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Impact of operatoŕs experience on *peri*-procedural outcomes with Watchman FLX: Insights from the FLX-SPA registry[2]

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Abbreviations: ICE, intracardiac echocardiography; LAA, left atrial appendage; LAAO, left atrial appendage occlusion; OAC, oral anticoagulation; TEE, transesophageal echocardiography.

[2] Every author takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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ABSTRACT

Background: The Watchman FLX is a device upgrade of the Watchman 2.5 that incorporates several design enhancements intended to simplify left atrial appendage occlusion (LAAO) and improve procedural outcomes. This study compares *peri*-procedural results of LAAO with Watchman FLX (Boston Scientific, Marlborough, Massachusetts) in centers with varying degrees of experience with the Watchman 2.5 and Watchman FLX.

Methods: Prospective, multicenter, "real-world" registry including consecutive patients undergoing LAAO with the Watchman FLX at 26 Spanish sites (FLX-SPA registry). Implanting centers were classified according to the center's prior experience with the Watchman 2.5. A further division of centers according to whether or not they had performed ≤ 10 or > 10Watchman FLX implants was prespecified at the beginning of the study. Procedural outcomes of institutions stratified according to their experience with the Watchman 2.5 and FLX devices were compared.

Results: 359 patients [mean age 75.5 (SD8.1), CHA_2DS_2-VASc 4.4 (SD1.4), HAS-BLED 3.8(SD0.9)] were included. Global success rate was 98.6%, successful LAAO with the first selected device size was achieved in 95.5% patients and the device was implanted at first attempt in 78.6% cases. There were only 9(2.5%) major *peri*-procedural complications. No differences in efficacy or safety results according to the centeŕs previous experience with Watchman 2.5 and procedural volume with Watchman FLX existed.

Conclusions: The Watchman FLX attains high procedural success rates with complete LAA sealing in unselected, real-world patients, along with a low incidence of *peri*-procedural complications, regardless of operatoŕs experience with its previous device iteration or the number of Watchman FLX devices implanted.

1. Introduction

Left atrial appendage occlusion (LAAO) is an established non-pharmacological alternative to oral anticoagulation (OAC) for stroke prevention in patients with non-valvular atrial fibrillation (AF) at high bleeding risk [1]. Since conception of this technique, several LAAO dedicated devices with differential design features have been developed [1,2]. Amongst them, the Watchman 2.5 device (Boston Scientific, Marlborough, Massachusetts, US) gathers the greatest body of evidence supporting its safety and efficacy, both in the form of randomized clinical trials and multicenter registries [3–4]. Notwithstanding, LAAO with the Watchman 2.5 device can be challenging in certain left atrial appendage (LAA) anatomies such as broad and shallow LAA, those with a complex internal architecture as well as chicken-wing–shaped LAA with a short proximal segment and an acute bend [1,5].

The Watchman FLX is a device upgrade of the previous Watchman 2.5 that incorporates substantial design changes aimed to simplify the LAAO procedure in a broader range of LAA anatomies. Since its approval by CE mark authorities in 2019, several registries have reported promising *peri*-procedural outcomes with the Watchman FLX, including lower need for device recapture and repositioning, reduced number of devices used per procedure and a high degree of complete LAA sealing [6–7]. More recently, the PINNACLE FLX trial confirmed consistent favorable results at 1-year follow-up [8]. Notwithstanding, these studies were performed in centers with a high volume of LAAO procedures, by operators with prior experience with the Watchman 2.5 device, which could have exerted a positive bias on the results. In order for new centers to incorporate the Watchman FLX device into their therapeutical arsenal, it remains relevant to assess if operators without prior experience with the Watchman 2.5 device, as well as those with a shorter experience with the Watchman FLX, may achieve similarly favorable *peri*-procedural outcomes [9].

The aim of the multicenter FLX-SPA registry is to report and compare *peri*-procedural outcomes with the Watchman FLX device in centers with and without prior experience with the Watchman 2.5 device, as well as in centers with varying degrees of procedural volume with the Watchman FLX.

[1] Both Authors have contributed to this work in the same amount and should both be considered as first authors.

2. Methods

2.1. Study population

The FLX-SPA is a multicenter, prospective, open-label registry that included consecutive patients with non-valvular AF undergoing LAAO with the Watchman FLX device (Boston Scientific, Marlborough, Massachusetts, US) in 26 Spanish centers between October 2019 and January 2021.

The device was implanted on an all-comer basis in unselected patients undergoing LAAO. All patients underwent standard diagnostic evaluation including estimation of thromboembolic and bleeding risk based on CHA_2DS_2-VASc and HAS-BLED scores. Baseline clinical and imaging characteristics as well as procedural details were collected prospectively and registered in a dedicated database at each of the participating centers.

The study protocol complied with the Helsinki Declaration and was approved by the Ethics Committee and all subjects provided informed consent prior to the procedure.

2.2. Implanting centers

Specific training for LAAO with the Watchman FLX was conducted prior to patienťs enrollment in every center. All procedures were performed by interventional cardiologists with at least 2 years prior experience in interventional cardiology. In each center, there were 2 operators involved in LAAO procedures, with the exception of institutions contributing with ≤ 6 cases, in which only one operator was involved. There was no run-in period and all patients from the first case performed with the Watchman FLX were included. Implanting centers were classified according to their previous experience with the Watchman 2.5 device: centers without prior experience were categorized as "Watchman 2.5 naïve centers", while institutions that already had practice with the Watchman 2.5 device were considered separately. In addition, implanting centers were assorted in two further groups, according to whether or not they had implanted ≤ 10 (initial Watchman FLX experience) or > 10 Watchman FLX devices (established Watchman FLX experience). The cut-off value for comparisons was established at 10 Watchman FLX implants, as this was the minimum number of procedures deemed necessary to become proficient with this device. Baseline

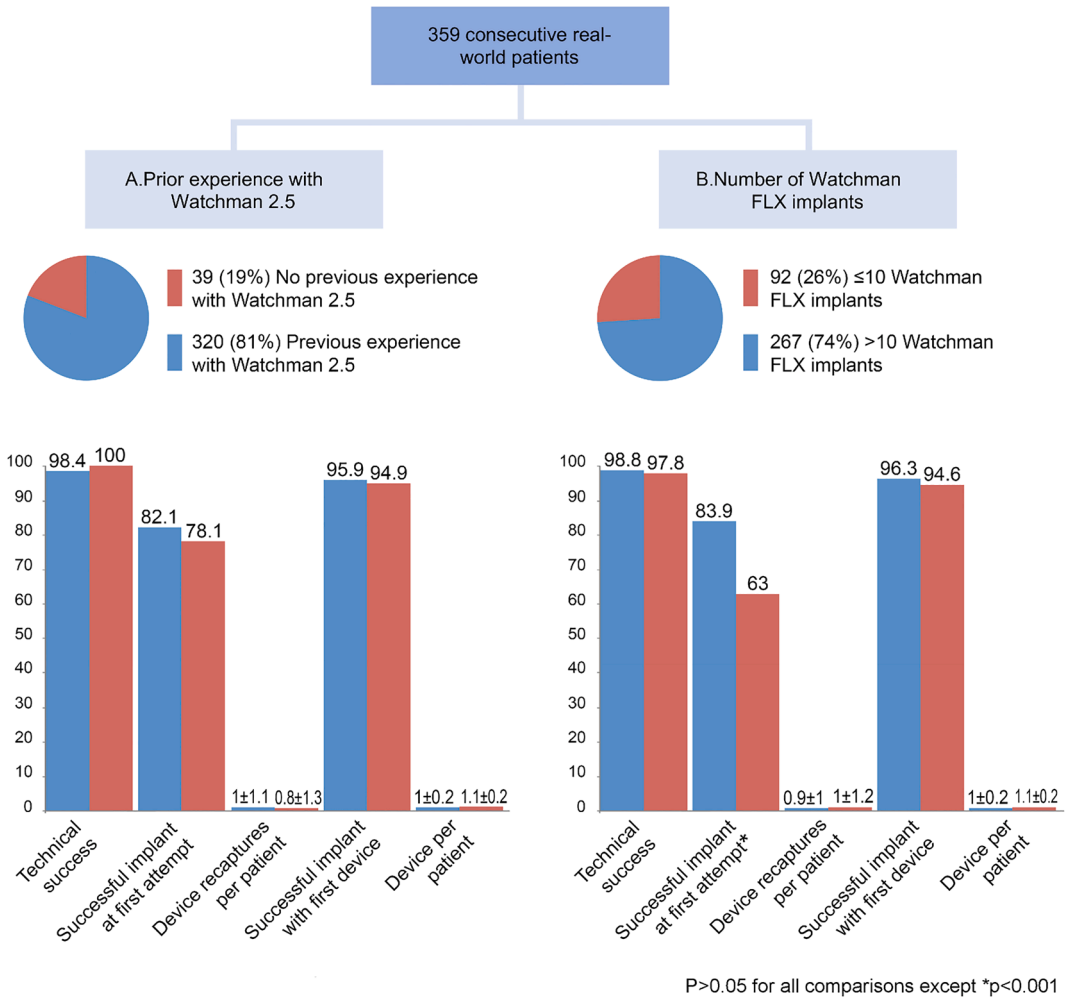

Fig. 1. Patients distribution and procedural outcomes according to centers experience and procedural volume. A. 320(81%) patients underwent LAAO at centers with prior experience with the Watchman 2.5 device, while the remainder 39(19%) were treated at "Watchman 2.5 naïve" centers. B. 267(74%) patients were managed at institutions that had performed over 10 Watchman FLX implants, whereas 92(26 %) were treated at institutions that had performed ≤ 10 procedures. Device recapture was more frequent in centers that had performed ≤ 10 Watchman FLX implants. No other differences in procedural details between both groups of institutions existed. *P-value < 0.001. P-value > 0.05 for all other comparisons.

clinical and imaging features, procedural details and *peri*-procedural results of both groups were compared.

2.3. Watchman FLX device

Specific design features of the Watchman FLX device have been previously described [6–8]. Main refinements in the design of the Watchman FLX in comparison to the Watchman 2.5 include a 10–20% length reduction and a closed end configuration that facilitate device implantation in shallow LAA (minimum depth required is 50% of device size). Additionally, device advancement within the LAA can be performed while partially deployed in the "ball" configuration, thanks to its atraumatic distal end with a fluoroscopic marker that reduces the risk of distal perforations. Furthermore, polyester fabric coverage has been extended to reduce *peri*-device leaks, the delivery cable screw recessed to reduce device related thrombus (DRT) and fixation mechanisms enhanced, with the addition of an extra row of 18 J-shaped anchors.

2.4. Pre-procedural imaging

Pre-procedural evaluation of the LAA was performed with TEE in all cases and its morphology and dimensions registered. The landing zone (LZ) was measured from the inferior part of the ostial plane at the level of the circumflex coronary artery, to a point 1–2 cm distal to the left upper pulmonary vein ridge. Patients with LAA thrombus, prior LAA surgical ligation as well as those with a LAA anatomy unsuitable for Watchman FLX implantation as per manufactureŕs instructions of use (LZ diameters < 17 mm or > 31 mm and LAAs shorter than the diameter of the required occlusion device) were excluded. No other morphological exclusion criteria for Watchman FLX implantation existed. Device sizing was selected according to the maximal LZ diameter, with oversizing aimed to attain final device compression between 10 and 30%.

2.5. Procedural details and outcomes

LAAO was performed under general anesthesia or conscious sedation, employing transesophageal echocardiography (TEE), micro-TEE or intracardiac echocardiography (ICE) according to local practice. Technical success was defined as complete LAA exclusion with no *peri*-device leak > 5 mm on color-Doppler TEE and no device-related complications. Peri-procedural outcomes were recorded during the first 7 days after LAAO. Major *peri*-procedural adverse events were registered according to the definitions in the Munich Consensus Document on LAAO [10] and included, but were not limited to, device embolization and thrombosis, cardiac perforation, tamponade and pericardial effusion requiring intervention, major bleeding defined as type ≥ 3 of Bleeding Academic

Table 1
Baseline clinical characteristics.

	Total sample (n = 359)
Age(years)	75.5 ± 8.1
Sex, male(n, %)	218 (60.7)
BMI,kg/m^{2}*	27.9 ± 4.5
Arterial hypertension*(n, %)	272(86.9)
Diabetes mellitus*(n, %)	107(34.2)
Coronary artery disease*(n, %)	77(24.6)
Heart failure*(n, %)	92(29.4)
LVEF,%	57.5 ± 9.6
Chronic kidney disease(n, %)	91(25.3)
Dialysis(n, %)	34(9.5)
Arterial vascular disease*(n, %)	69(22.0)
Prior ischemic stroke/transient ischemic attack*(n, %)	133(42.5)
Intracranial hemorrhage(n, %)	100(27.9)
Prior bleeding(n, %)	290(80.8)
Recurrent bleeding(n, %)	159(44.4)
Contraindication to OAC(n, %)	
Absolute	147(40.9)
Relative	163(45.4)
None	49(13.6)
Indication for LAAO†(n, %)	
Bleeding	290(80.8)
High bleeding risk	38(10.6)
Stroke despite OAC	41(11.4)
Labile INR	46(12.8)
High risk falls	6(1.7)
CHA_2DS_2 –VASc Score	4.4 ± 1.4
HAS-BLED Score	3.8 ± 0.9

Values: mean ± SD or n(%).
*N = 313. †: All indications that applied in every single patient were recorded. BMI:body mass index;GI: gastrointestinal; LAAO:left atrial appendage occlusion; LVEF:left ventricular ejection fraction; OAC:oral anticoagulation.

Research Consortium (BARC), major vascular complications, stroke or transient ischemic attack, systemic embolism, myocardial infarction and death. Peri-device leaks were classified according to the width of the color-Doppler jet on TEE as follows: mild (1–3 mm), moderate (>3mm but ≤ 5 mm) and severe (>5mm) [10]. Antithrombotic treatment at discharge was adjusted according to individual bleeding and ischemic risk, at each of the participating centers.

2.6. Statistical analysis

Categorical variables were expressed as frequencies and percentages, and continuous variables as mean (SD) or median (interquartile range). Comparisons between centres were performed by means of Chi-square tests or Fisher exact tests for categorical variables and T-Student and Mann–Whitney U-tests for continuous variables, as appropriate, after testing for normality by means of the Shapiro-Wilk test. Statistical analyses were performed with SPSS 21.0 for Windows (IBM, Chicago, Illinois).

3. Results

359 consecutive patients from 26 participating centers were included. The distribution of patients according to the centeŕs experience with the Watchman 2.5 device and the centeŕs procedural volume with Watchman FLX is depicted in the Fig. 1 and Supplementary Figure 1.

The main baseline clinical characteristics of included patients are displayed in Table 1. Mean age was 75.5 (SD 8.1) years and mean CHA_2DS_2-VASc and HAS-BLED Scores were 4.4 (SD 1.4) and 3.8 (SD 0.9), respectively. Overall, 133 (42.%) of patients had a history of prior ischemic stroke or transient ischemic attack, while previous bleeding complications were present in 289 (80.5%) patients. Baseline features of patients according to the centers' prior experience with the Watchman 2.5 device and volume of Watchman FLX implants are depicted in **Supplementary** Tables 1 and 2.

3.1. Peri-procedural details

Imaging and procedural characteristics according to centeŕs experience and procedural volume are summarized in Tables 2 and 3.

Mean maximal and minimal LZ diameters were 20.9 ± 3.8 mm and 18.1 (SD 3.5) mm, respectively, range 12 to 34 mm, and mean LAÁs depth was 25.1 (SD 6.1) mm. In 54 (15.1%) of patients, the LAÁs depth was shorter than the maximal LZ diameter, a factor that would have precluded LAAO with the Watchman 2.5 device. In addition, the LZ diameter exceeded 31 mm in 2 (0.6%) patients and was ≤ 17 mm in 44 (12.3%) of cases. Overall, 78 (21.7%) of patients undergoing LAAO with the Watchman FLX in our sample would have been unsuitable candidates for LAAO with the Watchman 2.5, according to the instructions for use.

LAAO was performed under general anhaesthesia in 201 (56%) patients. The majority of procedures were guided by TEE (68.5%), while micro-TEE and ICE were used in 27.6% and 3.4% of patients, respectively. Centers that had performed ≤ 10 Watchman FLX implants employed general anesthesia more frequently (83.7% versus 46.4% p = 0.001), while use of micro-TEE was more common in centers that had performed > 10 Watchman FLX implants (36% versus 3.3%, p = 0.001) as well as in those with prior experience with the Watchman 2.5 device (30.3% versus 5.1, p = 0.001). Overall, 7 (1.9%) patients underwent combined procedures with LAAO (1 transcatheter aortic valve implantation, 2 percutaneous edge-to-edge mitral valve repair and 4 pulmonary vein ablation), without differences according to the hospitaĺs characteristics.

The most frequently implanted device size was Watchman FLX 27 mm, in 38.2% of patients. Technical success was achieved in 354 (98.6%) cases, without differences between centers, Fig. 1. Successful LAAO with the first selected device size was achieved in 343 (95.5%) cases and the device was implanted at first attempt in 282 (78.6%) patients. Device recapture and repositioning was significantly more frequent in centers that had performed ≤ 10 Watchman FLX implants, whilst "Watchman 2.5 naïve centers" employed a greater volume of contrast than centers with prior experience.

3.2. Peri-procedural and in-hospital outcomes

Major *peri*-procedural and in-hospital complications recorded during the first 7-days post-procedure occurred in 9 (2.5%) patients, as depicted in Tables 4 and 5, Fig. 2. No patient died within index hospitalization. BARC ≥ 3 bleedings were the most frequent complication in 4 (1.1%) patients and there was just 1 (0.3%) pericardial tamponade requiring pericardiocentesis. Acute device-related complications included 1 (0.3%) early DRT that was successfully managed with low-molecular weight heparin for 4 weeks. There were no cases of device embolisation. Complete LAA sealing post-procedure was confirmed by TEE in 344 (97.2%) patients and there were no severe (>5mm) *peri*-device leaks. No differences in *peri*-procedural complications between centers existed.

Mean length of hospital stay was 1.8 (SD 1.8) days. At discharge, 164 (45.7%) were managed with dual antiplatelet therapy, 73 (20.3%) with single antiplatelet therapy, 86 (23.9%) with anticoagulation alone and 27 (7.5%) with an antiplatelet agent on top of anticoagulation, Table 4 and 5.

4. Discussion

Our study provides further evidence on procedural safety and efficacy of LAAO with the Watchman FLX device in real-world practice with similarly favorable results regardless of the centeŕs degree of expertise.

Its main findings can be summarized as follows: first, technical success rates with the Watchman FLX were remarkably high at 98.6%, regardless of LAA anatomy and there were no cases of severe (>5 mm)

Table 2
Peri-procedural characteristics according to centerś experience with Watchman 2.5 device.

	No prior experience Watchman 2.5 (n = 39)	Prior experience Watchman 2.5 (n = 320)	Total sample (n = 359)	Difference of the means (95% CI)	p-value
LAA morphology(n,%)*					0.030
Chicken-wing	9(37.5)	67(27.3)	76(28.4)		
Windsock	9(37.5)	116(47.3)	124(46.3)		
Cauliflower	1(4.2)	45(18.4)	46(17.2)		
Cactus	5(20.8)	17(6.9)	22(8.2)		
LAA landing zone(mm)					
Maximal diameter	20.6 ± 4.5	20.9 ± 3.8	20.9 ± 3.8	−0.26 (-1.9, +1.3)	0.946
Minimal diameter	17.2 ± 3.8	18.2 ± 3.5	18.1 ± 3.5	−0.98 (-2.3, +0.4)	0.215
LAA length(mm)	27.3 ± 8.5	24.9 ± 5.7	25.1 ± 6.1		0.341
Unsuitability for Watchman 2.5 device (n,%)	9(23.1)	69(21.6)	78 (21.7)		0.829
Procedural anhaesthesia(n,%)					0.182
Superficial sedation	14(35.9)	144(45)	158(44)		
General anhaesthesia	25(64.1)	176(55)	201(56)		
Procedural imaging guidance(n,%)					0.001
TEE					
Micro-TEE	36(92.3)	210(65.6)	246(68.5)		
ICE	2(5.1)	97(30.3)	99(27.6)		
	1(2.6)	13(4.1)	14(3.9)		
Combined procedure(n,%)	1(2.6)	6(1.9)	7(1.9)		0.556
Size of implanted device					0.689
FLX-20mm	7(17.9)	35(10.9)	42(11.7)		
FLX-24mm	13(33.3)	124(38.8)	137(38.2)		
FLX-27mm	12(30.8)	89(27.8)	101(28.1)		
FLX-31mm	6(15.4)	56(17.5)	59(16.4)		
FLX-35 mm	1(2.6)	16(5)	17(4.8)		
Technical success(n,%)	39(100)	315(98.4)	354(98.6)		0.561
>1 device per patient(n,%)	2(5.1)	13(4.1)	15(4.2)		0.754
Devices per patient	1.0 ± 0.2	1.1 ± 0.2	1.0 ± 0.2	0.007(-0.06,+0.08)	0.903
Device recapture(n,%)	7(17.9)	70(21.9)	77(21.4)		0.682
Device recaptures/patient	0.8 ± 1.3	1.0 ± 1.1	0.9 ± 1.1	−0.2 (-0.8, +0.3)	0.182
Device compression(%)	23.1 ± 12.3	27.2 ± 12.4	26.8 ± 12.4	−4.1(-9.2, +1.0)	0.118
Fluoroscopy time(minutes)	12(6–18)	14(9–20)	14(9–20)	−0.4(-5.1, +4.3)	0.142
Contrast media volume(ml)	112(85–134)	75.5(48.8–105)	80(52–107)	34.9 (7.1,62.7)	<0.001

Values:mean ± SD, median (interquartile range) or n(%).*N = 269.
CI: Confidence Interval. ICE:intra-cardiac echocardiography; LAA:left atrial appendage; TEE:transesophageal echocardiography.

peri-device leaks on post-procedural TEE. Second, LAAO with the Watchman FLX was safe, with a low incidence of major *peri*-procedural adverse events during the first 7 days after LAAO (2.5%) and no cases of device embolization or death. Third, operators with no experience with the previous device iteration, the Watchman 2.5, as well as those that had performed ≤ 10 Watchman FLX implants, attained similar technical success and *peri*-procedural complication rates than more experienced operators.

The Watchman FLX has recently emerged as a valuable option for LAAO that enables a simpler implantation procedure in a wider span of LAA anatomies than its previous device iteration, thanks to several design enhancements [6–7]. These finding were recently confirmed in the PINNACLE FLX randomized trial [8].

Our registry provides similarly high technical success rates as previous studies in a large sample of real-world patients with unselected LAA anatomies, including 21.7% of cases that would have been perceived as technically challenging or unsuitable for LAAO with the Watchman 2.5. Of note, complete LAA sealing was achieved with the first selected device size in 95.5% of cases, with a low number of device recaptures per patient at 0.9 (SD 1.1). This value is lower than previously described for the Watchman 2.5 [11–12], despite a substantial proportion of cases being performed at centers with limited experience with the device. Altogether, these results support that LAAO procedure can be simplified with the Watchman FLX, as compared to its prior device iteration.

Moreover, there were no severe *peri*-device leaks and mild-to-moderate leaks occurred in only 2.8% of patients. Although our study does not provide follow-up TEE data, lack of progression from mild to severe leaks described in prior reports along with minor variations in the prevalence of *peri*-device leaks during follow-up after Watchman FLX implantation are comforting and suggest that post-procedural outcomes observed in the current study are likely to maintain over time [6,8].

Regarding *peri*-procedural safety, we observed 9 (2.5%) major procedural and in-hospital complications, an outcome largely determined by post-procedural bleeding events, which occurred in 4 (1.1%) patients. Our safety results are similar to those reported in previous registries with the Watchman FLX but substantially higher than those described in the PINNACLE FLX study [8]. However, the latter did not include bleeding events into the primary safety endpoint and targeted patients with a substantially lower bleeding risk, as predicted by HAS-BLED Score [3.8 (SD 0.9) in the SPA-FLX registry versus 2.0 (SD 1.0) in the PINNACLE FLX trial], two factors likely to have influenced these findings. Of importance, there was only one pericardial effusion in our study which was successfully managed with percutaneous drainage and no cases of death or device embolization, a complication that led to market retrieval of a previous version of the Watchman FLX in 2017, but

Table 3
Peri-procedural characteristics according to the centerś procedural volume.

	Centers with ≤ 10 Watchman FLX implants (n = 92)	Centers with > 10 Watchman FLX implants (n = 267)	Total sample (n = 359)	Difference of the means (95% CI)	p-value
LAA morphology(n,%)*					0.039
Chicken-wing	23(31.9)	53(26.9)	76(28.4)		
Windsock	28(38.9)	97(49.2)	124(46.3)		
Cauliflower	10(13.9)	36(18.3)	46(17.2)		
Cactus	11(15.3)	11(5.6)	22(8.2)		
LAA landing zone(mm)					
Maximal diameter	20.6 ± 3.9	21 ± 3.8	20.9 ± 3.8	−0.4(-1.5, +0.60)	0.401
Minimal diameter	17.9 ± 3.3	18.2 ± 3.6	18.1 ± 3.5	−0.3(-1.2, +0.60)	0.500
LAA length(mm)	26.4 ± 6.2	24.5 ± 5.9	25.1 ± 6.1		0.021
Unsuitability for Watchman 2.5 device(n,%)	22(23.9)	56(21)	78(21.7)		0.555
Procedural anhaesthesia (n,%)					<0.001
Superficial sedation	15(16.3)	143(53.6)	158(44)		
General anhaesthesia	77(83.7)	124(46.4)	201(56)		
Procedural imaging guidance(n,%)					<0.001
TEE					
Micro-TEE	87(94.6)	159(59.6)	246(68.5)		
ICE	3(3.3)	96(36)	99(27.6)		
	2(2.2)	12(4.5)	14(3.9)		
Combined procedure(n,%)	4(4.3)	3(1.1)	7(1.9)		0.074
Size of implanted device					0.537
FLX-20mm	12(13)	30(11.2)	42(11.7)		
FLX-24mm	36(39.1)	101(37.8)	137(38.2)		
FLX-27mm	29(31.5)	72(27)	101(28.1)		
FLX-31mm	13(14.1)	49(18.4)	59(16.4)		
FLX-35 mm	2(2.2)	15(5.6)	17(4.8)		
Technical success(n,%)	90(97.8)	264(98.9)	354(98.6)		0.606
>1 device per patient(n,%)	5(5.4)	10(3.7)	15(4.2)		0.485
Devices per patient	1.1 ± 0.2	1.0 ± 0.2	1.0 ± 0.2	0.01 (-0.04,+0.06)	0.351
Device recapture(n,%)	34(37)	43(16.1)	77(21.4)		<0.001
Device recaptures/patient	1 ± 1.2	0.9 ± 1.0	0.9 ± 1.1	0.07 (-0.3, +0.45)	0.718
Device compression(%)	25.7 ± 12.7	27.3 ± 12.3	26.8 ± 12.4	−1.6 (-4.9, +1.7)	0.354
Fluoroscopy time(minutes)	16(8–23)	14(9–19)	14(9–20)	2.8(-0.6, +6.2)	0.281
Contrast-media volume(ml)	80(50–100)	80(52.8–119)	80(52–107)	−14.3 (-27.7, −0.83)	0.087

Values:mean ± SD, median (interquartile range) or n(%).*N = 269.
CI: Confidence Interval. ICE:intra-cardiac echocardiography; LAA:left atrial appendage; TEE:transesophageal echocardiography.

which has not been reported in studies with the newer generation of the device [6–8].

Our study provides an important contribution to existing evidence as it supports the adoption of the Watchman FLX by less experienced centers, with similar procedural safety and efficacy outcomes than more expert institutions. This finding is relevant given the continuous raise in LAAO procedures along with LAAO operators and implanting centres that is taking place across the world in the last few years [9].

The association between operatorś experience and LAAO procedural results has been previously described. Indeed, several real-life studies have reported that increasing operatorś experience and hospital procedural volume are linked with a lower rate of *peri*-procedural adverse events, while the association with procedural success is more limited [12–15]. Similarly, the latest registries with the Watchman 2.5 have reported growing technical success rates along with a declining incidence in *peri*-procedural complications, as compared to studies reporting on the initial experience with this device [3–4,9].

Thus, our findings suggest a lower learning curve for LAAO with the Watchman FLX than that previously reported for the Watchman 2.5 device, with high procedural success rates achievable not only by more expert operators, but also by those performing a lower volume of procedures and no prior experience with the Watchman 2.5 device. These outcomes can be justified by several novel features of the Watchman FLX device that facilitate optimal device alignment and positioning, including its ability to be totally recaptured and repositioned both proximally as well as distally in the "ball" configuration and the possibility to perform rotational adjustments during deployment, without the need to completely retrieve or change the device.

In summary, the results of the present study reaffirm the outstanding device performance of the Watchman FLX in unselected, real-world patients. In addition, the Watchman FLX emerges as an attractive option for institutions that are initiating a LAAO program, given its reproducible safety and efficacy results in centers unfamiliar with its prior device iteration and with lower procedural volume. However, studies assessing longer-term outcomes following LAAO with the Watchman FLX are warranted, in order to establish firm conclusions regarding the safety and efficacy of this device.

5. Limitations

We acknowledge several limitations, inherent to the observational design of this study.

Although information was entered prospectively by trained cardiologists involved in the procedure, we lacked a central core lab to assess imaging and procedural data and event adjudication between the different sites was not crosschecked. Of note, certain procedural details such as procedural time or transseptal puncture technique were unavailable for analysis. In addition, our study was circumscribed to the

Table 4
Procedural and 7-day outcomes according to centerś experience with Watchman 2.5 device.

	No prior experience Watchman 2.5 (n = 39)	Prior experience Watchman 2.5 (n = 320)	Total sample (n = 359)	p-value
Peri-procedural complications(n,%)	0	9(2.8)	9(2.5)	0.605
Death(n,%)	0	0	0	
Ischemic stroke/ transient ischemic attack / Systemic embolism(n,%)	0	1(0.3)	1(0.3)	0.891
Hemorrhagic stroke(n, %)	0	0	0	
Major bleeding (BARC ≥ 3)(n,%)	0	4(1.3)	4(1.1)	0.630
Pericardial effusion requiring intervention(n,%)	0	1(0.3)	1(0.3)	0.891
Major vascular complication(n,%)	0	1(0.3)	1(0.3)	0.891
Ventricular arrythmia (n,%)	0	1(0.3)	1(0.3)	0.891
Device-related complications(n,%)	0	0	0	0.891
Device embolization	0	1(0.3)	1(0.3)	
Device thrombosis				
LAA leak post-procedure(n,%)	1(2.6)	9(2.9)	10(2.8)	0.697
Mild(1–3 mm)	1(2.6)	6(1.9)	7(2.0)	
Moderate(3–5 mm)	0	3(1)	3(0.8)	
Significant(>5mm)	0	0	0	
Antithrombotic therapy at discharge (n,%)				0.004
None	1(2.6)	8(2.5)	9(2.5)	
Any antiplatelet therapy	34(87.2)	203(62.4)	237 (66.1)	
Any anticoagulation	4(10.3)	109(34.1)	113 (31.5)	

Values:mean ± SD or n(%).
BRAC: Bleeding Academic Research Consortium; ICE:intra-cardiac echocardiography; LAA:left atrial appendage.

procedural phase and follow-up results including long-term device-related outcomes were not evaluated. Notwithstanding, prior studies with the Watchman FLX have reported low incidence of DRT and only small variations in the incidence of *peri*-device leaks, as compared to acute results assessed at the end of the procedure. Finally, the non-randomized design of the study and lack of a control group constitute a further limitation, and the possibility of patient selection bias cannot be discarded.

6. Conclusions

The Watchman FLX attains high procedural success rates with complete acute LAA sealing in a wide range of LAA anatomies, along with a very low rate of *peri*-procedural complications. Favorable *peri*-procedural outcomes following LAAO with the Watchman FLX are not influenced by operatorś prior experience with the Watchman 2.5 device and are reproducible by operators at their initial experience with the Watchman FLX device.

Table 5
Procedural and 7-day outcomes according to the centerś procedural volume.

	Centers with ≤ 10 Watchman FLX implants (n = 92)	Centers with > 10 Watchman FLX implants (n = 267)	Total sample (n = 359)	p-value
Peri-procedural complications(n,%)	1(1.1)	8(3.0)	9(2.5)	0.457
Death(n,%)	0	0	0	
Ischemic stroke/ transient ischemic attack /Systemic embolism(n,%)	1(1.1)	0	1(0.3)	0.256
Hemorrhagic stroke (n,%)	0	0	0	
Major bleeding (BARC ≥ 3) (n,%)	0	4(1.5)	4(1.1)	0.576
Pericardial effusion requiring intervention(n,%)	0	1(0.4)	1(0.3)	0.744
Major vascular complication(n,%)	0	1(0.4)	1(0.3)	0.744
Significant procedural arrythmia(n,%)	0	1(0.4)	1(0.3)	0.744
Device-related complications(n,%)	0	0	0	0.744
Device embolization	0	1(0.4)	1(0.3)	
Device thrombosis				
LAA leak post-procedure(n,%)	3(3.3)	7(2.6)	10(2.8)	0.488
Mild(1–3 mm)	2(2.2)	5(1.9)	7(2.0)	
Moderate(3–5 mm)	1(1.1)	2(0.8)	3(0.8)	
Significant(>5mm)	0	0	0	
Antithrombotic therapy at discharge(n,%)				0.021
None	6(6.5)	2(0.7)	9(2.5)	
Any antiplatelet therapy	57(61.9)	181(67.8)	238 (66.3)	
Any anticoagulation	29(31.5)	84(31.5)	113 (31.5)	

Values:mean ± SD or n(%).
BRAC: Bleeding Academic Research Consortium; DOAC:direct oral anticoagulants; LAA:left atrial appendage; LMWH:low-molecular weight heparin; VKA: vitamin K antagonists.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

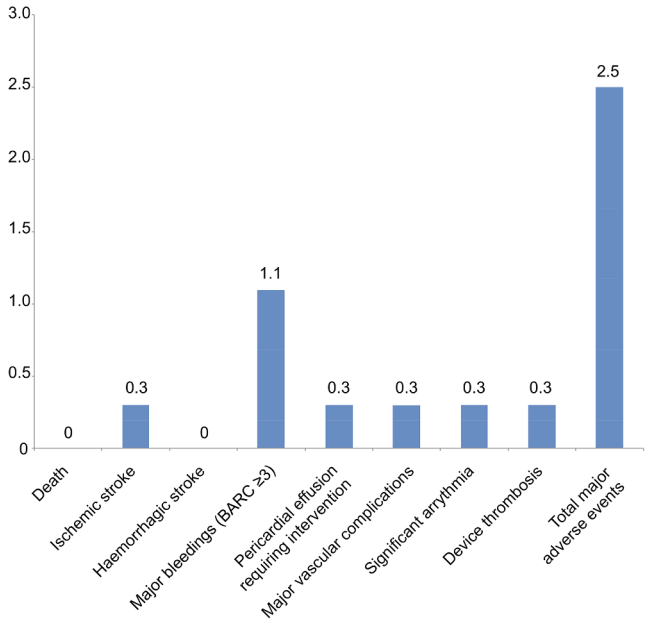

Fig. 2. Peri-procedural complications. Peri-procedural major adverse events following LAAO with the Watchman FLX. P-value > 0.05 for all comparisons.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2021.100941.

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