and may be an important part of the reminder's effectiveness.
We designed this intervention with the goal of creating a low-cost and simple system that could easily be incorporated into clinical practice and EMR workflow. A strength of our study was that candidates for the intervention (namely, individual <80 years with LVEF $\geq$ 35%, no record of ICD placement, and no follow-up at our facility) could be determined electronically without chart review. This makes the intervention easy to implement at any facility with an EMR with searchable databases. It is directly applicable to all the 1100+ clinics and hospitals within the VA health care system since they use the same electronic medical record. Chart review was not performed to select patients, thus several already had a discussion regarding ICDs. However, we found that the reminder led to a change in opinion regarding ICD placement. This may have occurred because the patients’ clinical status changed or the views of risk and harm from an ICD changed.

Another potential benefit of the reminder was an increase in the documentation of a discussion regarding an ICD placement. Such documentation is a new performance measure of the American College of Cardiology, American Heart Association, and American Medical Association Physician Consortium for Performance Improvement (24). We found that 70% of intervention patients versus 51% of control patients had documentation discussing potential candidacy for defibrillators at six months after the reminder. While this did not reach statistical significance ($p=0.09$), it is likely the reminder prompted the provider to write a note based on prior discussions or to have a new discussion with the patient. The reminder also provides an educational opportunity to providers regarding who is and is not an ICD candidate, which could lead to sustained high levels of documentation regarding ICD discussion.

There are several potential limitations of the study. Our analysis involved predominantly males, which may limit the generalizability of these findings. This study was not powered for the
endpoint of actual defibrillator implantation, although we believe that defibrillator evaluation rather than implantation is a more meaningful endpoint in the context of patient-centered care. Thus, larger studies in other care settings are needed to confirm the findings. We excluded patients over age 80 years even though some of these patients may be appropriate ICD candidates. Since the reminder note was part of the medical record we could not completely
blind the outcome data abstractors to the randomization group. While there was a small observed survival benefit with the reminder the difference was borderline significant and larger studies are needed to confirm this finding. Finally, the reminder benefit we observed may be an underestimate if significant contamination occurred where a provider had patients in both control and intervention groups and a reminder for one patient altered her care for other patients.

In summary, a simple electronic medical record-based intervention routed to the patient's provider(s) increased the rate of referral for an ICD. Specifically, in our study, approximately 22 additional patients were referred for ICD consideration for every 100 reminders sent. Importantly, patient's can be identified electronically allowing for low-cost implementation at any facility with an electronic medical record.

APPENDIX A

ICD CANDIDACY REVIEW NOTE
The patient may be a candidate for defibrillator (ICD) therapy due to a low left ventricular ejection fraction $\leq 35\%$ and no VA records of a prior defibrillator.

If you would like to consider your patient for possible ICD, options include:
A) referral to cardiac electrophysiology clinic (recommended) ["Outpatient Orders" $\rightarrow$ "Consult" $\rightarrow$ "Cardiology EP/Arrhythmia Clinic Consult Palo Alto"].
B) referral to cardiology clinic : ["Outpatient Orders" $\rightarrow$ "Consult" $\rightarrow$ "Cardiology Outpt Clinic/Pad"]
C) direct referral for defibrillator implantation ["Outpatient Orders" $\rightarrow$ "Procedure" $\rightarrow$ "Palo Alto" $\rightarrow$ "Electrophysiology"]
Not all individuals are appropriate candidates for defibrillator therapy referral. Potential responses for non-referral are listed below. You may respond via an addendum to this note with any of these reasons for non-referral.

1) The patient already has a defibrillator.
2) Other physicians manage the patient's cardiac disease.
3) More information is needed to determine candidacy for defibrillator (including patient preference)
4) This patient is not an appropriate candidate for defibrillator because:
   4A) The patient refused.
   4B) The patient does not have a reasonable expectation of survival with good functional status for approximately more than 1 year.
   4C) The patient is NYHA Class IV with drug-refractory CHF and is not a candidate for cardiac transplantation or cardiac resynchronization therapy.
   4D) The patient has significant psychiatric illness that may be aggravated by device implantation or that may preclude systematic follow-up.
   4E) The patient has potential for improvement in his cardiac function, for example due to active medical therapy optimization and/or planned intervention/ revascularization procedure.
   4F) The patient is asymptomatic (NYHA Class I) with nonischemic cardiomyopathy.
   4G) The most recent LVEF is >35%.

Sources of Funding

Partially supported by a Medtronic External Research Grant. Dr. Turakhia is supported by a Veterans Health Services Research & Development Career Development Award (CDA09027-1) and an American Heart Association National Scientist Development Grant (09SDG2250647). Partially supported by the VA Chronic Heart Failure Quality Enhancement Research Initiative (04-326).

Disclosures

Anurag Gupta: None; Parisa Gholami: None; Mintu P. Turakhia Research grant from Medtronic > $10,000, Consultant for Medtronic, St Jude Medical , and Boston Scientific each < $10,000;
Karen Friday: None; Paul A. Heidenreich: None.
Disclaimer

The content is solely the responsibility of the authors and does not necessarily represent the official views of the Department of Veterans Affairs.

References

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Table 1. Baseline characteristics of the study population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Reminder</th>
<th>Control</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>46</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Age, y (mean ± SD)</td>
<td>66 ± 8</td>
<td>64 ± 8</td>
<td>0.24</td>
</tr>
<tr>
<td>Male (%)</td>
<td>43 (93)</td>
<td>43 (100)</td>
<td>0.24</td>
</tr>
<tr>
<td>Left ventricular ejection fraction % (mean ± SD)</td>
<td>27 ± 4</td>
<td>26 ± 4</td>
<td>0.36</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>39 (85)</td>
<td>36 (84)</td>
<td>0.89</td>
</tr>
<tr>
<td>Diabetes mellitus (%)</td>
<td>26 (57)</td>
<td>22 (51)</td>
<td>0.61</td>
</tr>
<tr>
<td>Ischemic heart disease (%)</td>
<td>24 (52)</td>
<td>27 (63)</td>
<td>0.31</td>
</tr>
<tr>
<td>Diagnosis of renal disease (%)</td>
<td>11 (24)</td>
<td>16 (37)</td>
<td>0.17</td>
</tr>
<tr>
<td>Medications (VA Prescription in prior 6 months)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommended beta-blocker (carvedilol, metoprolol</td>
<td>24 (52)</td>
<td>21 (49)</td>
<td>0.58</td>
</tr>
<tr>
<td>succinate or bisoprolol)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiotensin converting enzyme inhibitor</td>
<td>17 (37)</td>
<td>14 (33)</td>
<td>0.75</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>6 (13)</td>
<td>4 (9)</td>
<td>0.58</td>
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<tr>
<td>Co-management with facility cardiologist (%)</td>
<td>31 (67)</td>
<td>29 (67)</td>
<td>0.82</td>
</tr>
<tr>
<td>Co-management with both facility and non-facility</td>
<td>1 (2)</td>
<td>3 (7)</td>
<td>0.35</td>
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<tr>
<td>cardiologist (%)</td>
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</table>

SD= standard deviation
Table 2. Six-Month Outcomes Following Reminder of ICD Candidacy

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Reminder</th>
<th>Control</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referred for an ICD, primary outcome N (%)*</td>
<td>11 (24)</td>
<td>1 (2)</td>
<td>0.004</td>
</tr>
<tr>
<td>Evidence of ICD discussion, secondary outcome N (%)</td>
<td>31 (67)</td>
<td>19 (44)</td>
<td>0.05</td>
</tr>
<tr>
<td>Non-referral following discussion N (X)</td>
<td>20 (43)</td>
<td>18 (42)</td>
<td></td>
</tr>
<tr>
<td>Already had ICD N (%)</td>
<td>2 (4)</td>
<td>1 (2)</td>
<td></td>
</tr>
<tr>
<td>Not an ICD candidate N (%)</td>
<td>11 (24)</td>
<td>13 (30)</td>
<td></td>
</tr>
<tr>
<td>Refused ICD N (%)</td>
<td>7 (15)</td>
<td>4 (9)</td>
<td></td>
</tr>
<tr>
<td>No evidence of Discussion N (%)</td>
<td>15 (33)</td>
<td>24 (56)</td>
<td></td>
</tr>
<tr>
<td>Died without discussion N (%)</td>
<td>1 (2)</td>
<td>4 (9)</td>
<td></td>
</tr>
<tr>
<td>Survived without discussion N (%)</td>
<td>14 (30)</td>
<td>20 (47)</td>
<td></td>
</tr>
</tbody>
</table>

ICD=implantable cardioverter defibrillator

* percent of total. Referral occurred in 11/31 (35%) of those with a discussion in the reminder group compared to 1/19 (5%) in the control group (p=0.02).
Figure Legends

Figure 1. Flow of study participants through the trial including exclusions is displayed. At the time of analysis there was documentation of a pre-randomization ICD discussion in 10 in the intervention and 5 in the control arm. However, all patients were analyzed with an intention to treat design.

Figure 2. Primary outcome (referral for ICD consideration) at 6 months following randomization is displayed along with the secondary outcome of documentation of an ICD discussion (before or after randomization). The difference was statistically significant in referral (p=0.004) and borderline for discussion (p=0.05).

Figure 3. Survival following randomization. There were 26 deaths (17 control group, 9 reminder) during long-term follow-up. Survival was slightly better for those randomized to the reminder (p=0.03).
Figure 1

330 with LVEF <=35%

89 randomized

46 reminder

46 analyzed for primary outcome
Prior ICD discussion in 10

43 control

43 analyzed for primary outcome
Prior ICD discussion in 5

241 Excluded
128 known prior ICD
85 no longer followed in healthcare system
28 > 89 years old
Figure 2

![Bar chart showing intervention and control groups for ICD referral and discussion.](http://circheartfailure.ahajournals.org/)
Figure 3

The figure shows the survival rate over days post randomization for participants with and without reminders. The graph compares the survival rates of two groups: Reminder and No Reminder. The survival rates are plotted against the number of days post randomization. The table at the bottom lists the number of participants at risk for each group at different time points: 46 for the Reminder group and 43 for the No Reminder group, with corresponding numbers of participants remaining at risk: 45, 42, and 41 for the Reminder group, and 39, 34, and 29 for the No Reminder group. The p-value is 0.03, indicating a statistically significant difference between the groups.
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Circ Heart Fail. published online December 6, 2013;
Circulation: Heart Failure is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 1941-3289. Online ISSN: 1941-3297

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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Data Supplement (unedited) at:
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