SHORT COMMUNICATION

Watchman FLX: the initial Polish experience with a new device for left atrial appendage occlusion

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Introduction Convincing data from randomized trials and several meta-analyses have shown that left atrial appendage (LAA) occlusion could be used as an alternative to oral anticoagulation (OAC).[1-3] In Europe, based on the current recommendations of the European Society of Cardiology and Polish Cardiac Society, LAA occlusion has emerged as a common procedure for stroke prevention in patients with atrial fibrillation and contraindications to OAC.[4] Despite a high success rate and low procedural risk associated with the current generation of the Watchman device, Watchman 2.5 (Boston Scientific, Marlborough, Massachusetts, United States), a new generation of the device has been developed, namely, Watchman FLX.[5,6]

The aim of the study was to analyze data on the implantation technique, procedural safety, complications, and patient outcomes in a single-center registry summarizing early experience with the new generation of the Watchman FLX LAA occluder.

Material and methods During the study, Watchman FLX was used as the first-choice device for all patients scheduled for LAA occlusion (patients included in the Watchman FLX LMR and Watchman FLXibility registries). The study group (the second largest in Europe) included 38 patients (24 men and 14 women) at a mean (SD) age of 70.4 (7.5) years. The mean (SD) CHA_2DS_2VASc and HAS-BLED scores were 4.7 (1.4) and 3.5 (0.9), respectively. Previous ischemic stroke or transient ischemic attack was reported in 15 patients. Indications for LAA closure were as follows: gastrointestinal bleeding (n = 15); intracranial hemorrhage (n = 9); other bleedings (n = 6); stroke during treatment with OACs or non–vitamin K antagonist oral anticoagulants (NOACs; n = 5); and other absolute contraindications to OAC or NOACs (n = 3). The most common LAA morphology was broccoli (n = 22), chicken-wing (n = 7), windsock (n = 7), and other (n = 3).

All LAA closure procedures were done under general anesthesia with vascular access from the femoral vein. Transseptal puncture was undertaken under transesophageal echocardiography (TEE) guidance. Next, the Watchman True Seal access sheath was advanced over a stiff guidewire into the left upper pulmonary vein and then repositioned to the LAA over a 6F pigtail catheter. The morphology of LAA was analyzed on TEE and angiography for proper device selection. The Watchman delivery system was prepared and flushed, inserted into the access sheath, and advanced under fluoroscopic guidance. The device was then deployed into the LAA, first forming a "ball" and then using one of the following techniques: 1) unsheathe method (like with Watchman 2.5); 2) advancement method; or 3) a combination of both methods. A 10-second push forward on the distal knob maneuver was then carried out, which helped better engage fixation barbs and conform the implant to LAA walls. The proper position of the device was confirmed by TEE and fluoroscopy. If the position was not optimal, the device could be repositioned several times both proximally and distally using the "ball technique." The standard PASS criteria (position, anchoring, size, seal) for device release were then analyzed. The tug test was then carried out to confirm the stability before the final device release.

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All patients were included in the Watchman FLX LMR and Watchman FLXibility registries. The study was approved by a local ethics committee. Prior to inclusion, all patients received detailed information on the risks and benefits of the procedure and signed informed consent.

Results and discussion The LAA closure procedure was successful in all 38 patients, without the need for intraprocedural changes of the device size in all except 1 patient (1.026 devices per patient). None of the patients had gaps around the device of more than 5 mm (there were gaps of 1–3 mm in only 3 patients). The first position of the device was appropriate in 17 patients (44.7%). Partial recapture (1–5 per patient) was necessary in 21 patients (55.3%): 13 of the 18 patients (72.2%) during initial experience with the device and 8 of the 18 patients (44.4%) in the second cohort of patients. The combined ball technique of implantation was used in all 38 patients (100%).

The mean (SD) final maximum diameter of the implanted Watchman FLX device was 22.2 (4.8) mm, with the mean (SD) compression of 21.1% (4.2%). The mean (SD) procedure time was 27 (9) minutes (min–max, 15–54 minutes). The distribution of Watchman FLX sizes used during the study was as follows: 20 mm (n = 0), 24 mm (n = 12), 27 mm (n = 13), 31 mm (n = 9), and 35 mm (n = 4). No cases of device embolization, pericardial effusion, or periprocedural stroke were observed in our cohort. A total of 33 patients were switched to dual antiplatelet therapy after LAA occlusion, and 5 patients remained on OACs (the group with stroke on OAC or NOACs).

Three-month follow-up data are so far available for 27 patients. There were no serious adverse events, including stroke or severe bleeding. The position of the device was unchanged in all patients. We did not observe any thrombi on the device. Leaks around the device (less than 3 mm) were noted in 2 patients.

Watchman FLX is the new generation of the LAA closure system, available in Europe since March 2019. The device has several new features when compared with the current generation of Watchman 2.5 but also with the previous generation of Watchman FLX, which was withdrawn from the market by Boston Scientific at the end of March 2016 due to a higher device embolization rate (3.8%) than initially predicted (although our own observations were quite satisfactory even with the previous generation).[7]

The new Watchman FLX device has been significantly redesigned, although the key benefits of its previous version were maintained. The device comes in 5 sizes (20 mm, 24 mm, 27 mm, 31 mm, and 35 mm) for LAA ostia measuring from 14 mm to 31.5 mm. Therefore, compared with the current generation of Watchman 2.5, both smaller and larger LAA ostia can be treated. Due to the reduced device length, implantation even in shallower LAA anatomies is now possible (a minimum required depth is only 50% of the device size). Watchman FLX has the nitinol 18-strut frame structure (10-strut frame in Watchman 2.5), with self-expanding properties. It not only provides more contact points of the device to the LAA ostium but also expands radially to maintain a proper position in the LAA. Permeable polyester fabric (extended more distally than in Watchman 2.5) covers the part of the device facing the left atrium. Closed distal end with a fluoroscopic marker is atraumatic and enhances procedural guidance. Eighteen "J" fixation anchors in 2 rows (10 anchors in one row

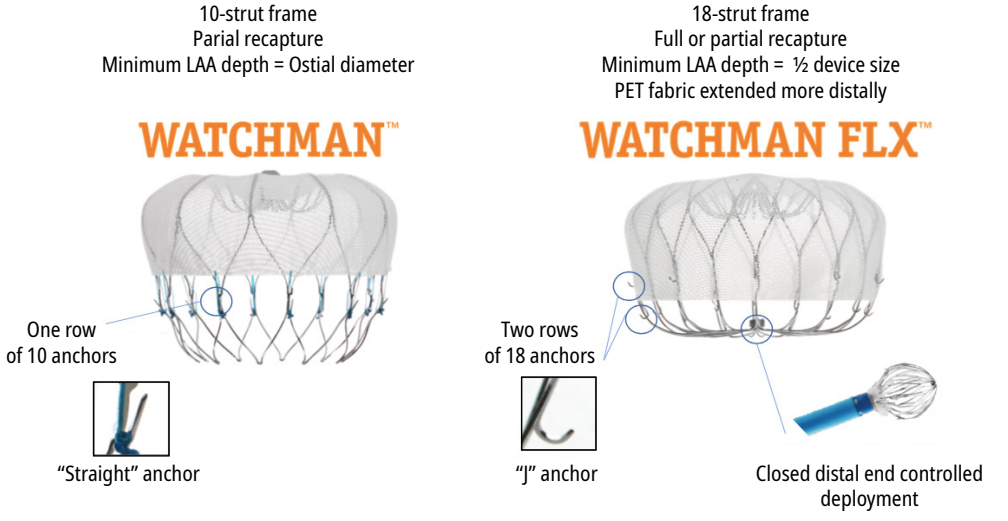

FIGURE 1 Key feature changes of Watchman FLX in comparison with the previous Watchman 2.5 device: an 18-strut frame vs 10 struts for Watchman 2.5, closed distal end with a fluoroscopic marker, reduced device length, 2 rows of the "J" shape anchors (9 in each row), and more permeable polyester fabric that extends down to the distal row of the anchors.

in Watchman 2.5) are located more distally than in Watchman 2.5 and facilitate device stabilization in various LAA anatomies. Due to the intra-LAA placement, the contact of the device with the left atrial wall is reduced and potential interference with the left upper pulmonary vein and mitral valve is minimized. The new Watchman FLX device can be recaptured several times into the access sheath and repositioned either proximally, as the current generation of the device, or advanced distally before the final release due to the atraumatic closed distal end and the use of the new ball technique, which helps position the device properly and safely. Thanks to the optimized frame shape, the delivery and recapture of the device is smoother and easier than with Watchman 2.5. The new version of Watchman FLX is preloaded in the novel delivery system—Watchman True Seal (Boston Scientific) (14F outer diameter compatible with all FLX device sizes). It comes in 3 curve configurations—single, double, and anterior—for different LAA anatomies. The key feature changes of Watchman FLX in comparison with Watchman 2.5 are presented in FIGURE 1.

In conclusion, periprocedural and short-term follow-up data from the Polish single-center registry seem to suggest that the new Watchman FLX occluder is safe and highly effective in LAA closure. However, the performance and safety of the device, although very promising, should be confirmed in a larger series of patients, with the involvement of other centers and operators.

ARTICLE INFORMATION

CONFLICT OF INTEREST MG is a proctor for Watchman and an advisory board member for Boston Scientific. The other authors do not declare any conflicts of interest.

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