Arrhythmias - Holter Monitoring

Real-world experience with the insertion of a new implantable cardiac monitor

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Background: Implantable Cardiac Monitors (ICM) provide continuous long-term heart rhythm monitoring. The new ICM BIOMONITOR III / IIIm (BM III) is provided with a single-step insertion tool.

Purpose: To report on the insertion procedure of the BM III in a large real-world patient population.

Methods: The BM III combines a low cross-section (4.5 x 8.5 mm) with an extended ICM length (77 mm, including flexible antenna). It is inserted into subcutaneous tissue with an ‘injection’ tool that forms the pocket and delivers the device in a single step. We report results of the insertion procedure from a pooled data set from the BIO|CONCEPT BM III (completed) and the BIO|MASTER BM III and BIO|STREAM-ICM (ongoing) studies.

Results: From 54 investigational sites in 11 countries, 455 insertions were reported (including 39 BM IIIm). The patients were 63 ± 16 years old, had a BMI of 27.6 ± 5.4, and 43% were women. The indications were syncope or pre-syncope (57%), cryptogenic stroke (23%), management of AF (11%) or other (9%). Insertions took 1.7 ± 1.8 minutes until removal of the insertion tool, 4.7 ± 3.4 minutes until wound closure, and 7.1 ± 5.6 minutes including wound cleaning. The wound was sutured (79%) or closed with staples (10%) or adhesive strips (10%). General anaesthesia was used in 8% of the patients and antibiotic prophylaxis in 50% (44% systemic and 6% local). Insertions took place in the catheter laboratory (62%), operating theatre (22%) or in a consultation room (16%) without specific precautional equipment.

The insertion site was parallel to the heart"s long axis (56%), parasternal (39%), in the 2nd/3rd intercostal space (3.5%), axillary (0.9%) or at the clavicula (0.7%). The device was repositioned in one case (0.2%). 13 adverse events were reported in connection to the insertion procedure. 5 cases of device pocket bleeding or hematoma occurred. In 5 further cases, the device migrated, posing the risk of extrusion, or actually extruded. Three of these cases used only adhesive strips or no wound closure at all. In two cases, an incorrect usage of the incision tool and substantial subcutaneous fatty tissue may have contributed. One device was damaged by a 200 J defibrillation shock with a shock electrode placed over the device. One patient suffered from dyspnoea, possibly due to psychogenic hyperventilation. One patient had a vasovagal syncope due to pain after an insertion with insufficient local anaesthesia. No infections were reported until the day of analysis, which was more than 30 days after insertion in 92% of all cases.

Conclusion: The new BM III was inserted in typically less than 5 minutes until wound closure. A relevant number of insertions took place in a consultation room. Prophylactic antibiotics may be unnecessary, because no pocket infections were reported, although no antibiotic prophylaxis was used in one half of all cases (N = 229). In summary, the insertion with the new tool is fast and has a low risk of complications.