

OptiSense™ Lead Annotated Bibliography

The Effect of Far-field Signals on Device Therapy

Far-field signals and inappropriate mode switching

Kolb C, Wille B, Maurer D et al. Management of far-field R-wave sensing for the avoidance of inappropriate mode switch in dual-chamber pacemakers. Results of the FFS-test study. *J of Cardiovasc Electrophysiol* 2006; 17:992-997.

Summary

A Far-Field Study Test Group trial concluded that optimized post-ventricular atrial blanking (PVAB) period programming played a significant role in reducing the chance of an inappropriate mode switch in pacemakers due to far-field R-wave sensing. St. Jude Medical Identity™ DR or Identity™ ADx DR dual-chamber pacemakers were used on 207 patients (84 sinus nodal disease, 79 atrioventricular block, 35 binodal disease, nine other indications). After implant, 100 randomized patients in the experimental group were given optimized PVAB programming and the 107 control group patients were programmed at regular PVAB. Inappropriate mode switches had occurred in 26% (28/107) of patients with standard PVAB programming at the three-month follow-up. Only 10% (10/100) of patients with optimized PVAB programming experienced inappropriate mode switches during the same period.

Analysis

This study focused on programming PVAB to reduce the incidence of inappropriate mode switch due to far-field R-wave sensing. However, inappropriate mode switches due to far-field R-wave sensing can now be overcome with the OptiSense™ lead (model 1699).

Far-field signals and AF management

Padeletti L, Porciani MC, Michelucci A et al. Interatrial Septum Pacing: A new approach to prevent recurrent atrial fibrillation. J Interv Card Electrophysiol 1999; 3:35-43.

Summary

In a study, researchers concluded that permanent interatrial septum pacing at the posterior triangle of Koch was effective in preventing effects tied to atrial fibrillation (AF). The 34-patient study found that the treatment approach was effective in averting reoccurring arrhythmic episodes with patients who had a prior history of the condition. In a brief follow-up period tracking implants within the experimental group (six with sinus bradycardia, two with second-degree AV block and one with carotid sinus hypersensitivity), there were two occurrences of symptomatic arrhythmia. These results represented a significant drop of AF-related episodes among the experimental group in comparison to before the implant. The results illustrated that the triangle of Koch at coronary sinus ostium level is influential in the initiation of AF. Yet, the researchers conceded that more permanent and randomized studies on patients with and without AF must be conducted in order to test the overall feasibility of the procedure.

Analysis

Interatrial pacing at Koch's triangle significantly reduces interatrial arrhythmic effects and appears to be effective in preventing arrhythmias in sinus bradycardia patients. The OptiSense™ lead allows placement for pacing in the triangle of Koch – a means for AF prevention.

Far-field signals and AF management (cont.)

de Voogt WG, van Mechelen R, van den Bos AA et al. Electrical characteristics of low atrial septum pacing compared with right atrial appendage pacing. *Europace* 2005; 7: 60-66.

Summary

In a study comparing the effects of varied atrial septum placement, researchers found that the electrical characteristics associated with low atrial septum (LAS) were safe and reliable as an alternative to right atrial appendage (RAA) pacing. Tendril™ DX model 1388T active-fixation atrial leads were placed in the RAA in 86 patients and another 86 patients had leads placed in the LAS. There was no difference in the electronic readings of the leads in RAA and LAS during short and mid-term follow-ups. Still, far-field R-wave signals were experienced among both groups (RAA 88% and LAS 93%).

Analysis

The OptiSense lead with its 1.1 mm tip-to-ring spacing allows for more options in targeted lead placement, as well as more sensitive programming of atrial sensitivity levels.

Far-field signals and AF management (cont.)

Nash A, Fröhlig G, Taborsky M et al. Rejection of atrial sensing artifacts by a pacing lead with short tip-to-ring spacing. Europace 2005; 7: 67-72.

Summary

This study concluded that reduced tip-to-ring spacing in a new pacing lead design allows for programming of high atrial sensitivity, eliminating atrial sensed artifacts. By optimizing the bipolar spacing in atrial leads, the study illustrated the role that reduced spacing plays in deterring incidences of far-field R-wave sensing, allowing for more favorable P-wave to far-field R-wave ratio amplitudes. All experiments and readings were performed in 66 patients, and collectively showed more far-field wave sensing with 10 mm tip-to-ring lead spacing. Far-field R-wave sensing was observed in 18.2% (12) of patients with an atrial sensitivity of 0.25 mV and an atrial blanking of 50 ms. Myopotentials still occurred and were sensed in three patients. The measured P-wave amplitude in all patients was two times the estimated amplitude of far-field R-wave at an atrial blanking of 50 ms. Optimal electrical performance was also maintained.

Analysis

Elimination of atrial-sensed artifacts can be achieved by optimizing the bipolar atrial lead design. Reducing the tip-to-ring spacing reduces the incidence of far-field R-wave sensing and improves the amplitude ratio of P-waves to far-field R-waves.

OptiSense™ lead publications and abstracts

de Voogt WG, van Hemel N, Willems A et al. Far-field R-wave reduction with a novel lead design: Experimental and human results. *PACE* 2005; 28: 782-788.

Summary

In a study that compared the experimental results of animals and humans implanted with a bipolar lead designed to decrease far-field R-waves (FFRW), researchers found that the lead played a significant role in decreasing the unwanted signals in humans. Following positive results in trials with nine canines which resulted in the generation of an optimal P-wave to FFRW ratios in OptiSense lead (model 1699) by taking advantage of a tip-to-ring electrode spacing distance of 1.1 mm, similar results were found among 15 human patients. The mean P-wave value in humans was slightly larger in human trials in comparison to animal trials, but the results were not significantly different ($P=0.13$). Pacing settings were comparable in both trials.

Analysis

The most optimal tip-to-ring spacing appears to be 1.1 mm because, at this distance, the ratio between the near-field P-wave and far-field R-wave is maximized. The OptiSense™ lead allowed for a sensitivity setting of 0.3 mV in all patients without sensing far-field signals. This increased sensitivity setting allows for improved detection of atrial tachyarrhythmias.

OptiSense™ lead publications and abstracts (cont.)

Yu C, Sperzel J, Fung, WH et al. Initial Clinical Evaluation of a new far-field signal reduction (FSR) pacing lead in the right atrium. *Heart Rhythm* 2006; 3: 26-27. Abstract.

Summary

Following encouraging studies of a new bipolar lead that yielded effective results in decreasing far-field R-waves in healthy humans and animals, researchers found similar results in pacemaker patients for the first time. By the end of a 90-day follow-up period, the far-field signal reduction leads implanted in the right atrium of standard pacemaker patients were effective at reducing far-field signals while maintaining consistent pacing and sensing performance. It also improved pacemaker performance and therapy.

Analysis

The overall sensing and pacing performance of the OptiSense™ lead was excellent, suggesting that this lead has significant potential to provide improved pacemaker therapy and performance.



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