Characteristics of patients and implantable defibrillators associated with failure to sense device alert systems

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Aims
In the era of increasing implantable cardioverter defibrillator (ICD) complexity, the ICD patient alert is deemed to be an important feature in the early detection of ICD system malfunction and is either an audible or a vibratory alert. We sought to evaluate the patient’s ability to detect these ICD alerts in the device clinic setting as a surrogate endpoint of clinical utility.

Methods and results
From 1 November 2006 to 31 March 2008, 563 patients with an ICD equipped with either an audible patient alert (APA, Medtronic and Guidant; n = 485) or a vibratory monitoring alert (VMA, St Jude Medical; n = 78) had their alarm demonstrated in the quiet clinic setting. The ability to recognize the alert was analysed and then stratified by gender, age, manufacturer, type of alert, and pocket location. The average patient age was 63.3 (± 13.6) years and 82.8% of patients were male. Implantable cardioverter defibrillator manufacturers were Medtronic (n = 464), Boston Scientific (n = 21), and SJM (n = 78). The APA was heard in 86.0% of patients. This was less likely in patients who were older, male, and where the device was placed in the submuscular position. Every patient with a VMA sensed their alert.

Conclusion
In the current ICD alert technology, the ability to sense the ICD alert in the device clinic appears to be higher for the VMA than for the APA. In particular, older patients and male patients are less likely to sense the APA.

Keywords
ICD • Lead dysfunction • Advisory

Introduction
With the ever-expanding indications for implantable cardioverter defibrillators (ICDs) and their increased complexity, device system malfunction is commonly seen in the device clinic.1–3 As such, device manufacturers have developed patient-warning systems to alert patients to early device and lead malfunction. These alerts have been shown to reduce the time to presentation following device malfunction and, as such, may reduce the morbidity associated with device malfunction.4 The method of alert is either an audible tone (Medtronic or Boston Scientific) or a vibratory alarm [St. Jude Medical (SJM)]. Previous investigators have shown that the ability of the patient to hear the Patient Alert™, the audible tone featured on the Medtronic devices, decreases with age.5 To our knowledge, a comparison of the ability of patients to sense different alerts (audible vs. vibratory) is unknown.

The objective of the present study was to assess the patient’s ability to sense both the audible patient alert (APA) and vibratory monitoring alarm (VMA) by using the clinic setting as a surrogate for that of the outpatient setting.

Methods
Patients seen in the device clinic for routine follow-up between 1 November 2006 to 31 March 2008 and who had either an APA or a VMA were prospectively included. At our centre, three manufacturers supply devices that contain a patient alert. The Medtronic and Boston Scientific devices included have an APA, and the SJM devices have a
VMA. The APA that is featured with the Medtronic defibrillators is either a high-frequency (1260–1499 Hz) alert or a low-frequency (819–1170 Hz) alert. Although both of these can be demonstrated in the clinic, high-frequency tone is that which was tested in this study. These alerts are triggered if the lead impedance is out of range, the battery is at elective replacement indicator (ERI), the charge time is excessive, or if all therapies in a zone have been delivered (personal communication: Medtronic Technical Services; 16 November 2009). The APA emitted from the Boston Scientific devices is a 1778 ± 10 Hz alert that is emitted for 100 ± 6 ms and is designed to be 60 dB at a distance of 3 in. This alert is identical to that which is emitted in the case of device ERI (personal communication: Boston Scientific Technical Services; 16 November 2009). The VMA (SJM) is a 150 Hz vibratory stimulus, which can be programmed on or off. The vibration duration is programmable from 2 to 16 s (the default duration is 6 s). This alert is triggered when the device is at ERI, if the charge time limit is reached, if the device hardware or software has been reset, or if the lead impedance is out of range (personal communication: SJM Technical Services; 4 December 2009).

Each of these alerts can be demonstrated for patients in the quiet clinic setting. In this study, each patient was warned that their alert was going to be demonstrated, and that they would be asked if they could sense it. It was then demonstrated. During this demonstration, the audibel tone is emitted for 5 s and the vibratory alert for 6 s as per their default programmed durations. This method was performed as per a pre-defined protocol and was performed only on one occasion in each patient. The ability to sense the alert was documented and stratified by pre-specified subgroups, including gender, age, manufacturer, type of alert (APA vs. VMA), and pocket location (submuscular vs. subcutaneous).

All measured variables were reported as mean values ± standard deviation. Continuous variables between groups were compared using the t-test, and a χ² test was used to compare the categorical variables. All authors had full access to the data and take full responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

A total of 563 patients were included. The average patient age was 63.4 ± 13.6 years and 466 (82.8%) were male. The alerts were either audible (n = 485) or vibratory (n = 78). The ICDs included were Medtronic (n = 464), Boston Scientific (n = 21), and SJM (n = 78; see Appendix for included models).

Of the patients who had devices featuring the APA (n = 485), the average patient age was 63.4 years and 401 (82.6%) were male. Overall, 417 (86.0%) patients with devices that featured the APA could sense their alert.

The patients who had a Boston Scientific ICD were aged 66.6 ± 8.3 years and 18 (85.7%) were male. The auditory alert was heard in 13 (61.9%) patients. In the group who had a Medtronic ICD, the mean age was 63.3 ± 13.2 years and 383 (82.5%) were male. The auditory alert was heard in 404 of 464 (87.1%) of the patients in this group.

Of the patients who had devices featuring the VMA, the average age was 63.2 ± 14.3 years and 65 (83.3%) were male. All of the 78 patients who had devices that featured the VMA could sense their alert.

Table 1 summarizes these results when stratified by subgroup. Patients who could not hear the audible alert were more likely to be older (71.4 vs. 62.1 years, \(P < 0.001\)) or have submuscular defibrillator pockets (\(P = 0.035\), Boston Scientific devices (\(P = 0.007\), or an audible alert (audible alert vs. vibratory alert 14.0 vs. 0%, \(P < 0.001\)). In addition, there was a trend towards an increase in frequency for male patients not to be able to hear the alerts [male vs. female who could not hear the alert, 62 of 401 (15.5%) vs. 6 of 84 (7.1%), \(P = 0.075\)]

### Table 1. Ability to hear the auditory alert: results stratified by pre-specified subgroup

<table>
<thead>
<tr>
<th></th>
<th>Able to hear</th>
<th>Not able to hear</th>
<th>(P)-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>([n = 417] (86.0%))</td>
<td>([n = 68] (14.0%))</td>
<td></td>
</tr>
<tr>
<td>Male (n = 401)</td>
<td>n = 339 (84.5)</td>
<td>n = 62 (15.5)</td>
<td>0.075</td>
</tr>
<tr>
<td>Female (n = 84)</td>
<td>n = 78 (92.9)</td>
<td>n = 6 (7.1)</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>62.1</td>
<td>71.4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Guidant (n = 21)</td>
<td>13 (61.9)</td>
<td>8 (38.1)</td>
<td>0.007</td>
</tr>
<tr>
<td>Medtronic (n = 464)</td>
<td>404 (87.1)</td>
<td>60 (12.9)</td>
<td>0.035</td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>392 (86.7)</td>
<td>60 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Submuscular (n = 33) 25 (75.8)</td>
<td>8 (24.2)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Compares the inability to hear the tone by pre-specified subgroup.

Discussion

To our knowledge, this is the first study to compare the ability of patients to sense different ICD patient warning systems. We have shown that the majority of patients can sense the APA and the VMA, but that the ability to sense the VMA was higher than that of the audible alert. Furthermore, the ability to sense the audible alert was higher in women, younger patients, and when the ICD was located in the subcutaneous position when compared with the submuscular position.

Several investigators have described the sensitivity of the APA for the detection of device malfunction. Depending on the criteria necessary to trigger the APA, its sensitivity for detecting ICD lead failure is between 30 and 86%. However, none of these studies assessed how well the patient alert would be sensed or if it would prompt patients to seek medical attention.

In the study by Vollman et al., 2 of the 10 patients (20%) in whom the alert was triggered did not hear the alarm tone. In the remaining patients, the average time from alert trigger to ICD interrogation was 5.3 days. These results are consistent with our findings. In our study, 417 (14.0%) of the 485 patients could not hear the APA.

Simons et al., 3 analysed patients’ ability to sense the audible tone featured in the Medtronic devices. In their study, they tested both high- and low-frequency alerts in 102 patients whose mean age was 71.8 years. Overall, only 58.8% of all patients could hear at least one of the tones. There was an increased ability of patients to hear the tone if they were younger (94% if younger than 60 years and 52% if older than 60 years, \(P < 0.001\), and 91% if younger than 70 years and 43% if older than 70 years,
stratified by gender. Overall, 56% of the 79 male patients could cant difference in the ability of patients to sense the tone when compared with 70% of the 23 female patients tone as this would probably have had a higher sensitivity for iden-
tronic devices, we analysed the ability to hear the higher frequency
emitted from their device. These factors would probably increase
respond to whether they could hear the tone or feel the vibration
the quiet clinic setting and the patients were prompted to
5. Simons EC, Feigenblum DY, Nemirovsky D, Simons GR. Alert tones are frequently
a. Appendix
The included Medtronic models were Virtuoso® DR AT model D164AWG, Virtuoso® VR model D164WVC, Intrinsic® DR model 7288, EnTrust® model D154ATG, EnTrust® model D154VR, Maximo® DR model 7278, Maximo® VR model 7232CX, Marquis® DR model 7274, Marquis® VR model 7230CX, Gem® III DR model 7275, Gem® III VR model 7231, Gem® II DR model 7273, Gem® II VR model 7229, Gem® DR model 7271, Gem® model 7227, Onyx® VR model 7290CX, Concord® model C174AWK, InSync Marquis™ model 7277, InSync ICD® model 7272, InSync Sentry® model 7298, and InSync III Marquis™ model 7279.

The included Guidant models were Contact Renewal 2® model H155, Contact Renewal 4® model H190, Contact Renewal 4®E HE models H199 and H199, Ventak VR® model 1774, Ventak Prizm VR® model 1850, Ventak Prizm DR® model 1851, Ventak Prizm HE VR® model 1852, Ventak Prizm HE DR® model 1853, Ventak Prizm II VR® model 1860, Ventak Prizm II DR® model 1861, Vitality VR® model 1870, Vitality DR® model 1871, Vitality Avt® model A155, Vitality 2DR EL® model T167, and Vitality 2VR EL® model T177.

The included models from St. Jude Medical were Atlas VR® model 168, Atlas VR® model 268, Atlas VR® model 367, and Current DR® model 220.

**References**