



Automatic analysis of pacemaker diagnostic data in the identification of atrial tachyarrhythmias in patients with no prior history of them

A. Schuchert^{a,*}, S. Lepage^b, J.J. Ostrander^c, R.J. Bos^d,
M. Gwechenberger^e, A. Nicholls^f, G. Ringwald^g

^a Heart Center, University Hospital Hamburg-Eppendorf, Hamburg, Martinistrasse 52, D-20251 Hamburg, Germany

^b Centre Hospitalier Universitaire de Sherbrooke, Sherbrooke, QC, Canada

^c Grey Bruce Health Services Corporation, Owen Sound, ON, Canada

^d Franciscus Ziekenhuis, Roosendaal, The Netherlands

^e AKH, Wien, Austria

^f Leeds General Infirmary, Leeds, UK

^g Gemeinschafts Praxis, Bruchsal, Germany

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Abstract **Aims** Modern pacemakers provide a large amount of diagnostic data. Given the limited time available during a pacemaker follow-up visit essential information may be overlooked. This registry was conducted to assess the utility of an expert system that analyses the diagnostic data collected by an implanted pacing device and notifies and advises the physician about suspected technical issues and arrhythmias that need further attention.

Methods Patients with various standard indications for pacing were included in this registry and received single or dual chamber pacemakers. Data were collected and analysed by the expert system during at least two subsequent follow-up visits. The evaluation of this system focused on data obtained from patients with a dual chamber pacing device without prior history of atrial arrhythmias.

Results A total number of 239 patients without prior history of atrial tachyarrhythmias were included in this analysis. Atrial tachyarrhythmias were detected in 73 (31%) of these patients. The highest incidence of newly detected arrhythmias occurred in the group of patients with high-degree AV block and VDD pacemakers.

* Corresponding author. Tel.: +49 404 717 5304; fax: +49 404 717 7420.
E-mail address: schuchert@uke.uni-hamburg.de (A. Schuchert).

Furthermore, newly detected arrhythmias predominantly occurred in the period shortly after implantation. Device programming suggestions by the expert system were adopted in 30% of the cases. Following detection of atrial tachyarrhythmias by the expert system, pharmacological management was adjusted at 71% of the first follow-up visits and at 27% of later follow-up visits.

Conclusion Results of this registry show that this expert system provides a valuable tool for the detection of atrial tachyarrhythmias during pacemaker follow-up visits.

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Introduction

Modern pacemakers are capable of storing a large amount of diagnostic data related to various arrhythmias. One of the most striking advantages of having such diagnostic data is that it is collected on a 24-h day and 7-day week basis. This allows physicians to evaluate the appropriate function of the device, the status and progression of the patient's arrhythmias and the effects of pacing and pharmacological therapies [1–4]. However, it also means that the data have to first be retrieved and carefully analysed, which adds considerably to the length of each follow-up visit. Furthermore, correct interpretation of the retrieved data requires extensive experience with pacemaker management, especially since specialized information in the form of textbooks or original reports is rare.

One solution to this problem is to develop software that is capable of automatically analysing the data obtained during pacemaker interrogation. Such software, which is also referred to as an expert system, combines the expert knowledge that is embedded in the software with individual patient diagnostic data. It is designed to provide relevant messages if technical issues arise such as sensing failures or if significant arrhythmic events occur. The progressively increasing functionality of modern pacemaker programmers allows for the introduction of such an expert system, known as Diagnostic Observations (DOs), into daily clinical routine.

The DORE registry (Diagnostic Observation REgistry) was designed to carry out a prospective evaluation of the performance of an expert system for the automatic analysis of diagnostic pacemaker data in a large patient population.

Only patients with a newly implanted pacemaker that had the DOs feature were included in the registry. Since newly implanted devices in particular often require reprogramming, automatic systems that evaluate device performance and alert the physician to significant arrhythmic events are expected to have the most utility during the immediate post implantation period.

Methods

Patients and devices

Patients with a wide variety of pacemaker indications, who received both single and dual chamber pacemakers, were included in the registry. No specific inclusion criteria applied to this registry.

For the study we used the Clarity DDDR, Clarity SSIR and the Collection 3 series of pacemakers (Saphir VVD/R, Diamond DDDR, Ruby DDD and Topaz SSIR, Vitatron BV, Arnhem, The Netherlands). These are state-of-the-art pacemakers equipped with the DO function.

These pacemakers continuously collect data on cardiac events and carry out measurements by, for example, periodically measuring the amplitude of atrial signals. This information is then stored in the pacemaker memory for later retrieval and automatic analysis by the DOs function. The diagnostic information used by the DOs function is identical to the information provided to the physician; the DOs function interprets these data and presents condensed information and recommendations to the physician. Information related to possible atrial tachycardia is based on diagnostics, emanating from the mode switching algorithm, such as the amount of atrial sensed rhythm that is classified as pathological and the percentage of atrioventricular (AV) dissociation. Mode switching itself is an algorithm that has been used for many years in these devices and is based on a beat-to-beat analysis of the atrial rhythm [5].

Messages such as "Low paced atrial rates" (indicative of chronotropic incompetence), or "Suspected atrial undersensing" can be solved by reprogramming sensing parameters or activating rate adaptive pacing. Messages indicating significant arrhythmic events may require additional intervention or adjustment of pacing parameters and/or pharmacological therapy. This is very important if the events are new or have not previously been seen. Particularly relevant is any suggestion of the presence of atrial

tachyarrhythmias (AT) that the expert system detects on the basis of a relatively low percentage of AV synchrony ("Less than 96% AV synchrony") in combination with mode switching (percentage of pathological atrial rates).

Design

One year of postoperative pacemaker follow-up data were used for the DORE registry. This could include up to four follow-up visits: one week after implantation, and after 3, 6 (as an option), and 12 months. Unscheduled follow-up visits were separately reported.

At the start of each follow-up visit, patient symptoms were recorded and pacemaker data were retrieved. Upon retrieval, the expert system analysed the diagnostic information and recognized and responded to several events. The physician was alerted to any notable events by an appropriate message (a Diagnostic Observation), which was displayed on the programmer screen. All DOs were documented at each follow-up. The physician was asked to confirm the presented message by reviewing the underlying diagnostic data, such as 24 h heart rate trend and various histograms and event counters. Subsequently, any changes in pacing and drug therapy and their relationship to the DOs were documented.

Analysis

The DORE registry included patients with a wide variety of pacemaker indications and included single and dual chamber pacemakers. The data analysis presented in this manuscript focuses on the detection of AT, the most frequent observation in dual chamber devices. Our particular interest was in patients with no known history of AT and the proportion of these patients in whom the expert system detected the presence of this tachyarrhythmia. In addition we stratified the patients by indication for pacing.

Results

Patients

Multiple centres from eight European countries and from Canada contributed to the registry. A total of 358 pacemaker patients were entered, comprising 192 (53%) males and 166 (47%) females.

In the first year after implantation, all patients underwent at least two follow-up examinations, with 46% of them having at least three. Hospital

discharge data were available for 351 patients. The 1–3 months follow-up was reported for 276 patients, the 5–7 months follow-up for 175 patients and the 10–14 months follow-up for 146 patients.

Of all included patients, 280 patients with a dual chamber device had at least two scheduled follow-up visits from which diagnostic pacemaker data were available. Of these 280 patients, 145 were males (age 62.5 ± 12 years), and 135 were females (age 82.0 ± 8.4 years).

At the time of pacemaker implantation, 36% of patients had bradycardia–tachycardia syndrome, 33% were in sinus rhythm, 30% had sinus node dysfunction and 1% had other atrial rhythms. With respect to the ventricular rhythm, 59% of patients had normal ventricular activation, 25% presented with idioventricular rhythms, 6% had frequent premature ventricular complexes and 10% had other ventricular rhythms.

The indication for pacemaker implantation was high-degree AV block in 52% of patients, sinus node dysfunction in 47%, and other diagnoses in 1%.

As mentioned earlier, we analysed only patients without a history of AT. Of the 280 dual chamber patients with diagnostic data from at least two follow-up visits, 239 patients had no prior history of atrial tachyarrhythmias. These patients were stratified according to the indication for pacing. We considered two main subgroups: those with a high-degree AV block ($n = 168$) and those without AV block, i.e. with intact AV conduction ($n = 71$). The first group was subdivided into patients receiving a dual lead (DDD, $n = 128$) and a single lead (VDD; $n = 40$) dual chamber pacemaker.

Frequency of diagnostic observations

A total of 1433 follow-up visits were reported and in 323 (23%) one or more DOs were presented. During the follow-up period, 43% of all patients presented with at least one DOs.

Fig. 1 shows that 43% of all DOs messages were related to a low percentage of AV synchrony ("Less than 96% AV synchrony") and that 12% were related to "High sensed atrial rates". Both messages are indicative of the presence of AT. The device responds to high sensed atrial rates by means of mode switching; mode switching itself reduces the percentage of AV synchrony.

Fig. 2 illustrates the distribution of DOs over the various follow-up visits. Although the absolute number of DOs decreases over time, the percentage of patients with DOs does not substantially decline. This may be explained by the fact that during early follow-ups many DOs are related to

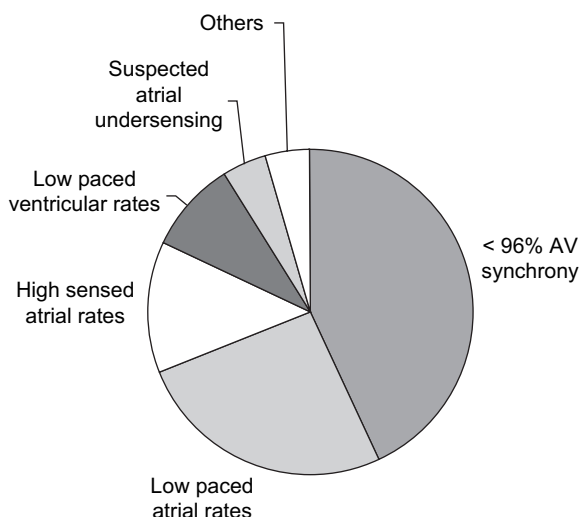


Figure 1 Incidence of diagnostic observations.

technical issues such as over- or undersensing. Once these issues are resolved, other issues that are possibly related to the occurrence of AT remain and will trigger the expert system. Non-scheduled follow-ups were usually due to significant symptoms. However, DOs obtained during these non-scheduled follow-ups did not frequently result in the detection of AT that was not previously known.

Atrial tachyarrhythmia detection

Patients with high-degree AV block and a DDD(R) pacemaker

Table 1 shows the proportion of patients with a DDD(R) pacemaker and high-degree AV block and no prior history of AT in whom the expert system issued a message indicating that such an arrhythmia had indeed been detected. At the first scheduled follow-up after approximately 3 months, AT was detected in 24 patients (19%) and within 1 year of follow-up AT was first detected in 36 of these patients (almost 30%).

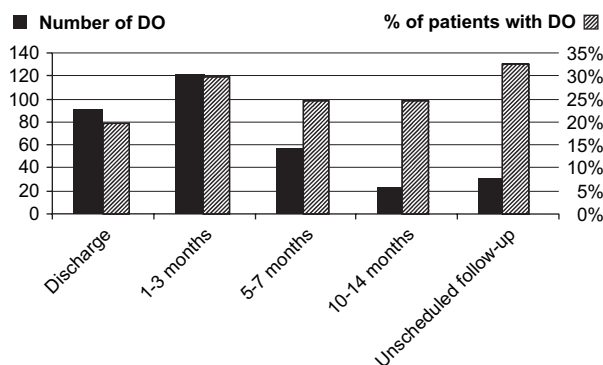


Figure 2 Distribution of DOs over the various follow-up visits.

Patients with high-degree AV block and a VDD pacemaker

Table 2 shows the number of patients with high-degree AV block, a single lead VDD pacemaker and no prior history of AT in whom the expert system issued a message indicating that such a tachyarrhythmia had been detected. At the first scheduled follow-up visit after approximately 3 months, AT was detected in 14 patients (35%). In 50% of these patients, the presence of AT was detected for the first time within 1 year.

Patients without high-degree AV block

Table 3 shows the number of patients with intrinsic AV conduction and no prior history of AT in whom the expert system issued a message indicating that such a tachyarrhythmia had been detected. At the first scheduled follow-up visit after approximately 3 months, AT was detected in 10 patients (14%). In 22.5% of these patients, the presence of AT was detected for the first time within 1 year.

The cumulative incidence of newly detected AT stratified according to the indication for pacing is shown in Fig. 3. Combining all the data shows that in 73/239 patients (31%) with no prior history of AT, such an arrhythmia was detected over a 1-year follow-up period. AT is predominantly detected in the period shortly after implantation and diminishes after the 3-month follow-up visit. These findings are in line with earlier reports [6].

Response to diagnostic observations

Responses to DOs were either pacemaker reprogramming, adaptation of the drug regimen or diagnostic strategy.

In response to DOs, the suggested programming recommendations were followed in 30% of cases. In 71% of the first follow-ups and in 27% of the later follow-ups, the pharmacological management was adjusted after atrial tachyarrhythmias had been detected.

Table 1 Frequency of newly detected atrial tachyarrhythmias in patients with AV block and a DDD(R) pacemaker and no known previous history of atrial tachyarrhythmias ($n = 128$)

Follow-up	Patients with newly detected AT
1–3 months	24 (19%)
5–7 months	6 (5%)
10–14 months	6 (5%)
Unscheduled follow-up	1 (0.8%)

Table 2 Frequency of newly detected atrial tachyarrhythmias in patients with AV block and a VDD pacemaker and no known history of atrial tachyarrhythmias ($n = 40$)

Follow-up	Patients with newly detected AT
1–3 months	14 (35%)
5–7 months	4 (10%)
10–14 months	2 (5%)
Unscheduled follow-up	0 (0%)

Discussion

In 43% of all follow-up visits, the DOs function reported significant diagnostic events.

A major result of this study was the detection of AT in 31% of patients with no known history of them. AT may be asymptomatic and unrecognized in many patients as has been reported in previous studies. For instance, in the AIDA trial, 65% of the patients in whom atrial tachyarrhythmias were detected had no documented history of them. Detection of AT in asymptomatic patients is important, given the risk of AT related stroke [7,8].

Most first detections of AT occur shortly after implantation and diminish after the 3-month follow-up visit. These findings are in line with earlier reports [9].

Since this registry was not designed to investigate the effects of atrial and ventricular pacing on the incidence of AT we did not statistically analyse our data with respect to this issue. However, the trends observed in this study with regard to the percentage of patients with AT in relation to the amount of atrial and ventricular pacing are consistent with earlier reports. Patients treated with dual chamber pacing have been reported to show a lower incidence of AT, compared with patients receiving ventricular pacing [10]. Consistently, the percentage of patients with AT detected by the pacemaker in combination with the expert system was considerably higher in the

Table 3 Frequency of newly detected atrial tachyarrhythmias in patients without AV block and no known history of atrial tachyarrhythmias ($n = 71$)

Follow-up	Patients with newly detected AT
3 months	10 (14%)
6 months	5 (7%)
12 months	1 (1.5%)
Unscheduled follow-up	0 (0%)

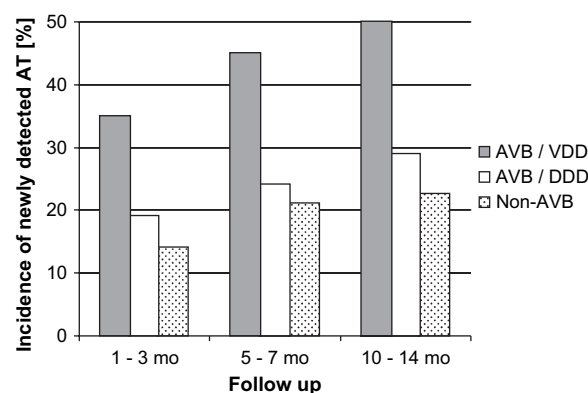


Figure 3 Cumulative incidence of newly detected AT in patients with no prior history of AT.

subgroup with a single lead VDD pacemaker, compared with patients with a dual lead dual chamber device. It is possible that the ventricular pacing which occurs at a lower rate in VDD mode contributed to this AT detection. In addition, in patients with a high-degree AV block, who are expected to receive a high amount of ventricular pacing, the percentage of newly discovered AT over a 1-year follow-up period was higher than in the group with intact AV conduction (30% versus 22.5%). This observation is in line with previous reports that conclude that frequent ventricular pacing correlates with a higher incidence of AT [11,12].

Atrial undersensing is a common issue with a VDD lead and may have been related to inappropriate detection of atrial tachyarrhythmias. This would suggest that the amount of AT detected by the expert system in patients with a VDD device is an underestimation. The expert system notifies the user with regard to suspected undersensing, based on the available diagnostic information.

The expert system evaluated in this registry proved to be valuable in detecting new onset or asymptomatic episodes of AT. It needs to be emphasized that pacemaker DOs were particularly frequent during non-scheduled follow-up examinations of patients with significant symptoms. However, apart from one follow-up (see Table 1), the expert system did not detect AT in patients without a history of atrial tachyarrhythmias during these non-scheduled follow-up visits. This registry was conducted in order to assess the ability of the expert system to alert the user of issues potentially requiring adjustment in the therapy. The relationship between these adjustments in response to DOs and the effects on symptoms has not been investigated during this study. Future studies should address to what extent the expert system may be helpful in effectively reducing symptoms.

Conclusion

The expert system evaluated in this registry proved to be valuable in detecting new onset or asymptomatic episodes of AT in patients without prior history of AT.

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