Autocapture compatibility in patients with the MembraneEX lead and Affinity pulse generators

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The first Autocapture generation worked well with all recommended leads. The newer Autocapture generation provides a more sensitive resolution for evoked response testing and its implementation in a dual-chamber device. The purpose of the study was to evaluate the performance of the Affinity SR/DR pacemaker with the new Autocapture algorithm in combination with the small surface area pacing lead MembraneEX in 129 patients. Autocapture ventricular threshold, sensing threshold, lead impedance, evoked response (ER) and polarization signals were determined at implantation and discharge, as well as after 1 and 3 months. Autocapture recommendation rate was based on the ER sensitivity test. The median pacing threshold was 0.38, 0.50, 0.75, 0.75 V at implant, discharge, 1 and 3 months post-implant, respectively. The respective data for median lead impedance were 744, 605, 649 and 691 ohms; median sensing threshold was 12.5 mV at all visits. The median ER amplitude was 9.0, 10.1, 9.9 and 10.1 mV at all visits. The frequency of recommended Autocapture activation was 98.3%, 99.2%, 98.3% and 96.2% of all patients at implant, at discharge, 1 and 3 months post-implant respectively. In conclusion, the studied pulse generator enabled, in combination with this pacing lead, in >95% of all patients activation of Autocapture.

Introduction

The ventricular Autocapture pacing system combines beat-by-beat capture verification with output optimization[1,2,3]. The main benefits of Autocapture are to ensure effective pacing at a low ventricular output, despite variable pacing thresholds, which prolongs pulse generator longevity[1,2]. The current Autocapture system requires bipolar leads with low polarization reliably to detect the evoked response amplitude[1]. The first Autocapture generation worked well with all recommended leads[1,2,3]. It was also used with other leads with less favourable results especially with small surface area electrodes[4,5]. The new Autocapture generation has been improved with more sensitive resolution for evoked response testing and its implementation in a dual-chamber device.

The purpose of the study was to evaluate the clinical performance of the new Autocapture algorithm in patients who had received a small surface area, low polarization, pacing lead.

Methods

Patients

The multicentre study was conducted in 13 clinics from six countries. The study enroled, from February 1999 to August 1999, 129 patients (67 ± 14 years, male n=76) with an Affinity DR in 101 and an Affinity SR pulse generator (St. Jude Medical, Sylmar, CA, U.S.A.) in 28 cases. The ventricular lead was, in all patients, the MembraneEX type (St. Jude Medical, Veddesta, Sweden). Indications for cardiac pacing were advanced AV-block in 84, sick sinus syndrome in 47, and slow
ventricular rates in the presence of atrial fibrillation in six. There were some patients with more than one indication.

**Pulse generator**

The single-, dual-chamber pulse generator Affinity SR/DR provides the Autocapture function which mainly consists of beat-by-beat capture verification and output optimization. Compared with the previous models the present Autocapture function measures polarization with a higher resolution, actually below 1·0 mV. Pacing threshold measurements are performed in steps 0·125–0·25 V compared with 0·3 V in the earlier version. Finally, the working margin of the pacing output above the actual pacing threshold is 0·25 V instead of 0·3 V. The pacemaker detects the presence of the evoked response (ER) signal within a window from 15·0 to 62·5 ms after every pacing pulse (Fig. 1). The diagnostic pacemaker functions in combination with the APS III programmer (St. Jude Medical) to enable measurement of the ER signal and lead polarization. The programmer recommends on the basis of the actual ER amplitude, ER sensitivity and polarization signal to turn Autocapture ON or OFF.

**Pacing lead**

The Membrane EX 1470/1472 T pacing lead is a bipolar, steroid-eluting pacing lead with a 2·3 mm² electrode tip. The electrode tip consists of titanium, covered by titanium nitride and is coated with a semipermeable membrane containing <13μg dexamethasone. The model 1470T has tines and the model 1472T fins for passive fixation in the ventricle.

**Study protocol**

The pacing lead was implanted in the apex in all patients except one in the diaphragmatic wall of the right ventricle. It was recommended to place the lead in the ventricle independently of the ER amplitude and polarization signal. Follow-ups were at discharge, 1 and 3 months post-implant.

At each follow-up, the ventricular pacing threshold at 0·40 ms pulse duration was determined with the Autocapture function as well as ventricular sensing threshold and lead impedance. The most insensitive setting for ventricular sensitivity is 12·5 mV so that R-waves with higher amplitudes cannot be more exactly assessed. The specific measurements for the Autocapture function were the determination of the ER amplitude and polarization as well as the frequency of recommended Autocapture activation based on the ER sensitivity test. Autocapture activation is not recommended, if the ER amplitude is <2·5 mV, the polarization signal >4 mV, the ER amplitude — ER sensitivity ratio <1·8 or the ER sensitivity — polarization ratio <1·7.

**Results**

Follow-ups were completed in 98% at discharge, in 93% at month 1 and in 92% at month 3 after implantation. There were three deaths with two of them due to heart failure. In addition, there were three ventricular lead dislocations.

The pacing threshold at 0·4 ms pulse duration was, at implantation, in 95% of the patients ≤5·0 V and at the 3-months follow-up in 81% ≤1·0 V (Table 1). Mean lead impedance revealed a typical decrease after implantation and ranged between 650 and 700 ohms during subsequent follow-ups (Table 1). An intrinsic rhythm was observed in 110 patients at implantation. Median sensing threshold was ≥12·5 mV at the maximum measurable threshold at all follow-ups (Table 1).

Mean ER amplitude remained >10 mV at implantation and at all follow-ups (Fig. 2). ER amplitudes higher than the minimum required value of 2·5 mV were present in all patients with exception of 1, 6, 3 and 4 cases at implant, discharge, 1 and 3 months post-implant, respectively. An inadvertent programmer interaction in the preliminary version caused the low ER amplitude in 5, 1 and 2 patients at discharge and after 1 and 3 months, respectively. The median polarization signal was 0·39 mV at all visits (Fig. 3). Polarization signals above the maximum acceptable value of 4·0 mV were observed in one patient at the 1 and 3-month follow-up each. This patient also had a low ER amplitude of <2·5 mV and another patient a lead dislocation. The pacing system was recommended to activate Autocapture in >95% of the patients (Fig. 3). Autocapture was not recommended to activate in four patients: One patient had a low ER amplitude at all follow-ups, two patients a lead dislodgment, and one patient an unfavourable ER/polarization ratio at the 3-months follow-up.

**Figure 1** The bar on the left side is the pacing pulse. Polarization occurs immediately after the pacing pulse. As the detection window starts 14 ms after the pacing pulse, the algorithm does not detect the polarization. An effective pacing pulse induces an evoked response which is present within the 45 ms detection window.
The present study is the first evaluation of the new pulse generator with an improved Autocapture algorithm. ER amplitude was in most patients >10 mV and polarization <1·0 mV. Autocapture could be activated in >95% of all patients. Pacing threshold was <1·0 V at 0·4 ms pulse duration in >80% of the patients throughout the study and mean lead impedance ranged between 650–700 ohms. The present study demonstrated the reliability of Autocapture in patients with this small surface area pacing lead.

The mean ER amplitude in the present study was mainly similar to the value reported in previous investigations with the first Autocapture generation[1,3]. A direct comparison cannot be performed because other leads were used in these studies. The polarization measurements in the present study revealed that polarization detected by Autocapture is definitely below 1·0 mV in most patients. This resulted in an excellent ER amplitude/polarization ratio and may explain the high frequency of recommended Autocapture activation in this study.

Pacing impedance is inversely related to pacing current. Therefore, pacing leads with high pacing impedance additionally reduce the pacing current at the same output. As the reduction of the electrode surface area mainly increases pacing impedance, this is a specific characteristic of some newer pacing leads. Some small surface area leads revealed, after connection to pacemakers with the Autocapture function, polarization signals >1·0 mV which caused a diminished frequency of recommended Autocapture activation in these patients[4,5]. The studied pacing lead also had a small electrode surface area, but the tip was designed to provide low polarization. The low polarization is well demonstrated in the present study and the potential disadvantages seen with previous not recommended leads were no longer observed. The dislodgement rate in the present study, 2% is similar to other present-day leads[6,7].

In conclusion, the pulse generator—pacing lead combination studied enabled in >95% of all patients activation of Autocapture.

### References


[3] Schuchert A, Ventura R, Meinertz T. on behalf of the AUTOCAP Investigators. Autocapture Activation without the
Appendix

Participants of the Affinity MembraneEX Study Group according to the number of implants: R. Kolk, University Hospital of Tartu, Estonia; J. Voitk, Mustamäe Hospital, Tallinn, Estonia; O. Thomas, Clinique Ambroise Paré, Neuilly sur Seine, France; F. Fossati, Polyclinique du bois, Lille, France; E. Stammwitz, Kreiskrankenhaus Leer, Germany; A. Schuchert, University-Hospital Eppendorf, Hamburg, German; I. Filice, Ospedale S. Paolo, Savona, Italy; A. Carboni, Ospedale Maggiore E Riuniti, Parma, Italy; L. Pavia, Presidio Osp. Piemonte, Messina, Italy; J. Ansabergs, Stradina Universitates Kliniska Slimnica, Riga, Latvia; J. Beiras, Hospital Xeral Cies, Vigo, Spain; C. Llorente, Marco Hospital Xeral Calde Lugo, Spain; A. Cercas, Hospital Del Sas De Jerez, Spain.