The BIO|CONCEPT.BIOMONITOR III study: Insertion success and procedure assessment of a new miniaturized Implantable Cardiac Monitor

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Introduction: Implantable Cardiac Monitors (ICMs) are suitable for long-term detection and monitoring of cardiac arrhythmias. The BIOMONITOR III device (BM III, BIOTRONIK, Germany) is a novel ICM combining a miniaturized profile while retaining the long sensing vector of the predecessor device, the BioMonitor 2. The BM III is available with a new two-pieces toolset for a fast injection-like procedure. The incision tool has a blade of stainless steel to enable an appropriate incision through the skin. The Fast Insertion Tool (FIT OneStep) supports device pocket formation and device placement in a simplified, single-step procedure.

Methods: In this prospective, non-randomized trial (CT-ID: NCT03850327), we investigated insertion success of the BM III device in 10 Australian investigation sites. 48 patients with any indication for an ICM were enrolled and followed up for one month. 15 investigators performed device insertions and assessed the insertion procedure and both tools. Additionally, times between first skin cut and procedure completion (including / excluding wound closure procedures) were measured. Assessment results were rated by means of a symmetrical 5-step scale ranging from 1 ("very poor") to 5 ("excellent").

Result: Primary indications reported for BM III insertion were syncope or pre-syncope in 28 patients (58%), AF monitoring in 15 patients (31%) and cryptogenic stroke in 5 patients (10%). In total, 47 insertions were performed and assessed. One patient did not receive a device for organizational reasons. All 47 insertion attempts were successful (100% insertion success rate). The median time from skin cut to device placement was 39 sec [IQR: 19 - 65], excluding wound closure. Including wound closure, the median procedure time was 4.1min [IQR: 2.0 - 5.0]. No device repositioning was performed. The investigator rating regarding both tools as well as the rating on overall insertion performance was on average 4.8 out of 5, with a median value of 5 ("excellent"). The reasonability of different tool features were assessed as "excellent" in >80% of all cases. “Force needed for tunnelling” was rated "fair" in 9 %, “good" in 34 % and “excellent” in 57 % of all cases. All assessments ranged from fair to excellent. Throughout the trial, neither procedure-related adverse events nor serious adverse device effects occurred. One device malfunction due to cardioversion was reported. Two cases of device extrusion were caused by a handling error and resolved without sequel.

Conclusion: Data from this clinical investigation suggest that the newly developed insertion tools and insertion procedure for BM III achieved convincing results in terms of implantation success, procedure
duration and physicians assessments of insertion results. The data did not reveal any unexpected safety findings.