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Authors: Marek Grygier, Agata Markiewicz, Aleksander Araszkiewicz, Anna Babicz-Sadowska, Rafał Płaksej, Anna Komosa, Olga Trojnar ska, Maciej Lesiak

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

Authors: Marek Grygier MD PhD, Agata Markiewicz MD, Aleksander Araszkiewicz MD PhD, Anna Babicz-Sadowska MD*, Rafał Plaksej MD PhD*, Anna Komosa MD PhD, Olga Trojnarska MD PhD, Maciej Lesiak MD PhD

From: Chair and 1st Department of Cardiology, Poznan University of Medical Sciences, Poznan, Poland

* Cardiology Department, Copper Health Center, Legnica, Poland

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Corresponding Author:
Marek Grygier MD PhD
Chair and 1st Department of Cardiology,
Poznan University of Medical Sciences
Długa ½ 61-848 Poznań/Poland
Phone/Fax: +48618549223
e-mail: mgrygier@wp.pl

Conflict of interest
Marek Grygier – proctor for Watchman and Advisory Board Member for Boston Scientific
Agata Markiewicz – no conflict of interests
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Olga Trojnarska – no conflict of interests
Maciej Lesiak – no conflict of interests
INTRODUCTION

Convincing data from randomized trials and several meta-analysis have shown that left atrial appendage (LAA) occlusion could be used as alternative to oral anticoagulants [1-3]. In Europe, however, based on current recommendations of 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 contraindication for oral anticoagulation [4]. Despite high success rate and low procedure risk associated with current generation of Watchman device - Watchman 2.5 (Boston Scientific, Marlborough, USA) a new generation of the device – the Watchman FLX - is now available [5-6].

AIM OF THE STUDY

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

MATERIAL AND METHODS

During study period Watchman FLX was used for all patients scheduled for LAA occlusion as the first choice device (patients included in Watchman FLX LMR and Watchman FLXibility registries). The study group (the second largest in Europe) comprised of 38 patients (24 males and 14 females). Mean patients age was 70.4±7.5 years, CHA₂DS₂VASc 4.7±1.4 and HAS-BLED 3.5±0.9. 15 patients in the study group had previous ischemic stroke or TIA. The indications for LAA closure were: a) gastrointestinal bleeding – 15 patients; b) intracranial haemorrhage – 9 patients; c) other bleedings – 6 patients; d) stroke during treatment with OAC/NOACs – 5 patients; e) other absolute contraindications to OAC/NOACs
– 3 patients. 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 femoral vein. Transseptal puncture was undertaken with transoesophageal echocardiography (TEE) guidance. Then, 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 the 6F pigtail catheter. The morphology of LAA was analysed in TEE and angiography for proper device selection. The Watchman delivery system was prepared and flushed, inserted into the access sheath, and advanced with fluoroscopic guidance. The Watchman FLX device was then deployed into the LAA first forming “a ball” and then deployed using one of the techniques: 1). unsheathe method (like with Watchman 2.5), 2). advancement method 3). combination of both techniques. Ten seconds push forward on distal knob manoeuver was than carried out - it helped better engage fixation barbs and conforms the implant to LAA walls. The proper position of the Watchman FLX was confirmed by TEE and fluoroscopy. If position was not optimal, the device could be repositioned several times both proximally or distally using “a ball technique”. The standard PASS criteria, described before, for device release were then checked out. Tug test was then carried out to confirm the stability before final device release.

RESULTS AND DISCUSSION

The LAA closure procedure was successful in all 38 patients without the need for intraprocedural device size changes in all except one patient (1.026 devices per patient). No patients had gaps around the device of more than 5mm (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 (from 1 to 5 per patient) was necessary in 21 patients (55.3%) – 13 out of 18
(72.2%) patients during initial experience with device and 8 out 18 (44.4%) patients in the second cohort of patients. Combined „ball technique“ of implantation was used in all 38 cases (100%).

Final maximum diameter of implanted Watchman FLX device was 22.2mm±4.8mm with compression of 21.1%±4.2%. Mean procedure time was 27min.±9min. (min. 15 min.; max. 54 min.) The distribution of Watchman FLX sizes used during study was as follow: 20mm (n=0), 24mm (n=12), 27mm (n=13), 31mm (n=9), 35mm (n=4). No device embolizations, pericardial effusions or periprocedural strokes were observed in our cohort. 33 patients were switched to dual antiplatelet therapy after LAA occlusion and 5 remained on OACs (group with stroke on OAC/NOACs).

3-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 3mm) were noted in only 2 patients.

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

The new version of Watchman FLX has been significantly redesigned, however with the aim to maintain key benefits of its previous version. The device is accessible in 5 sizes (20, 24, 27, 31 and 35mm) for LAA ostia measuring from 14.0 mm to 31.5 mm – therefore, when compared to the current generation of Watchman 2.5, both smaller and larger LAA ostia can be treated now. Due to the reduced device length implantation even in more shallow LAAs
anatomies is now possible (minimum required depth is only 50% of the device size). The Watchman FLX is a nitinol 18 struts frame structure (10 struts 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 radially expands to maintain a proper position in the LAA. Permeable polyester (PET) fabric (extended more distally than in Watchman 2.5) covers the part of the device facing the left atrium. Closed distal end with fluoroscopic marker is atraumatic and enhances procedural guidance. Eighteen “J” fixation anchors in two rows (10 anchors in one row in Watchman 2.5) are located more distally than in Watchman 2.5 and help in device stabilisation in various LAA anatomies. Due to the intra-LAA placement, contact of the device with the left atrial wall is reduced and potential interference with left upper pulmonary vein and mitral valve is minimized. The new Watchman FLX can be several times recaptured into the access sheath and repositioned either proximally, as current generation of the device, or advanced distally before final release due to the atraumatic closed distal and usage of new “ball technique” which helps to position device not only properly but also safely. Thanks to optimized frame shape the delivery and recapture of the device is more smooth and easier than with Watchman 2.5. The new version of Watchman FLX is pre-loaded in the novel delivery system – Watchman True Seal (Boston Scientific, Marlborough, USA) (14 French outer diameter compatible with all FLX device sizes). It comes in three curve configurations – single, double and anterior for different LAA anatomies. The key feature changes of Watchman FLX in comparison to Watchman 2.5 are presented in Figure 1.

CONCLUSION

Periprocedural and short term follow-up data from Polish single-center registry seems to suggest that the new Watchman FLX occluder is safe and very effective in LAA closure. The performance and safety of that device, although very promising, should be confirmed in larger series of patients coming from other centers and operators.
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Figure 1 Graph representing key feature changes of Watchman FLX in comparison to previous Watchman 2.5 device - an 18 strut frame (vs. 10 struts for Watchman), closed distal end with a fluoro marker, reduced device length, two rows of “J” shape anchors (nine in each row - arrows), more PET fabric that extends down to the distal row of anchors.