The BIO|CONCEPT.BIOMONITOR III study: Sensing performance and Home Monitoring transmission success of a new miniaturized Implantable Cardiac Monitor

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Introduction: Implantable Cardiac Monitors (ICMs) are widely used for the long-term detection and monitoring of cardiac arrhythmias. The BIOMONITOR III device (BM III, Biotronik, Germany) is a novel miniaturized ICM. BM III uses the established BIOTRONIK Home Monitoring system to transmit daily messages that contain arrhythmia detection statistics, subcutaneous ECG episodes and data on device sensing performance. In BM III, fractal coating of electrode tips and improved signal filtering were introduced to improve visibility of P-waves signals as an important diagnostic criterion.

Methods: In this prospective, non-randomized trial (CT-ID: NCT03850327), we investigated the sensing performance of the BM III device in 47 patients at 10 Australian sites. Patients were enrolled with ICM-indications of syncope/pre-syncope, cryptogenic stroke and AF monitoring. During a 1-month observation period, Home Monitoring data were evaluated for R-wave amplitude, noise burden and overall home monitoring transmission success. Noise burden is the fraction of daily time during which sensing is restricted by noise, e.g. electrical interference or muscle potentials. Transmission success is the percentage of days with a message between first and last message. Additionally, 15 investigators assessed ECG recordings for visibility of P-waves, which is reported as fraction of expected P-waves which were unequivocally identified by the physician.

Result: 44 patients transmitted data. The overall transmission success was 96.7%. Averaged R-waves from 44 patients were 0.69 +/- 0.38 mV. Reported separately for each week after insertion, amplitude values showed no recognizable trend. The daily variability of the R-wave was 0.044 +/- 0.028 mV (standard deviation of R-waves of each patient). After one week, noise burden stabilized near 1%, with 0.9 +/- 1.7% in week 2 and 1.1 +/- 1.9% in week 4 after insertion. Periodic subcutaneous ECGs from the Home Monitoring Service Centre were evaluated by 15 investigators. Evaluation of 83 sECGs from 28 patients yielded a mean P-wave visibility of 91.3 +/- 22.1%, with a median value of 100%. Low P-wave visibility was a rare exception, so that a major fraction of assessments (83%) showed a P-wave visibility of >90%.

Conclusion: Analysis from Home Monitoring data from this clinical investigation showed that the novel BM III provided the established high level of transmission success during the 1-month observation period. The mean R-wave amplitude of 0.69 mV corresponds to the long sensing vector which is derived from the predecessor device, BioMonitor 2. Low noise burden and excellent P-wave visibility of BM III
represent improvements in sensing performance which might increase the diagnostic value of BM III.