Clinical Results of Left Atrial Appendage Closure with Watchman Device in Patients with Atrial Fibrillation

Phattaraphong Pheerawong MD*,
Smonporn Boonyaratavej Songmuang MD**, Vorarit Lertsuwunseri MD**,
Sudarat Satitthummanid MD**, Suphot Srimahachota MD**

** Department of Medicine, Buriram Hospital, Buriram, Thailand*
*** Cardiac Center and Division of Cardiology, Department of Medicine, Faculty of Medicine, King Chulalongkorn Memorial Hospital, Chulalongkorn University, Bangkok, Thailand*

Background: *In patient with non-valvular atrial fibrillation (AF), over 90% of thrombus accumulation originates in the left atrial appendage (LAA). Warfarin significantly reduces risk of stroke. However, long-term anticoagulant therapy is associated with a significant risk of major bleeding, particularly in elderly. Transcatheter occlusion of left atrial appendage with Watchman device has proved to be non-inferior to warfarin in preventing stroke in non-valvular AF patients. No previous report of transcatheter occlusion of LAA was found in Thailand.*

Objective: *To evaluate short-term results of left atrial appendage closure with the Watchman® device in patient with non-valvular AF performed at King Chulalongkorn Memorial Hospital (KCMH).*

Material and Method: *Between November 2012 and December 2014, 12 consecutives patients underwent percutaneous transcatheter left atrial appendage closure. Data included patient's characteristics, embolic risk factors, bleeding risk score, procedural finding, complications, in-hospital outcomes, and antithrombotic management were retrospectively reviewed.*

Results: *Percutaneous LAA occlusion was successfully performed in all 12 patients. The mean age was 71.2±8.1 years. The history of previous bleeding was seen in four patients (33%). All patients had good left ventricular systolic function. The mean $CHADS_2$ score was 3.2±1.3, the mean CHA_2DS_2-VASc score was 4.8±1.6 and the mean HAS-BLED score was 2.5±0.9. The average LAA orifice diameter was 21.7±3.4 mm, and the median implant size was 27.0 mm. The compression ratio was 15.2±6.2%. Three patients (25%) were performed under general anesthesia, nine patients (75%) were performed with local anesthesia. The average procedure time was 61.2±18.5 minutes. The average fluoroscopy time was 6.8±3.3 minutes. There was no device embolization or pericardial effusion. There was no periprocedural cerebral event, assess site bleeding, or death during hospital admission. Mild peridevice leak was observed in three patients (25%), and all had disappeared on TEE performed at the 45-day follow-up. The median length of stay was two days.*

Conclusion: *The result of the present study showed that percutaneous LAA occlusion with the Watchman device was feasible and safe. The successfulness of the procedures and periprocedural complications were similar to standard in literature.*

Keywords: *Atrial fibrillation, Atrial appendage, Watchman*

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Atrial fibrillation (AF) is the most prevalent significant cardiac arrhythmia in the world[1]. Stagnation of blood flow within left atrial leads to hypercoagulability and increased risk of thrombus formation[2]. In patient with non-valvular atrial fibrillation, over 90% of thrombus accumulation originates in the left atrial appendage (LAA)[3]. Stroke prevention is a primary goal of AF treatment. Patients with AF, whether paroxysmal or permanent, have a five-fold risk of stroke in comparison to a matched population in sinus rhythm[4]. In generally, the risk factor of stroke in patient with non-valvular AF is 5% per year[5].

Warfarin can significantly reduce risk of stroke in patients with AF[6]. With the appropriated dosing, warfarin reduces stroke risk by 60% to 70% compared with no treatment and by 30% to 40% compared with aspirin alone[7]. However, long-term anticoagulant therapy is associated with a significant risk of major bleeding, particularly in elderly[8,9]. Only 50% to 60% of patients on warfarin are in therapeutic range and overall withdrawal rate from warfarin therapy is 10% to 38% after one year[10,11]. New oral anticoagulants (OAC) have shown promising data for reducing bleeding complication when compared

Correspondence to:
Srimahachota S, Division of Cardiovascular Disease, Department of Medicine, King Chulalongkorn Memorial Hospital, Bangkok 10330, Thailand.
Phone & Fax: +66-2-2564291
E-mail: s_srimahachota@yahoo.co.th

with warfarin[12,13], however, it is costly and the antidote is not available when patients develop bleeding complication.

Mechanical occlusion of LAA is a strategy to eliminate cardiac emboli[3]. Surgical exclusion of LAA is recommended during mitral valve surgery in patients who have had embolic events while receiving adequate anticoagulant as a mean of eliminating potential source of embolic event[14]. However, successful LAA surgical exclusion can be variable[15]. Significant early and late postoperative failure rate were observed[16]. Incomplete closure of LAA failed to eliminate risk of thromboembolic event. Transcatheter occlusion of LAA was first introduce with the percutaneous left atrial appendage transcatheter occlusion (PLAATO) device (Medtronic). This device was pulled off the market due to difficult implantation technique, although clinical results were favorable[17]. The Watchman® device (Boston Scientific) has proved to be non-inferior to warfarin in preventing stroke in non-valvular AF patients[18]. In Thailand, there was no previous report of transcatheter occlusion of LAA. The present study demonstrated the feasibility and safety implantation of Watchman® device in Thai population.

Objective

The purpose of the present study was to evaluate the short-term results associated with left atrial appendage closure with the Watchman® device in patient with non-valvular AF.

Material and Method

The present study was a retrospective, observational study to characterize the clinical profile, management and in hospital outcomes of patients with non-valvular AF who received transcatheter LAA occlusion with Watchman® device at King Chulalongkorn Memorial Hospital (KCMH) between November 2012 and December 2014.

All medical records were retrospectively reviewed. The inclusion criteria were: age >18 years, non-valvular AF, $CHADS_2$ score ≥1, and a contraindication or aversion to long-term OAC therapy. Contraindication for OAC use were recognizes as 1) hemorrhagic/bleeding tendencies-define as active peptic ulcer disease or history of overt bleeding of gastrointestinal, genitourinary, or respiratory tract, central nervous system hemorrhage, and 2) blood dyscrasias. Exclusion criteria included left ventricular ejection fraction <30%, LAA thrombus, comorbidity other than atrial fibrillation that required long-term warfarin use, and significant mitral stenosis or mitral regurgitation.

Data collection were performed and included patient's characteristics, embolic risk factors, bleeding risk score, procedural finding, complications, and in-hospital outcomes of patients. Non-valvular AF was defined as AF in the absence of rheumatic mitral stenosis, a mechanical or bioprosthetic heart valve, or mitral valve repair. Paroxysmal AF was defined as AF that terminated spontaneously or with intervention within seven days of onset. The $CHADS_2$ score (scale 0 to 6) included Congestive heart failure, Hypertension, Age ≥75 years, Diabetes mellitus, and prior Stroke or transient ischemic attack (TIA [2 point]). The CHA_2DS_2-VASc score (scale 0 to 9) included the same components but with two points for Age ≥75 years and one point for Vascular disease, Age 65 to 74 years, or Sex category (female sex). The HAS-BLED score (scale 0 to 5) included Hypertension, Abnormal renal/liver function, Stroke, Bleeding history, Labile international normalized ratio (INR), Elderly (>65 years), and Drug or alcohol uses. Diabetes was diagnosed when the patient's fasting plasma glucose was 126 mg/dl or higher on at least two occasions or the presence of a history of diabetes treated with either dietary control or antidiabetic medication. Hypertension was defined as systolic blood pressure >140 mmHg or diastolic blood pressure >90 mmHg or a previous diagnosis of hypertension.

Watchman® LAA closure device and procedure

The Watchman® device (Fig.1) is made of self-expanding nitinol frame with fixation barbs. The left atrial surface of the device is covered with polyethylene terephthalate (PET) membrane. The procedure is performed under fluoroscopic and transesophageal echocardiogram (TEE) guide. After transseptal puncture, a pigtail catheter was placed into LAA for LAA angiogram. The device size is selected from LAA angiogram and TEE information. The initial device size is 20% larger than maximum ostial size of LAA. The device is advanced into LAA through the delivery sheath and then deployed. After proper positioning of the device confirmed by angiogram and TEE, a tug test was performed to test the stability of the device in LAA. Contrast injection assesses the adequacy of occlusion of LAA. If there is an inadequate seal or suboptimal position of the device, the device is collapsed and repositioned or exchanged for a different size. Optimally, the device should not

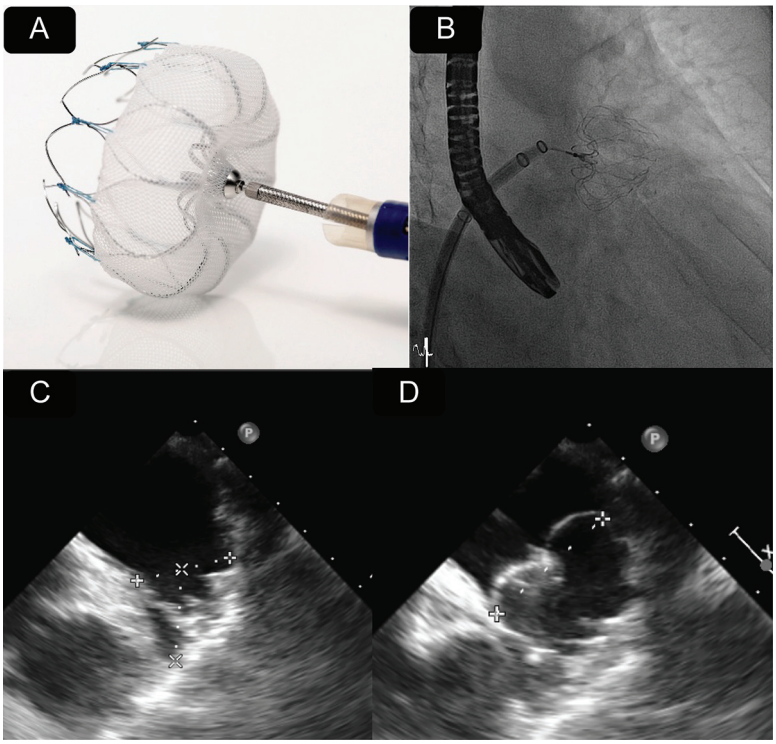

Fig. 1 (A) Watchman device made of self-expanding nitinol frame with fixation barbs and polyethylene terephthalate (PET) membrane covering the surface facing the left atrium. (B) Fluoroscopic of Watchman® device implantation in the left atrial appendage. Transesophageal echocardiogram showed left atrial appendage before (C) and after device implantation (D).

protrude more than 4 to 7 cm beyond the LAA ostium and should cover the entire ostium with no or minimal residual flow. When optimal positioning is confirmed, the device is released.

Heparin (100 U/Kg) is administered during the procedure in all cases to maintain activated clotting time (ACT) >250 seconds. After procedure anticoagulant or antiplatelet therapy consisting of aspirin (80 to 325 mg/24 hours) plus clopidogrel (75 mg/24 hours), or aspirin or clopidogrel alone are giving according to the operator's discretion for 45 days. Transthoracic echocardiogram is performed in one day and TEE is performed 45 days after the procedure. If TEE showed well-seated device without device-related thrombus, antithrombotic is changed to single or dual antiplatelets.

Statistical analysis

Categorical variables were reported as numbers and percentages. Continuous variables were presented as mean ± standard deviation or median (interquartile range) as appropriated.

Results

Percutaneous LAA occlusion was performed in 12 patients. Baseline characteristics of patients are shown in Table 1. The history of previous bleeding was seen in four patients (33%). Two had history of massive gastrointestinal bleeding and two had history of subdural hematoma that required craniotomy. All patients had normal left ventricular systolic function. Most of patients received anticoagulant. Seven patient received warfarin, two received dabigatran, and one received rivaroxaban. Two patient had previous coronary intervention with drug eluting stent that need long-term dual antiplatelet therapy combined with warfarin. The thrombotic and bleeding risk scores are shown in Table 2. The mean $CHADS_2$ score was 3.2±1.3, the mean CHA_2DS_2-VASc score was 4.8±1.6, and the mean HAS-BLED score was 2.5±0.9. Seven patients (58.3%) had HAS-BLED score ≥3.

Procedure results

The main procedure findings were showed in Table 3. The average LAA orifice diameter was

Table 1. Baseline characteristics of the patients (n = 12)

Age (year), mean ± SD	71.2±8.1
Male, n (%)	7 (58.3)
Atrial fibrillation type, n (%)	
Chronic	6 (50.0)
Paroxysmal	6 (50.0)
Hypertension, n (%)	9 (75.0)
Diabetes, n (%)	3 (25.0)
Congestive heart failure, n (%)	2 (16.7)
Coronary artery disease, n (%)	5 (41.7)
History stroke/TIA, n (%)	10 (83.3)
Previous bleeding episode, n (%)	4 (33.0)
LVEF (%), mean ± SD	68.2±9.8
Baseline antithrombotic treatment, n (%)	
Aspirin	1 (8.3)
Aspirin + clopidogrel	2 (16.7)
Warfarin	7 (58.3)
Other anticoagulant	3 (25.0)

TIA = transient ischemic attack; LVEF = left ventricular ejection fraction

Table 2. Thrombotic and bleeding risk score (n = 12)

Score	$CHADS_2$ n (%)	CHA_2DS_2-VASc n (%)	HAS-BLED n (%)
0	0 (0)	0 (0)	0 (0)
1	1 (8.3)	0 (0)	2 (16.7)
2	3 (25.0)	1 (8.3)	3 (25.0)
3	3 (25.0)	2 (16.7)	6 (50.0)
4	3 (25.0)	2 (16.7)	1 (8.3)
≥5	2 (16.7)	7 (58.3)	0 (0)
Mean ± SD	3.2±1.3	4.8±1.6	2.5±0.9

Table 3. Procedure finding and outcomes (n = 12)

LAA diameter by TEE (mm), mean ± SD	
At 0°	18.9±2.3
At 45°	18.0±2.6
At 90°	19.5±2.9
At 135°	20.6±4.1
Maximum LAA orifice diameter (mm), mean ± SD	21.7±3.4
Mean LAA pressure (mmHg), mean ± SD	10.4±5.2
Device size, n (%)	
24 mm	3 (25.0)
27 mm	6 (50.0)
30 mm	1 (8.3)
33 mm	2 (16.7)
Procedural success	12 (100)
Compression ratio (%), mean ± SD	15.2±6.2
Procedure time (minute), mean ± SD	61.2±18.5
Fluoroscopic time (minute), mean ± SD	6.8±3.3
Periprocedural complications, n (%)	
Peridevice leak	3 (25.0)
Device embolization	0 (0)
Pericardial effusion	0 (0)
Cardiac tamponade	0 (0)
Assess site bleeding	0 (0)
Stroke/TIA	0 (0)
Hospital length (day), median (IQR)	2.0 (2.0-2.8)

LAA = left atrial appendage; TEE = transesophageal echocardiogram; TIA = transient ischemic attack

21.7±3.4 mm and the median implant size was 27.0 mm. The compression ratio was 15.2±6.2%. The first three patients (25%) were performed under general anesthesia; subsequently, nine patients (75%) were performed under local anesthesia with conscious sedation. The average procedure time was 61.2±18.5 minutes. The average fluoroscopy time was 6.8±3.3 minutes. The procedures were successfully performed in all patients. Two patients needed to be changed with second device, one patient failed the tug test with the initial device, and successfully deployed with the larger one. For the second patients, the first device was placed too proximal; it was recaptured and redeployed with a same size device.

The procedural and in-hospital outcomes are shown in Table 3. There was no device embolization or pericardial effusion. There was no periprocedural cerebral event, assess site bleeding, or death during hospital admission. Immediately after the procedure, mild (<3 mm) peridevice leak was observed in three patients (25%), and all had disappeared on TEE performed at the 45-day follow-up. The median length of stay was two days.

Antithrombotic management was showed in Table 4. Most patients received anticoagulant alone or anticoagulant plus aspirin before procedure. After TEE at 45 days follow-up, all patients had well seated devices. No evidence of thrombus in LAA was noted. Antithrombotic was changed to single or dual antiplatelets.

Discussion

Atrial fibrillation increased the risk for cardioembolic event. Anticoagulant is effective in preventing embolic events in these patients with the risk reduction of almost 70%. It is superior to aspirin and aspirin plus low-intensity, fixed-dose

Table 4. Antithrombotic treatment (n = 12)

	Pre procedure, n (%)	Post procedure, n (%)	After 45 days, n (%)
Antiplatelet alone			
Single	0 (0)	0 (0)	3 (25.0)
Dual	2 (16.7)	2 (16.7)	9 (75.0)
Anticoagulant alone	8 (66.6)	7 (58.3)	0 (0)
Anticoagulant plus antiplatelet	2 (16.7)	3 (25.0)	0 (0)

warfarin treatment[5,19]. Restrictions in everyday life, pharmacologic interactions, and the potential risk of major hemorrhage limit this method of treatment[9,19]. Percutaneous LAA occlusion is an improved method, excluding the LAA from blood flow and preventing thrombus formation and subsequent thromboembolic complications. The advantages of this technique include a less invasive procedure, a faster recovery as compare with surgical ligation, and reducing risk of potential bleeding due to long-term anticoagulant therapy. The Watchman® LAA occluder device is the only device that has been evaluate in prospective, controlled, and randomized trial. The multicenter PROTECT AF trial proved the non-inferiority of Watchman® device implantation in comparison to chronic warfarin therapy in patient with non-valvular AF[5].

All patient in the present study had indication to long-term anticoagulation as recommended by current practice guideline[20]. From the $CHADS_2$ and HAD-BLED score, the expected adjusted stroke rate is between 5.9% and 8.5% per year and the bleeding complication is 1.9 to 3.7 per 100 patient-years[21]. They had different indications to LAA occluder device. Four patients had contraindication to OAC due to history of massive gastrointestinal or intracranial bleeding. Seven patients had high bleeding risk determined by HAS-BLED score ≥3. Two patient had previous coronary intervention with drug eluting stent that need long-term dual antiplatelet therapy combined with warfarin. The triple anticoagulant therapy causes a significant rise in bleeding risk[22].

In the PROTECT AF study, all patents were treated with warfarin for 45 days after device implantation to facilitated endothelialization. Warfarin would be stopped if TEE examination showed either complete occlusion of the LAA or if there was residual peridevice flow <3 mm in width. However, recent data support the safety and efficacy of LAA occlusion in patients with contraindication to temporary anticoagulation treated with antiplatelet only after device implantation[23].

Three patients in the present study received novel oral anticoagulants (NOACs) instead of warfarin to prevent embolic complication. Compare with warfarin, both factor Xa inhibitors and two doses of the direct thrombin inhibitor dabigatran showed a reduction in hemorrhagic stroke[12,13]. However, major bleeding rates with these agents exceed 2% to 3% per year. Within two years of initiating therapy with NOACs, 20% of patients had discontinue these agents[12]. One advantage of NOACs is that they do not require monitoring, which make NOACs more clinically acceptable than warfarin. However, lack of widely available antagonists make management problematic when emergency surgical procedures are necessary or when bleeding occurs. While many data showed that NOACs are equal or better than warfarin, no study compared them with percutaneous transcatheter LAA closure.

The mean compression ratio in the presented study was 15.2±6.2%. Oversized device is initially recommended 10% to 20%. In the later study, to optimize implantation result, many experienced centers used 15% to 30% compression ratio[24]. The most concerned periprocedural complication is pericardial effusion with an incidence of 5.2% in PROTECT AF and 2.2% in Continuous Assess Protocol (CAP) registry[25]. This data demonstrated a significant decline in rate of procedure-related safety events with increasing operator experience. In the present study, there was no pericardial effusion or other serious periprocedural complications. All procedures were performed by a single operator who had experience in transseptal puncture, the critical step of procedure.

Peridevice flow is common after Watchman® implantation. In the present study, peridevice flow was observed immediately after implantation in 25% of patients. Compare to patients with complete occlusion, there was no difference in thromboembolic events in those with any peridevice flow regardless of whether or not anticoagulant was continued[26].

Most operators use early or follow-up echocardiographic finding such as present of LAA

thrombus, the absent of large residual flow into the LAA as guide for antithrombotic drug prescription. In the present study, immediately after procedure, most patients received OAC according to the PROTECT AF algorithm (45 days warfarin, dual antiplatelet inhibition until six months post implantation, then aspirin monotherapy). The later evidence showed three months of dual antiplatelet therapy was found to be equally effective in preventing thrombus formation as compare to warfarin[24,27]. After 45-day TEE follow-up, anticoagulation was changed to antiplatelet in all patients.

Conclusion

The results of the present study showed that the percutaneous LAA closure with the Watchman® device is feasible and safe. The successfulness of the procedures and periprocedural complications are similar to standard in literature.

Limitation

The study was retrospective observation study. The significant bias may affect the patient selection. We have a short-term follow-up and limited numbers of patients. The procedure outcomes were highly depended on operator's experience and skill.

What is already known on this topic?

Percutaneous LAA closure is an alternative treatment in patients with non-valvular AF who had high bleeding risk or contraindication to OAC. The Watchman® device is the most evidence base device that its efficacy is proved to be non-inferior to warfarin therapy.

What this study adds?

The present study is the first report of percutaneous LAA closure in Thailand. Although limited numbers of patients, the success of the procedure and low periprocedural complication are similar to standard in literature.

Potential conflicts of interest

None.

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ผลทางคลินิกของการปิด left atrial appendage ผ่านทางสายสวนด้วยอุปกรณ์ Watchman® ในผู้ป่วย atrial fibrillation

ภัทรพงษ์ พีรวงศ์, สมนพร บุณยรัตเวช สองเมือง, วรฤทธิ์ เลิศสุวรรณเสรี, สุดารัตน์ สถิตย์ธรรมนิตย์, สุพจน์ ศรีมหาโชตะ

ภูมิหลัง: ในผู้ป่วยหัวใจห้องบนเต้นผิดจังหวะชนิด non-valvular atrial fibrillation (AF) มีจุดก่อเกิดลิ่มเลือดที่ส่วน left atrial appendage (LAA) การรักษาด้วยยา warfarin สามารถลดความเสี่ยงของภาวะสมองขาดเลือดได้แต่มีข้อพึงระวังคือ warfarin จะเพิ่มความเสี่ยงต่อภาวะเลือดออกในอวัยวะต่าง ๆ โดยเฉพาะในคนสูงอายุ การรักษาด้วยการปิด LAA ผ่านทางสายสวนโดยใช้อุปกรณ์ Watchman® สามารถลดภาวะสมองขาดเลือดได้ไม่ด้อยกว่ายา warfarin ในประเทศไทยยังไม่มีรายงานการรักษาด้วยวิธีนี้

วัตถุประสงค์: เพื่อศึกษาผลการรักษาระยะสั้นของการปิด LAA ผ่านทางสายสวนโดยใช้อุปกรณ์ Watchman® ในผู้ป่วย non-valvular AF ที่โรงพยาบาลจุฬาลงกรณ์

วัสดุและวิธีการ: ได้ทำการศึกษาย้อนหลังจากแฟ้มประวัติผู้ป่วย AF จำนวน 12 ราย ตั้งแต่ เดือนพฤศจิกายน พ.ศ. 2555 ถึง ธันวาคม พ.ศ. 2557 ที่ได้รับการรักษาด้วยวิธีปิด LAA ผ่านทางสายสวน โดยรวบรวมข้อมูลลักษณะทั่วไปของผู้ป่วย ปัจจัยเสี่ยงในการเกิดลิ่มเลือดอุดตัน ($CHADS_2$ และ CHA_2DS_2-VASc score) ปัจจัยเสี่ยงต่อการเกิดภาวะเลือดออก (HAS-BLED score) หัตถการ และผลแทรกซ้อนที่เกิดจากการรักษา

ผลการศึกษา: ผู้ป่วยจำนวน 12 ราย อายุเฉลี่ย 71.2±8.1 ปี มีประวัติเลือดออก 4 ราย (ร้อยละ 33) ค่าเฉลี่ย $CHADS_2$ เท่ากับ 3.2±1.3 ค่าเฉลี่ย CHA_2DS_2-VASc เท่ากับ 4.8±1.6 ค่าเฉลี่ย HAS-BLED เท่ากับ 2.5±0.9 ขนาด LAA เฉลี่ยเท่ากับ 21.7±3.4 มม. ค่ามัธยฐานขนาดอุปกรณ์เท่ากับ 27 มม. compression ratio เฉลี่ยเท่ากับ 15.2±6.2% ผู้ป่วย 3 ราย ได้รับการวางยาสลบระหว่างการรักษา 9 ราย รักษาโดยใช้ยาชาเฉพาะที่ ระยะเวลาในการทำหัตถการเฉลี่ยเท่ากับ 61.2±18.5 นาที ได้รับรังสีเฉลี่ย 6.8±3.3 นาที ไม่พบการหลุดของอุปกรณ์หลังการรักษา ไม่พบภาวะน้ำในช่องเยื่อหุ้มหัวใจ ไม่มีผู้ป่วยเสียชีวิต ผู้ป่วย 3 ราย มีการปิด LAA ไม่สนิท (mild peridevice leak) หลังหัตถการทันที ซึ่งไม่พบจากการตรวจ transesophageal echocardiogram ที่ 45 วัน มัธยฐานระยะเวลานอนโรงพยาบาลเท่ากับ 2 วัน

สรุป: ผลการปิด LAA ผ่านทางสายสวนโดยใช้อุปกรณ์ Watchman® มีความปลอดภัยของหัตถการเท่าเทียมกับมาตรฐานของผลการศึกษาก่อนหน้านี้