Abstract: P2855

Unexpectedly high rate of lead failure of the Microport (formerly Sorin/Livanova) Beflex and Vega pacemaker electrodes: A single centre experience

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Topic(s):
Device Complications and Lead Extraction

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INTRODUCTION

Pacing leads remain the weak link of current pacemaker systems. Various differences in design and material exist among companies. Lead performance is mainly assessed via post-marketing studies of the manufacturing companies. Reliable independent reports are rare. We aimed to study the early and long-term performance of the Microport (formerly Sorin/Livanova) Beflex and Vega leads at our centre, for which a lead survival >99% at 3 years has been reported by the company.

METHOD

In this single centre, retrospective study we analysed the performance of all right ventricular Microport pacemaker leads implanted at our centre between January 2014 and January 2018. Only first pacemaker implants were considered. Lead failure was defined as any lead issue requiring reintervention during follow-up (dislocation, perforation, electrical abnormalities such as lead noise or excessively high thresholds).

RESULTS

A total of 271 Microport right ventricular pacing leads were implanted (233 Beflex and 38 Vega leads). Mean patient age was 76±13.1 years (66% men). Dual chamber pacemakers were implanted in 162 patients (60%) and single chamber in 109 (40%). Mean threshold at implant was 0.6V/0.5ms (range 0.3-1.2V), mean R wave 13.2 mV (range 1.5-30mV) and mean impedance 816 Ohm (range 469-1639 Ohm). Patients without available follow-up information were excluded (N=18, 6.6%). The remaining 253 patients (93.4%) were analysed. Median follow-up was 1.26 years, IQR [25%=0.91 and 75%=2.24]. We observed a total of 25 lead failures (10%). Lead dislocation occurred in 2 cases (0.8%), lead perforation in 5 cases (2%), electrical abnormalities in 6 cases (2.4%) and excessively high threshold in 12 cases (4.8%; mean voltage 4V, range 2-7.5V; mean pulse width 0.75ms, range 0.35-1ms). Yearly incidence of lead failure per 100 leads was 6.1% (95%-CI [4.09-8.98] with a failure rate of 12.74% at 3 year in Kaplan-Meier analysis (Figure).

CONCLUSION

We found an unexpectedly high rate of lead failure of the Microport Beflex and Vega pacing leads at our centre. The two main reasons for premature lead failure were excessively high thresholds as well as electrical abnormalities during follow-up. Comparison of lead performance with other centres and against other leads are needed to further assess the magnitude of the problem.
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