Holter Recordings with Continuous Marker Annotation to Evaluate Pacemaker Function

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Background: Pacemaker marker annotations facilitate the interpretation of device behavior in addition to ECG recordings. However, they are only available in conjunction with a programmer. We studied the diagnostic value of a prototype Telemetry Holter Decoder (THD), providing continuous marker annotations on a conventional Holter.

Methods: The study included 20 patients with VDD or DDDR pacemakers. A 24-hour Holter was performed using the THD. Marker annotations are transmitted from the pacemaker to the THD, which transforms them into analog signals, which are recorded on one of the Holter channels.

Results: During a total recording time of 458 hours, high quality marker annotations were retrieved for every patient. Artefacts disturbed the recordings during 184 min (0.67%). The THD provided information not discernible on the ECG: intermittent atrial undersensing during sinus rhythm (1096 times). Atrial tachycardias, not visible on the ECG, were detected in 2 patients. The activation of tachycardia response algorithms was clearly annotated in 11,516 events. A total of 8875 PVC's occurred, 57.8% of which were classified incorrectly in the event counters as conducted or fusion beats. Atrial far-field sensing or VA conduction was demonstrated 4294 times. Electromagnetic interferences, not visible on the ECG, could be seen three times.

Conclusion: Recording of continuous high-quality marker annotation on a conventional Holter is feasible. The THD provides important information on device behavior, even in patients assumed to have regular device function, and shows to be clearly superior to ECG interpretation alone. Such data can be used for improved programming, troubleshooting and for the validation of new algorithms.

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Constantly adding new features to pacemakers make them not only more powerful, but also more difficult to use and manage. The effect of each of these features is easy to understand and to recognize on ECG when taken separately. Combined, they can become much more complex and hard to interpret from the surface ECG alone. To face this ever-increasing complexity, the physician needs sophisticated tools in order to under-

stand complex pacemaker behavior and some occult cardiac rhythm disturbances that appear on patient ECGs.

Most of the devices available today provide the possibility to record telemetered intracardiac electrograms with marker annotations. These non-invasive intracardiac electrogram signals can be recorded by means of the radiofrequency programmer, thereby elucidating device behavior. How-

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ever, they provide only short-term, in-house evaluations.^{1,2}

Twenty-four hour Holter recordings are often used in case of suspected pacemaker malfunction or for routine evaluation, or pacemaker programming optimization.³⁻⁸ Still, these Holter recordings can be difficult to interpret due to the multiple algorithms programmed or to inferior recording quality, which may render the detection of pacemaker spikes impossible.^{9,10}

A Telemetry Holter Decoder (THD), designed to continuously receive annotation markers from a pacemaker and to record them on one channel of a Holter recorder, has been studied previously. It has been shown to facilitate the interpretation of pacemaker ECGs and to allow verification of appropriate pacemaker programming.¹¹ Until now, the device has not been tested systematically during pacemaker follow-up, nor have the informations collected by the THD been quantified. Therefore the THD was used for the first time during routine follow-up visits of pacemaker patients in order to evaluate and quantify the clinical usefulness of such a device.

METHODS

The study included 20 patients (11 female, 9 male) with dual chamber pacemakers, mean age 65 ± 14 years, during routine follow-up visits. All patients had a chronically implanted pacemaker: 4 Unity 292-07 VDD, 6 Relay 294-03 DDDR, and 10 Marathon 294-09 DDDR (Intermedics Inc., Angleton, TX, USA). The indications for pacemaker implantation were: high degree AV-block in 8 patients, sick sinus syndrome in 1, binodal disease in 10, and hypertrophic obstructive cardiomyopathy in 1 patient.

First, a routine pacemaker follow-up was performed including electrogram telemetry. All patients showed a regular pacemaker function without undersensing, oversensing, or far-field sensing. Thereafter a 24-hour Holter recording (Tracker 2, Reynolds Medical Ltd., Hertford, Herts., UK) with the THD was performed for each patient. Each Holter recording was analyzed beat to beat.

THD

The THD works like a miniaturized programmer device for pacemakers of the same manufacturer. It has a size of 14.2 x 8.8 x 3.5 cm and a weight of

Figure 1. Picture of the Telemetry Holter Decoder with its miniaturized telemetry receiving coil. The cables from the Holter recorder are attached to the snaps on the right side.

210 g. The device is able to receive pacemaker annotations and to transmit them to the Holter recording, after signal processing. The collection of pacemaker annotations is performed using a miniaturized telemetry receiving coil that is taped on the patient's skin above the pacemaker (Fig. 1). Using the programmer, the pacemaker is enabled to transmit annotations continuously. These annotations are sampled every 2.56 msec and transmitted to the THD through the receiving coil. After demodulation of these radiofrequency pulses, the THD performs error checks in order to minimize artifacts. Whenever "noise" is detected or the THD loses communication with the pacemaker, an error code is generated and output made to the Holter. Based on the setting of selector switches, the microcontroller in the THD can output the decoded information in a variety of formats to the Digital/Analog converter and voltage scaler. These produce millivolt level analog voltage signals, which can be input to one channel of a Holter recorder. The THD is able to code up to 16 annotation codes as eight positive and eight negative voltage pulses ranging in amplitude from -2.5 mV to + 2.5 mV (Fig. 2). A list of possible annotations is given in Table 1.

The two leads of channel I of the Holter recorder are used to connect the Holter and the THD using

Figure 2. Example of a printout from a two-channel Holter recording. Top: Marker annotation of the Telemetry Holter Decoder. These annotations are digital signals of a pulse duration of 50 msec. Bottom: Surface ECG recording. As = atrial sense; Vp = ventricular pace; VRP = end of ventricular refractory period; PVARP = end of postventricular atrial refractory period.

two snaps at the side of the unit. The THD itself runs on 4 AA batteries. The energy used by the pacemaker to transmit the annotation codes continuously for 24 hours, shortens the pacemaker's lifetime by approximately 6 hours.

Table 1. Examples for Annotation Codes that may be Transmitted by the Telemetry Holter Decoder

- Atrial and ventricular pace event
- Atrial and ventricular sense event
- Premature ventricular contraction (PVC) event
- Maximum pacing rate
- Noise detection
- Cross-talk detection
- End of refractory periods
- Start of algorithms such as tachycardia termination algorithms

RESULTS

Easy interpretation of the annotation markers is facilitated by the use of rectangular pulses with a pulse duration of 50 msec. However, complex sequences of signal can lead to signals that are much more complicated to interpret. The small telemetry receiver coil and the lightweight Telemetry Holter Decoder were well accepted and tolerated by all patients. Annotation markers were obtainable in all patients. Artefacts were detected only occasionally and occurred during 184 minutes (0.67% of time). They were usually due to loose cable connections between the Holter and the THD. Upon analysis of the Holter recordings, the following situations where the THD proved to be diagnostically helpful or facilitated ECG interpretation were identified:

Figure 3. Example of atrial undersensing diagnosed with the THD. The surface ECG (bottom) seems to show regular AV-synchronous stimulation. The THD markers (top) show atrial undersensing of the first P wave, as an atrial pace (Ap) is delivered. The second P wave is sensed correctly. As = Atrial sense; Vp = Ventricular pace; VRP = End of ventricular refractory period; PVARP = End of postventricular atrial refractory period.

Figure 4. Diagnosis of intermittent atrial undersensing during atrial fibrillation. Atrial fibrillation with spontaneous conduction to the ventricle is seen on the surface ECG (bottom). On the left multiple atrial sense (As) event markers of the THD (top) document correct sensing of atrial fibrillation. After the second conducted beat, atrial undersensing occurs and the third ventricular beat is consequently annotated as a premature ventricular contraction (PVC). The amplitudes of the markers sometimes vary if they follow close one after the other, as there is no time for a return to baseline. As = atrial sense untracked; AMRP = atrial mini-refractory period; VRP = end of ventricular refractory period.

Additional Information Provided by the THD in the Presence of Low-Quality Holter ECG

The THD provided information that was not visible on the ECG in a variety of cases. Although all patients were thought to have appropriate pacemaker programming, the additional information provided by the THD showed multiple episodes of atrial undersensing, which could not be diagnosed from the ECG alone (Fig. 3). Such intermittent atrial undersensing episodes, especially during sinus rhythm with spontaneous conduction, were seen 1096 times. Thereby, the THD enabled optimal pacemaker programming.

In two patients, the THD showed evidence of atrial tachycardias that were not clearly visible on the ECG. Additionally, intermittent undersensing during atrial fibrillation was discovered (Fig. 4).

The annotation markers were also helpful in the presence of bipolar pacing spikes, which are sometimes difficult to recognize on the Holter ECG. Electromagnetic interference that was not visible on the ECG could be demonstrated three times. The appearance of atrial sensing markers during the postventricular atrial refractory period demonstrated atrial detection of ventricular far-field signals or VA conduction 4294 times (Fig. 5).

Figure 5. Diagnosis of atrial sensing of ventricular far-field signals or VA-conduction. The surface ECG (bottom) shows atrial (Ap) and ventricular stimulation (Vp). The marker annotations (top) show atrial sense events (As) during the refractory period which are therefore not tracked. AMRP = atrial mini refractory period; VRP = end of ventricular refractory period; PVARP = end of postventricular atrial refractory period.

Figure 6. The surface ECG (bottom) shows AV-synchronous stimulation with unclear variations of the AV interval. The THD markers (top) reveal that a tachycardia reaction algorithm (SMART-Tracking, Skillful Management of Atrial Rhythm Tracking) is active, causing these variations. Arrows show ventricular pacing at SMART-Tracking Rate; As = atrial sense; AMRP = atrial mini refractory period; VRP = end of ventricular refractory period; PVARP = end of postventricular atrial refractory period.

Activation of Special Algorithms Inside the Pacemaker

The operation of algorithms such as mode-switching or tachycardia termination algorithms can be annotated by the pacemaker and recorded on the Holter through the use of the THD. In the studied patient population, the activation of tachycardia termination algorithm was clearly annotated in 11,516 events, thus providing explanations for assumed atrial undersensing or unclear variations of the AV-interval (Fig. 6).

Pacemaker Event Misclassification

A total of 8875 PVCs were seen during the Holter recordings. Only 3745 (42.2%) of these were classified correctly by the devices as PVCs. In 5130 PVCs (57.8%), the THD proved that they were classified incorrectly (Fig. 7). These misclassified

events were recorded in the event counters as conducted beats or fusion beats. In 59% of the misclassified PVCs, they were marked as atrial-sensed followed by ventricular-sensed beats. In 29% of the cases, PVCs were classified by the pacemaker as ventricular-sensed events and in 7% of the cases, the PVC had not been seen by the pacemaker.

DISCUSSION

Nowadays, the electrograms of a patient with an implanted dual chamber pacemaker can be incredibly complex, due to the use of a large number of algorithms that have been implemented in order to manage patients' heart deficiencies and conduction problems. Holter monitoring has quickly become an essential tool in order to assess the pacemaker behavior and therefore deliver appropriate therapy to the patient. Still the Holter records surface ECGs

Figure 7. Two PVCs recorded from the same patient are shown. Left: The PVC (bottom), is inappropriately classified as an atrial sensed—ventricular paced (As-Vs) event by the pacemaker. Right: In this case, the PVC has been misinterpreted as an atrial sensed—ventricular paced (As-Vp) event, with the ventricular pacing spike not being visible on the surface ECG. As = atrial sense; Vp = ventricular pace; VRP = end of ventricular refractory period; PVARP = end of postventricular atrial refractory period.

only and from this information alone, it may remain difficult to assess appropriate pacemaker function during daily life.^{9,10} Short term evaluations with telemetered electrograms during patient follow-up provide the possibility to get pacemaker annotations as well, thereby helping to understand device behavior. However, long-term evaluations have not been possible.

Here we have studied the THD for the first time during routine follow-up visits in pacemaker patients. The device has the ability to transfer pacemaker annotations continuously on one of the channels of a conventional Holter recorder. This feature has the potential to open a new perspective for patient management. The use of this tool is easy and straightforward, and it is well accepted by the patients.

To use this device the pacemaker must be programmed to transmit marker annotations continuously to a miniaturized telemetry receiving coil. Therefore this concept should be feasible with the majority of pacemakers.

Artefacts disturbing the continuous marker annotations occurred in less than 1 % of the recording time.

During follow-up visits of pacemaker patients, much information is accessible from pacemaker diagnostic counters.⁸ Nevertheless, these data are susceptible to false-positive and false-negative data.¹² This problem was documented in the study which revealed an erroneous PVC classification concerning event counters in 58%. Additionally the presence of atrial-sensing far-field signals or VA conduction could be documented as well. Such

information is important for the interpretation of event counters and for improved device programming.

Furthermore, information that is invisible or very difficult to read or interpret from the ECG became clear with the help of the annotations provided by the THD. Examples are undersensing or external interferences during spontaneous conducted beats, which can only be diagnosed by marker annotation.

With increasing complexity of pacemakers, a large variety of algorithms have been implemented. Among these are the well-known and frequently used tachycardia termination or mode-switching algorithms. Even the action of such an algorithm renders the interpretation of pacemaker ECGs sometimes difficult, since it is often impossible to assess whether such an algorithm, or even a combination of algorithms, was active or not, thereby possibly explaining an unusual pacemaker behavior. Even with in-depth knowledge of device algorithms, interpretation of pacemaker ECGs may remain time-consuming, cumbersome or even impossible.

As the THD allows to annotate the activation of algorithms, it provides clear information whether an algorithm is active, which was the case more than 11,000 times in the 20 patients studied. Additionally the THD can be used to specifically check whether a given algorithm is functioning correctly. The flexibility of its programming allows the user to target specific issues for each patient. A future application of the THD might be the validation of new algorithms. Therefore, one could just choose markers to annotate the activation and deactivation of the algorithm in combination with sensing markers. In such a setting recordings are easy and fast to interpret, providing detailed information about algorithm function during daily life.

Many different combinations of signals are available from the THD but this can lead to very complex chains of annotation markers that become difficult to interpret. A careful selection of markers makes interpretation easier.

Regarding the great amount of information and insights into device behavior retrieved in the patients studied here, it must be highlighted that all of the patients were thought to have regular pacemaker function after a standard follow-up visit. Thereby optimized device programming can be achieved with the use of the THD. An important

additional application for the device are of course troubleshooting purposes.

Currently, only manual review of recordings is available, making this analysis sometimes time consuming and thus limiting the use of the THD. However, following a certain learning curve interpretation and evaluation became faster.

A combination of marker annotations and telemetered electrograms is technically feasible and should be even more helpful for detailed analysis.

CONCLUSION

Recording of continuous high-quality marker annotations on a conventional Holter is feasible. The THD provides important information about device behavior, even in patients assumed to have a regular device function, thus being clearly superior to ECG interpretation alone. Such data can be used for improved programming, troubleshooting, and for the validation of new algorithms.

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