Clinical Performance of the SYNOX High Impedance Pacemaker Lead

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Summary

Minimizing the geometric surface area of pacing electrodes increases impedance and reduces the current drain during stimulation. This results in a lower current consumption and thus, in greater pacemaker longevity. The influence of the smaller tip in clinical performance was the aim of this investigation in order to assess pacing threshold, sensing parameters, impedance measurements and complications of the high impedance lead SYNOX 60 Bipolar (Biotronik). Between 1996 and 1998 96 "SX60BP" leads have been implanted in the ventricular position at the University of Graz. The mean age of the patients (pts) was 69.4 years (7 - 94 years), 52 males, 44 females. We implanted a DDD pacemaker system in 49 and a VVI system in 47 pts. The mean pacing threshold at implant was 0.28 V @ 0.5 ms (0.1 - 1.0 V), the sensed R wave 14.6 mV (5.7 - 20 mV), the mean lead impedance 1135 Ohm (600 - 1990 W). During the follow-up, the threshold remained stable with 0.72 V @ 0.5 ms at 1 month, 0.76 V @ 0.5 ms at 3 months and 1.0 V @ 0.5 ms at 12 months. Specifically, only two pts had a threshold higher than 1.0 V @ 0.4 ms at 1 month follow-up, at 12 months only 3 pts. One patient developed a chronic threshold increase up to 3.5 V @ 0.4 ms and another patient presented with an exit-block 2 months post implant. The remaining 94 pts could be programmed to a low pacing output of 2.4 V @ 0.4 ms. The impedance measurements markedly decreased after implant but recovered and became stable after 3 months. The overall complication rate was 4.1% including 1 exit-block, 1 perforation and 2 lead dislocations during a follow-up period of 2 years.

Key Words

High impedance lead, small tip

Introduction

High impedance leads were designed to minimize energy consumption by reducing the tip surface in order to achieve lower pacing thresholds [1,2]. However, the small tip surface also has the side effects of increased lead instability and a likelihood of perforation. The purpose of our retrospective evaluation was to assess the clinical performance of the SYNOX 60 BP lead from Biotronik. This lead has a very small tip area of only 1.3 mm² and is fractally coated for better sensing behavior.

Materials and Methods

96 patients (52 male, 44 female) with a mean age of 69.4 years (7 - 94) were implanted with a SX60BP lead at the University of Graz in the years from 1996 to 1998. The pacing system was a DDD in 49 and a VVI pacemaker in 47 cases. Pacing lead impedance, pacing threshold and R wave sensing were measured at implant with an ERA 20 pacing analyzer and at the 1st, 3rd, 12th and 24th months follow-up by telemetric measurements of the implanted pacemaker.

Results and Conclusion

At implant a low acute threshold was obtained with a mean value of 0.28 V at 0.5 ms pulse width (0.1 - 1.0 V). The mean impedance value was 1135 Ω with a wide range from 600 - 1990 Ω. Lower impedance was not associated with higher pacing thresholds. The mean R-wave amplitude was 14.6 mV (5.7 to 20 mV). The implantation procedure was complicated in two

SX60BP	Implant	1 month	3 months	12 months	24 months
n	96	56	41	22	13
threshold (V)	0.28	0.72	0.76	1.0	
range (V)	0.1 - 1	0.3 - 3	0.4 - 2.5	0.3 - 3.5	
impedance (Ω)	1135	926	1088	986	1053
range (Ω)	600 - 1990	624 - 1410	679 - 1610	821 - 1200	683 - 1300

Table 1. Pacing threshold and impedance during follow-up.

patients. One patient developed ventricular fibrillation and needed defibrillation. In another patient, positioning of the lead proved to be extraordinary difficult with multiple intraoperative dislodgment. Table 1 shows the different results obtained during the follow-up.

The threshold showed a rise to 0.72 V at 1 month with only 2 leads developing a threshold over 1.0 V at 0.5 ms. One patient developed a high threshold with the need of corticoid therapy. Otherwise, the low chronic threshold remained stable over time, so that the pacemaker could be programmed to low output settings.

The mean lead impedance showed a significant decrease between implant and first follow-up.

The range of lead impedance values was large with a peak decrease of 835 Ω and a peak increase of 364 Ω one month after implant. The one lead with a high chronic threshold had an initial impedance of 1330 Ω which markedly decreased to 679 Ω during the first month and then remained stable (12 months follow-up). On the other hand the lead with the highest decrease in impedance (835 Ω) had a very low and stable threshold of 0.5 V at 0.5 ms. We were not able to predict threshold behavior by impedance measurements [3,4]. At the 3rd month follow-up, the chronic impedance recovered to higher levels and became stable, though remaining below initial values. The mean decrease to implant was 352 Ω (max.1084 Ω).

The overall complication rate during the follow-up period of up to 2 years was 4.1% (4 cases): 2 lead dislocations occurred within the initial postoperative period with need of revision. In another case, perforation with loss of capture was seen 5 days after implant and one patient presented with exit-block two months post implant. The lead had to be replaced.

In conclusion, we need to state the fact, that handling a small tip lead requires special care for finding a stable lead position and not perforating the myocardial wall. Once positioned well and in the hand of an experienced implanter, the Synox 60 bipolar lead showed very low and stable pacing thresholds with a high chronic lead impedance. 98% of the patients could be programmed to a low output settings at 2.4 V at 0.5 ms. Thus, pacemaker longevity is increased.

Reverences

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