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A Novel Therapy System for Salvage of Infected PPMs and ICDs

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Background: The currently recommended treatment for infected PPM and ICD is a complete extraction and replacement. Our objectives are to demonstrate the efficiency and safety of a novel therapy method of continuous in-situ-targeted, ultra high-dose antibiotics (CITUHA) under closed Regulated Negative Pressure Assisted Wound Therapy (RNPT) system, for infected devices limited to their pockets and proximal wiring, thereby reducing the need for explantation.
Methods: We treated 21 consecutive patients by administrating CITUHA under closed RNPT system (TANP) and, if indicated, minimal local manipulation of hardware. All procedures were performed in an operating room under strict sterile conditions applying mainly local or none anesthesia, and rarely, general anesthesia. Exposure of a generator or proximal wiring could be managed by either delayed direct closure or by coverage with minor local rotation flaps.
Results: TANP treatment lasted 6-14 days followed by a course of up to 4 weeks of oral antibiotics, as clinically indicated. Concentrations of antibiotics in the local pocket were threefold higher than normal target therapeutic plasma levels, effectively eradicating the infection. By controlling and adjusting the antibiotics concentrations in the pocket, the desired therapeutic or the low-therapeutic plasma levels were achieved, reflecting an apparent first-order pocket-to-plasma delivery. In all but 3 patients, devises were salvaged without recurrence of infection. The mean follow-up was 18.1±11.3 months (range 4-49 months).
Conclusions: Our clinical and laboratory experience demonstrates that infection of implanted device's pocket and/or subcutaneous proximal wiring can be efficiently and safely managed by TANP, markedly diminishing the need for a removal of the device. Moreover, CITUHA also provides concurrent controlled systemic antibiotic administration therapy method, adjusted to the patient's requirements and constraints.

Multipole Heart Rate Variability Analysis as a Predictor of Ventricular Arrhythmias in ICD Patients

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Background: Ventricular tachyarrhythmia (VTA) causing sudden cardiac death (SCD) is a major cause of mortality in the western world. Contemporary implantable cardiac defibrillators (ICD) enable collection and storage of multiple, pre-episode R-R interval recordings in patients who suffered from VTA. Timely prediction of VTA, using heart rate variability (HRV) analysis processing techniques, may allow time to implementation of preventive and therapeutic strategies.

Aim: To evaluate the novel multipole method of HRV analysis in prediction of imminent VTAs in ICD patients.

Methods: Our study population consisted of patients from the Biotronik HAWAII Registries (Heart Rate Analysis with Automated ICDs). Total of 28 patients from the HAWAI registry, having full medical records, who had experienced documented, verified VTA during the 2 year follow-up period, were included in our analysis. HRV during pre-episode recordings of 4500 R-R intervals from those patients was analyzed using the multipole method and compared to HRV of similar length recordings of the same patients that were not followed by arrhythmia. We used the combination between quadrupoles and the Dyx parameters to reveal early signs predicting imminent VTA in our patients.

Results: Our study population consisted of 28 patients, mainly men (89%), average age of 64.8±9.4, 92% with coronary artery disease. HRV during 64 pre-event recordings (2.3 events per patient on average) were analyzed and compared with 60 control recordings. The multipole method of HRV analysis showed 50% sensitivity and 91.6% specificity for prediction of VT/VF in the study population, with 84.5% positive predictive value. No statistically significant correlation was found between various clinical parameters and the pre-detection of imminent VTA in our patients.

Conclusion: The multipole method of HRV analysis emerges as a possible predictor of imminent VTA, providing an early warning that can be used to prepare for an arrhythmic episode.

Safety of Four Hours Bed Restriction Following Cardiac Device Implantation

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Introduction: Implantation of cardiac devices (pacemakers and defibrillators) is a standard procedure, which is performed in most medical centers using the same techniques. However, currently there are no official guidelines for the post-operative care and management of patients with newly implanted cardiac devices.
Objectives: In this study we tested the safety of short compared to long post operative bed restriction after a cardiac device implantation.
Patients and Methods: We enrolled 86 patients, who were blindly randomized to either 4 hours or 12 hours bed restriction after cardiac device implantation. Patients' demographics, clinical background, and comorbidities were recorded. Additionally lead parameters were assessed upon implantation as well as on day one post surgery and on day 7. The primary end point was defined as the need for repeat surgery due to dislodgement or hematoma in the device pocket. Secondary end point was defined as the changes in the electrical parameters of the implanted leads at three different time points; at implantation, one day later and 7 days post implantation in both patients' groups.
Results: During the study 4 patients required secondary surgical procedures due to lead dislodgement in the 12 hours group, while no such events were recorded in the 4 hours group. The change in sensing, pacing threshold and lead impedance did not change significantly over time and there was no significant difference in these changes between the two groups.
Conclusion: Four hours bed restriction policy after cardiac device implantation is feasible and seems to be at least as safe as 12 hours bed restriction policy.

Home Monitoring of ICD and CRTD Implanted Patients, the Israeli Experience

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Background: Home Monitoring is an automatic remote monitoring system that uses the cellular phone network, and enables physicians to remotely monitor clinical status and device status of ICD and CRTD implanted patients. Remote monitoring refers to the daily transmission of pre-defined alerts, allowing the physician to rapidly identify malfunction of the device. This advance in patients care may improve patient safety and satisfaction and has the potential of reducing costs.
Aim: To describe the follow up of 138 ICD and CRTD patients implanted at 3 different Israeli medical centers who were monitored by Home Monitoring Biotronik® system.
Methods and Results: 138 patients [119(86.3%) male, mean age 65.8±10 years, mean EF% 29±7] were implanted with CRTD 51(36.9%), dual chamber ICD 43(31.1%) and single chamber ICD 44(31.9%), during the years 2010 and 2011. Patients were follow up with the Home Monitoring system for a mean of 168±26 days. 25 different alerts were pre-defined, and divided in six groups: Implant alerts, Lead alerts, Bradycardia alerts, Atrial and Ventricular Arrhythmia alerts and Heart Failure alerts. Alerts were sub-classified in Red alerts (imminent potential harm for the patient) and Yellow alerts (non-imminent harm for the patient). A total of 474 alerts were registered during the follow up with 84(60.8%) of the patients having at least one alert, 6(1.26%) of the total alerts were red. 35(7.38%) of the alerts were responded with clinic scheduling, 23(4.85%) of the alerts were responded with a phone call to the patient, 10(4.74%) of the alerts were attended by changing program parameters of the device, 7(1.47%) of the alerts resulted in patient re-operation for lead reposition or device replacement and 399(84.17%) of the alerts required no action.
Conclusion: Home Monitoring of ICD and CRTD devices improved medical care by allowing the prompt recognition and rapid correction of device malfunction.

ICD Therapies in Patients Receiving an ICD for Primary Vs. Secondary Prevention Indications

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Introduction: Data regarding the distribution of implantable cardioverter defibrillator (ICD) therapies in patients receiving an ICD for primary vs. secondary prophylaxis indications are limited.
Objectives: To compare the characteristics, ICD therapies and predictors of appropriate vs. inappropriate therapies in patients receiving ICDs for primary vs. secondary prevention of sudden cardiac death.
Methods: Retrospective analysis of 601 patients receiving ICDs for primary (65%) or secondary (35%) implant indications in a single tertiary medical center between the years 1996-2009 was performed. Baseline characteristics, ICD therapies, and predictors of appropriate vs. inappropriate therapies were analyzed.
Results: Of 210 implants for secondary prevention, 21.4% patients received appropriate ICD therapy for VT/VF whereas only 10.5% of 391 implants for primary prevention received appropriate ICD therapy during median follow-up of 4.3 years ($p<0.001$). In addition, 6.4% of patient with primary prevention indication and 8.6% of patients with secondary prevention indication received ≥ 1 inappropriate shocks ($p=0.335$). Primary implants had more diabetes, more coronary artery disease and higher prevalence of left ventricular ejection fraction (LVEF) < 35%. LVEF < 35% was found to predict appropriate ICD shocks both on univariate (OR 2.03, 95% CI 1.1-3.76; P=0.024) and multivariate analysis (OR 2.37, 95% CI 1.3-5.73; P=0.008). Interestingly, pacing mode (VVI vs. DDD vs. CRT) was not predictive of inappropriate ICD therapy. Mortality was significantly higher in the secondary prevention group (39% vs. 27.4%; $p=0.03$).
Conclusions: Mortality and appropriate ICD shocks for VT/VF were more common among patients who received an ICD for secondary prevention of sudden cardiac death, whereas inappropriate shocks were relatively uncommon without a significant difference between the two groups.