Answer to the ECG Quiz

The pacemaker is functioning properly. This type of pacemaker has the AAI – safer algorithm incorporated. Based on this algorithm the device paces in AAI mode in the absence of AV block or in the presence of relatively accepatable episodes of first or second degree AV block. On the other hand, in the presence of marked AV conduction disturbances it switches to DDD mode. In this particular example, the device is using the criterion of the detection of two consecutive atrial events without intrinsic ventricular response (arrows). After this 2 blocked atrial depolarizations the pacemaker starts pacing in DDD mode. Note the shorter initial AV interval in the post-AAI DDD sequence. This is a programmable parameter aiming to minimize the total duration of the ventricular pause.

NEWS FROM THE INDUSTRY

Safety Announcements

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Medtronic informs that a software problem has been noticed in the following models: *Consulta CRT-D, Secura DR/VR, Concerto II CRT-D, Virtuoso II DR/VR, Maximo II CRT-D, Maximo IIDR/VR.* By April, 19 2010 Medtronic has received 5 confirmed reports from 144000 devices none of them associated with adverse effects of any kind. A particular sequence of the following 3 facts must take place within a few ms to cause this problem.

1. The high voltage capacitors obtain the programmed energy (termination of charge)
2. Battery voltage measurement is in progress and
3. The ventricular tachyarrhythmia is self-terminated and the subsequent therapy delivery is postponed.

In that case, all future high voltage therapies would have an elongated charge time or would fail to deliver due to charge circuit time-out. The alert systems of the devices will notify the patients to seek medical attention and this problem will be fixed with a new software installed. The possibility of this malfunction is estimated about 1/27000 devices per year and the possibility of a patient needing therapy before the device alert is activated is about 1/291000 per year.

Medtronic since September 2010 is updating the software of the EnRythm pacemaker and the telemetry device to correct certain problems concerning the battery to avoid loss of function in an estimated 0.08% of the patients. In short, the elective replacement indicator (ERI) changes from <2.59V to <2.81V and new criteria for the ERI determination have been endorsed. These modifications will shorten the pacemaker lifetime by 10-15%.

On October 2010 Medtronic notes that regarding the leads Sprint Quattro 6935 and 6947, over-retraction of the helix during the initial implant or repositioning may result to inability to extend the helix. There have been 193 reports out of an estimated size of 154000 leads used worldwide. This malfunction does not impair the performance of successfully placed leads.

Medtronic has also informed that the multi-channel Radio-Frequency generator GENius 990018 may interact with implanted cardiac devices and cause high frequency signals in the atrial or ventricular lead leading to inappropriate shocks. By October 27, 2010 Medtronic has received 4 confirmed and 1 unconfirmed reports out of 1000 patients with implanted device who underwent ablation using this particular system. In two of them external defibrillation was required. No deaths have been recorded.

From St. Jude Medical comes a report regarding the performance of the *Riata* and *Riata ST* endocardial ICD lead models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042. These leads use silicone as insulation material, which is known from the literature to be vulnerable to abrasion, although it is the most commonly used. The above-mentioned models have an abrasion rate of 0.49% over 9 years of use, which can cause oversensing, undersensing, loss of capture, changes in impedance or failure to deliver therapy. The newer generation leads use the Optim insulation material which shows a reduction of abrasion –related observations by 80% at 44 months of follow-up. The overall survival rate of patients with the new leads reaches 98.8% at 44 months, compared to 98.4% among the patients carrying the previous lead model. This difference may be attributed to the lower rate of abrasion.