Acute Changes in the Pacing Threshold After Lead Implantation
Comparison Between Retractable and Sweet-Tip Active-Fixation Leads
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Summary

Although the pacing threshold of steroid-eluting active-fixation leads remains stable over the long term, it changes rapidly after screw-in. We compared the pacing threshold in the acute phase between retractable and Sweet-Tip active-fixation leads. We studied 132 patients who were implanted with active-fixation leads for new pacemaker implantation or additional leads required due to disconnected/leaking leads. Pacing threshold was measured at 4 time points: before screw-in, immediately, and 5 and 10 minutes after screw-in. If the pacing threshold was > 1.5 volts (V) at 5 minutes, we changed the pacing site so that it became ≤ 1.5 V. A total of 169 retractable leads (Medtronic: 107 leads, St. Jude Medical: 62 leads) and 33 Sweet-Tip leads (Boston: 33 leads) were implanted. Eighty-nine leads were implanted in the atrium and 113 leads in the ventricle. Seventy patients were implanted with both atrial and ventricular leads. The pacing threshold of Sweet-Tip leads increased immediately after screw-in, while that of retractable leads decreased (Sweet-Tip: 0.20 ± 0.57 V, Retractable: -0.15 ± 0.53 V, P < 0.05). The pacing threshold of both types of leads decreased similarly from immediately to 5 minutes after screw-in (Sweet-Tip: -0.29 ± 0.43 V, Retractable: -0.25 ± 0.36 V, P = NS). Few changes in the threshold were detected between 5 and 10 minutes. Because the pacing threshold of Sweet-Tip active-fixation leads increased immediately after screw-in and that of both type leads decreased from immediately to 5 minutes, we should measure the pacing threshold from 5 minutes after screw-in. (Int Heart J 2012; 53: 108-112)

Key words: Pacemaker, Lead implantation, Active-fixation lead, Retractable lead, Sweet-Tip lead

In pacemaker implantation, there is a global shift toward the use of active-fixation leads with the advantage of reduced lead dislodgement, rapid implantation, and easier lead extraction than passive-fixation leads. There has also been an interest in atrial and ventricular selective-site pacing and active-fixation leads are required for secure attachment to selective sites. Initially, the high pacing threshold, including pacing failure, was observed in nonsteroid active-fixation leads about 1 week after implantation, but in steroid-eluting active-fixation leads, the pacing threshold remains stable over the long term. In the acute phase of lead implantation, the pacing threshold was reported to decrease within several minutes after screw-in. Nevertheless, we have experienced cases in whom the pacing threshold increased rapidly after that. It was speculated that the myocardium was temporarily injured by the screw, but then recovered in several minutes. We believe that construction differences in the screw-in system influenced the change in the pacing threshold. We therefore compared the pacing threshold in the acute phase between retractable and Sweet-Tip active-fixation leads.

Methods

Lead implantation: From May 2006 to November 2008, we studied 132 patients who underwent implantation of active-fixation leads for new pacemaker implantation (n = 110) or additional leads required due to disconnected/leaking leads (n = 22). Eighty-nine patients received atrial leads and 113 patients ventricular leads. Among these patients, 70 were implanted with both leads (Table).

We implanted two types of active-fixation leads: retractable active-fixation leads (5076-52/58 cm; Medtronic Inc., Minneapolis, MN, USA; and 14885-52/58 cm, 16885-52/58 cm; St. Jude Medical, St. Paul, MN, USA) and Sweet-Tip active-fixation leads (4470-52 cm, 4471-58 cm; Boston Inc., St. Paul, MN, USA). We had selected Medtronic or St. Jude Medical leads from May 2006 to June 2007 and Medtronic, St. Jude Medical, or Boston leads from July 2007 to November 2008 by rotation. However, patients with sick sinus syndrome and first-degree atrioventricular block were preferentially implanted with Medtronic leads in order to reduce ventricular pacing using the Managed Ventricular Pacing (MVP®) function. Patients with paroxysmal atrial fibrillation were preferably implanted with Medtronic leads in order to prevent atrial fibrillation (AF Suppression™ algorithm) or Sweet-Tip leads for selecting atrial septum more easily as a pacing site. Patients who required additional leads due to disconnected/leaking leads in pacemaker replacement were given the same lead from the same company as previously used. In the end, 76 patients were implanted with Medtronic leads, 36 with St. Jude Medical leads, and 20 with Boston leads (Table).
To compare acute changes in the pacing threshold over time, pacing thresholds at a pulse width of 0.6 milliseconds were measured at 4 time points: before screw-in, and immediately, and 5 and 10 minutes after screw-in. If the pacing threshold was > 1.5 volts (V) at 5 minutes, we changed the pacing site so that it became ≤ 1.5 V.

**Statistical analysis and informed consent:** Data are expressed as the mean ± SD. Patient characteristics among pacing lead companies were compared using one-way ANOVA. The pacing threshold over time was compared using repeated-measure ANOVA. Comparisons of the pacing threshold at each measurement point were evaluated using one-way ANOVA. \( P < 0.05 \) was considered statistically significant. Informed consent was obtained from all patients for pacemaker and lead implantation and for measuring pacing threshold several times.

### RESULTS

**Patient characteristics:** A total of 169 retractable leads and 33 Sweet-Tip leads were implanted. For the retractable leads, 107 were from Medtronic and 62 were from St. Jude Medical. The patient characteristics are shown in the Table. There were no significant differences among the groups.

**Pacing threshold of retractable and Sweet-Tip leads:** The time courses of the pacing threshold of retractable and Sweet-Tip leads measured at 4 time points are shown in Figures 1 and 3A. The mean pacing threshold of Sweet-Tip leads increased.
immediately after screw-in, while that of retractable leads decreased (Sweet Tip: 0.20 ± 0.57 V, Retractable: -0.15 ± 0.53 V, P < 0.05). The pacing threshold of both leads decreased similarly from immediately to 5 minutes later (Sweet Tip: -0.29 ± 0.43 V, Retractable: -0.25 ± 0.36 V, P = NS). Few changes were detected between 5 and 10 minutes later. The ratio of the pacing threshold increase from before to immediately after screw-in was higher in Sweet-Tip leads than in retractable leads (Figure 4).

**Pacing threshold of two types of retractable leads:** We compared the pacing threshold between two types of retractable leads: Medtronic and St. Jude Medical (Figures 2 and 3B). There was no significant difference in the time trend of the pacing threshold between the retractable leads, although the mean pacing threshold of Medtronic leads decreased and that of St. Jude Medical leads exhibited little change immediately after screw-in.

**DISCUSSION**

The use of active-fixation leads has been increasing as they have the advantages of rapid implantation and easier extraction than passive-fixation leads. Active-fixation leads have also been used for selective site pacing, such as ventricular septum, RVOT, or atrial septum pacing. A high pacing threshold was observed in nonsteroid active-fixation leads about 1 week after implantation, but in steroid-eluting active-fixation leads, the pacing threshold remained stable over the long term. It is believed that the screw of leads could injure the myocardium and accelerate inflammation, which would be healed by steroids eluted from the leads.

**Comparison between retractable and Sweet-Tip leads:** Active-fixation leads consist of two types: retractable and Sweet-Tip. Retractable leads have a tip designed for helix extension/retraction and Sweet-Tip leads have a screw-in helix, covered by a dissolvable mannitol capsule that protects the tissue during lead insertion. Sweet-Tip leads require some technique for handling. For example, if they become stuck in the myocardial muscle or vessel wall, they should be pulled while being turned counterclockwise. Nevertheless, Sweet-Tip leads are advantageous in terms of being easier to hook and fix into the selective site, such as the ventricular and atrial septum, because the screw is bare. In this study, we compared the pacing threshold in the acute phase between retractable and Sweet-Tip active-fixation leads. The pacing threshold of both leads decreased over time after screw-in, as previously reported, but the ratio of the pacing threshold increase from before to immediately after screw-in was higher in Sweet-Tip leads than in retractable ones. Several factors affect the pacing threshold: the response of the myocardium to electrical stimulation, the timing when steroids come into effect, and the stability of the electrode attachment to the myocardium.

Firstly, the response of the myocardium to electrical stimulation depends on the myocardium itself rather than the lead properties. Secondly, the timing when steroids come into effect may not differ between retractable and Sweet-Tip leads because the mechanisms of steroid elution from the lead tip are the same. In both type leads, a steroid-eluting collar is attached at the lead tip so that the steroids will affect the pacing threshold for at least 5 years. Thirdly, the stability of the electrode attachment to the myocardium is influenced by lead properties; therefore, the difference in the pacing threshold between retractable and Sweet-Tip leads in the acute phase may be affected mainly by the stability of the electrode attachment to the myocardium.

Before screw-in, the electrodes touch the myocardium faster in Sweet-Tip leads than in retractable ones because the
helix of the Sweet-Tip lead is bare. There were some cases whose pacing threshold before screw-in exhibited $> 1.5$ V, especially in retractable leads. In these cases, the cathode electrode, which is the lead helix, would attach to the myocardium loosely. It seems that air bubbles at the lead tip in retractable leads may also influence the pacing threshold before screw-in. As a whole, the pacing threshold of retractable leads became higher than that of Sweet-Tip leads before screw-in. There were some cases whose pacing threshold increased from before to immediately after screw-in in not only Sweet-Tip but also retractable leads. Nevertheless, there were more cases whose pacing threshold decreased immediately after screw-in in retractable leads than Sweet-Tip ones. Overall, the pacing threshold decreased in retractable leads and increased in Sweet-Tip leads immediately after screw-in. In retractable leads, improvement of the stability of the electrode attachment to the myocardium appears more emphasized than in Sweet-Tip leads. On the contrary, in Sweet-Tip leads it seems that the pacing threshold was increased by myocardial injury induced by screw-in, although myocardial injury would be induced to the same degree for both Sweet-Tip and retractable leads. Nevertheless, it is more important that the pacing threshold of both types of leads decreases in the first several minutes after screw-in. Myocardial damage induced by screw-in would be diminished within a few minutes; therefore, we should measure the pacing threshold not immediately but several minutes later. The pacing threshold at 10 minutes later was slightly lower than at 5 minutes later, but the difference was very small. Thus, we can efficiently determine the fixation site by measuring the pacing threshold at about 5 minutes later so as not to increase the operation time. The pacing threshold was supposed to be measured more frequently such as every 2 minutes, however, we must minimize any extra time that may be required. Thus, we did only 5 minutes and 10 minutes later. In this study, we were not able to definitively ascertain the precise timing to measure the pacing threshold. However, we believe it should be done not immediately, but rather after several minutes. We believe an appropriate rough indication is after about 5 minutes.

Comparison between two types of retractable leads: There was no significant difference in the time trend of the pacing threshold between the two types of retractable leads, but the pacing threshold of Medtronic leads decreased and that of St. Jude Medical leads exhibited little change from before to immediately after screw-in. The tip of the St. Jude Medical leads consists of a metallic tube, while that of the Medtronic leads is composed of a silicon cylinder. Therefore, the helix of Medtronic leads, which function as the cathode electrode, would attach to the myocardium looser than that of St. Jude Medical leads before screw-in. There were more cases whose pacing threshold before screw-in exhibited $> 1.5$ V in Medtronic leads than in St. Jude Medical leads. That is believed to be due to the same reason. After screw-in, the pacing threshold of both leads decreases over time in the same way; thus, the lead properties need not be considered several minutes later. If the pacing threshold is measured before screw-in, we should take the lead type, such as retractable or Sweet-Tip, and the shape of the tip into consideration. In retractable leads, the pacing threshold would be lower 5 minutes after than before screw-in. On the other hand, in Sweet-Tip leads, the pacing threshold would increase immediately after screw-in and then decrease 5 minutes later.

Recently, new leads have become available: 2088TC-52/58cm (St. Jude Medical). These leads have soft covers over the tip to diminish the risk of lead perforation. We do not have data on the pacing threshold of these new leads, and it will be studied in the future.

Clinical implications: The results of this study are helpful for lead implantation. If the pacing threshold before screw-in is $\leq 1.5$ V, the pacing threshold 5 minutes later will also be $\leq 1.5$ V; thus, we can reduce the times of the screw-in-measurement-repositioning procedure. In addition, even if the pacing threshold before screw-in is $> 1.5$ V, it decreases over time and could become $\leq 1.5$ V after 5 minutes, especially in the case of retractable leads. In such cases we should wait for about 5 minutes and then measure again.

Study limitations: There were two major study limitations. First, the number of patients implanted with Sweet-Tip leads was small because we had begun to use Sweet-Tip leads in July 2007 in our hospital. Moreover, choosing a lead from a specific company based on the situation of the patients may have influenced the study population bias. However, there were no significant differences in patient characteristics between the retractable and Sweet-Tip lead groups. Second, we do not have long-term follow-up data on pacing thresholds measured under the same conditions as during lead implantation; however, the pacing threshold was measured 1 week later and repeated regularly by each company’s programmer in all cases. Except for a few cases in which the pacing threshold rose 1 week later as a result of lead dislodgment, there was no or little change in the pacing threshold.

Conclusion: The pacing threshold of Sweet-Tip active-fixation leads increased immediately after screw-in and the pacing threshold of both types of leads decreased from immediately to 5 minutes. Therefore, we should measure the pacing threshold not immediately but about 5 minutes later.

References


