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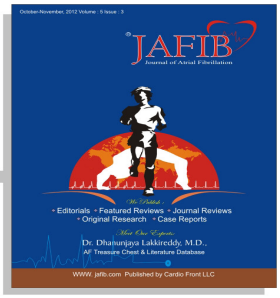

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Combined Catheter Ablation for Atrial Fibrillation and Watchman® Left Atrial Appendage Occlusion Procedures: A Single Centre Experience

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Abstract

Background : Patients with atrial fibrillation (AF) may be interested in undergoing concomitant interventions of left atrial catheter ablation and device occlusion of the left atrial appendage (LAA). We report on the feasibility and outcome of combined procedures in a single centre case series

Methods: Twenty-six patients underwent either first time or redo pulmonary vein isolation (PVI) procedures followed by successful implant of a Watchman® device.

Results: All procedures were uncomplicated with a mean case time of 233 ± 38 minutes. Maximal LAA orifice dimension was smaller in 3 of 26 patients post PVI (range 1mm) than on the pre-procedural transoesophageal echocardiogram (TOE). A new peri-device leak of maximum 3mm was noted in 5 of 26 patients at 6 week follow-up TOE, but resolved in 4 by the 6 month follow-up.

Conclusion: Combined procedures for catheter ablation for AF and Watchman® LAA implant appear to be feasible and safe with satisfactory occlusion of the LAA maintained at follow-up.

Introduction

Left atrial appendage (LAA) occlusion with the Watchman® device (Boston Scientific, Natick, MA, USA) has demonstrated efficacy in long term stroke prevention for patients with non-valvular atrial fibrillation (AF).[1] Catheter ablation therapy for atrial fibrillation is an efficacious rhythm control strategy for patients with symptomatic, drug-refractory AF[2,3] but its role in stroke prevention remains unproven. Patients with symptomatic AF may be interested in undergoing concomitant intervention of left atrial catheter ablation and device occlusion of the LAA.We report on the feasibility and outcome of combined procedures in a single centre case series.

Materials and Methods

Following commercial availability and Therapeutic Goods Administration approval of the Watchman® left atrial appendage occlusion device in Australia in December 2009, patients with a $CHADS_2$ score of 1 or greater seeking to undergo left atrial catheter ablation for symptomatic, drug-refractory non-valvular AF at a single centre were offered concomitant implant.

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Procedural Planning

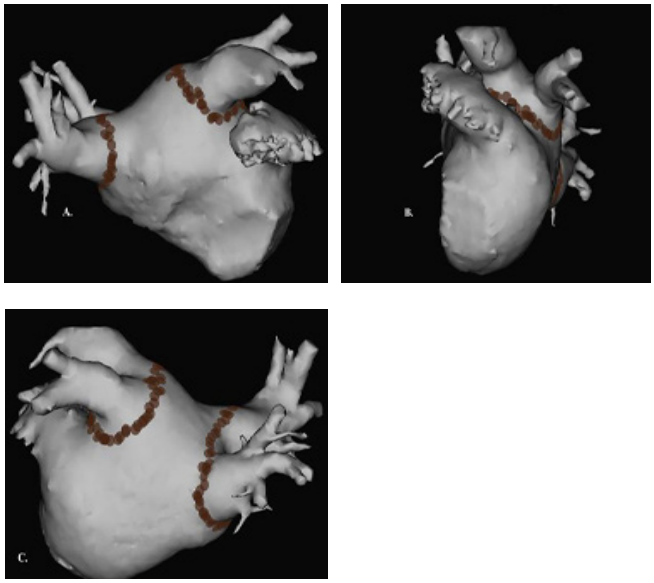
Patients underwent screening transoesophageal echocardiography (TOE) and a contrast 64-slice cardiac CT scan within 7 days of the planned procedure. Three-dimensional reconstruction of the left atrium and pulmonary veins and LAA was performed from the CT scan using Ensite Verismo software (St Jude Medical, St Paul, MN, USA) to assist with planning of the ablation lesion set and anatomical analysis of the LAA takeoff and morphology.[4] Pre-procedural TOE was utilised to exclude LAA thrombus and to assess suitability of the LAA ostial dimensions for percutaneous closure with the Watchman® device as previously described.[5]

Procedure

Antiarrhythmic drug therapy was ceased 3 days prior. Therapeutic warfarin therapy was continued uninterrupted. Dabigatran therapy was omitted for 2 doses and recommenced 4 hours post-procedureProcedures were performed under general anaesthesia using a bifemoral venous approach. Intracardiac echocardiography was utilised to guide double transeptal puncture and during left atrial electro-anatomic 3D mapping and during the ablation phase of the procedure. IV heparin was administered prior to the first transseptal puncture with a target ACT of ≥ 350 seconds. An oesophageal thermistor probe was positioned for monitoring of oesophageal temperatures during the ablation phase.

Ensite NavX 3-D cardiac navigational system (St Jude Medical, St Paul, MN, USA) with image integration of the segmented cardiac CT scan was utilised. A decapolar diagnostic catheter was positioned in the coronary sinus. A 20mm decapolar circular mapping catheter and an irrigated tip ablation catheter were utilised for mapping and radiofrequency ablation. Left and right-sided pulmonary vein antral ring electrical isolation was performed in all patients to an endpoint of complete pulmonary vein entrance and exit conduction block. Additional complex fragmented atrial electrogram (CFAE) guided or linear left or right atrial ablation was individualised according to requirements for persistent forms of AF or for redo ablation procedures. Patients undergoing ablation for persistent AF were cardioverted back to sinus rhythm following pulmonary vein isolation ± CFAE or linear ablation.

Figure 1: CT- integrated NavX model of left atrium showing typical first-time pulmonary vein antral ring isolation ablation. Ablation lesions shown as brown dots. Panel (A) shows superior view, (B) shows left lateral view and (C) posterior view



After completion of the ablation phase, intracardiac echocardiography equipment was removed and TOE imaging by a skilled EchoCardiologist commenced.The more favourable transeptal sheath location was retained (typically more posterior puncture site) and the second sheath withdrawn to the venous circulation.Repeat TOE assessment was performed of LAA ostial dimensions once a mean LAA pressure measurement of ≥ 10mmHg was obtained.Implant of a Watchman® LAA occluder device was then performed as previously described.[5] Post-procedure IV heparin was reversed with Protamine and Aspirin 100mg daily commenced.Antiarrhythmic drug therapy was recommenced.Patients were observed overnight in a Coronary Care Unit and generally discharged within 24 hours of the procedure.

Patient Follow-up

Consecutive Persistent early tachyarrhythmias lasting ≥ 48 hours were treated with electrical cardioversion. Follow-up TOE was performed at 6 weeks to reassess the Watchman® appearances, efficacy of LAA ostial occlusion, exclude pulmonary venous stenosis and the persistence of any

interatrial septal shunt. At 3 months if satisfactory TOE follow-up study had been confirmed and no further cardioversion or catheter ablation therapy was planned then anticoagulation with warfarin or dabigatran was discontinued and clopidogrel therapy commenced for a further 3 months.Further TOE assessment was performed at 6 and then 12 months if any peri-device leak into the LAA was noted at the 6 week study.Clinical follow-up for arrhythmia recurrence was performed at 3, 6 and 12 months guided by patient symptom reporting, 12 lead ECG and implanted cardiac rhythm device interrogation where applicable.Holter monitoring was performed at 12 months or as required to assess symptom recurrence.Antiarrhythmic drug therapy was ceased at or after 3 months according to physician and patient discretion.

Results

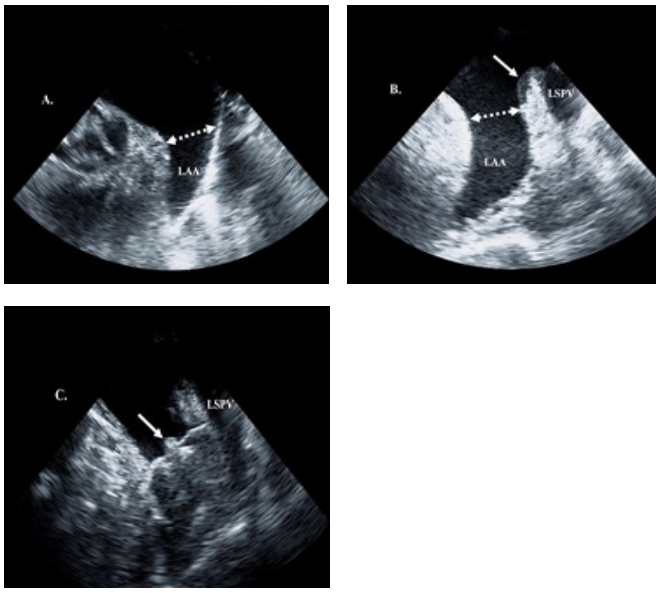
Patient Demographics

Twenty-six patients underwent combined left atrial catheter ablation and implant of a Watchman® LAA occlusion device between February 2010 and June 2012. An additional 4 patients were screened and excluded – 2 patients had LAA ostium dimensions >31mm and proceeded with catheter ablation therapy alone; 2 patients were found to have persistent LAA thrombus despite appropriate anticoagulation regimen of whom 1 subsequently proceeded to open surgical excision and oversew of the LAA.Twenty males and six females were included with a mean age of 63 ± 7 years (range 43-73).The group included 14 patients with paroxysmal, 8 with persistent and 4 with longstanding persistent forms of AF. The mean duration of AF prior to the procedure was 10 ± 9 years (range 1 – 40).The mean Symptom Score for AF (CCS-SAF)[6] was 3.7 ± 0.4. Twenty patients were undergoing a first time ablation procedure for AF and 6 patients were undergoing a redo (2nd procedure). The mean $CHADS_2$ score was 1.9 ± 0.7 (range 1 – 3) and mean $CHADS_2VASc$ score was 2.6 ± 0.8 (range 1 – 4).All patients had been on established anticoagulation prior to the procedure with 21 patients on warfarin and 5 on dabigatran.

Acute Procedural Success

Successful acute ablation endpoints were achieved in all patients, including complete pulmonary vein electrical isolation and return to stable sinus rhythm.Successful Watchman® LAA implantation was achieved in all patients with a small peri-device leak of 4mm accepted in 1 patient at implant. The mean total procedure time was 233 ± 38 minutes (range 160 – 330). The mean fluoroscopic time was 38 ± 8 minutes (range 20 – 63) and radiation dose area product (DAP) 21 ±17 Gycm2 (range 4 – 77).There were no acute procedural complications. All patients were discharged within 24 hours of the procedure.

Figure 2: Serial TOE images at 0° for an individual patient who underwent combined first-time ablation procedure and implant of Watchman® device. Dashed arrow shows approximate level of expected device occlusion. Panel (A) pre-procedure screening; (B) post-ablation – note proximal oedematous ridge (arrow) shared with left superior pulmonary vein (LSPV); (C) following deployment of Watchman® device (arrow). LAA = left atrial appendage



LAA Ostial Assessment

In patients undergoing first time ablation (ie. with an acute left pulmonary vein antral ring ablation) significant oedema of the proximal ridge or limbus between the left pulmonary veins and LAA opening was typically noted. (Fig 2.)Ostial dimensions at the planned approximate level of LAA device occlusion differed in 15 of 26 patients from the pre-procedure to post-ablation TOE.In 3 of the 15 patients the maximal LAA ostial dimension was smaller post-ablation (range 1mm), and in 12 patients the dimension was larger post-ablation (range 1 – 3mm).

TOE Follow-up

All patients had satisfactory Watchman® appearances and occlusion of the LAA at 6 week follow-up.No device thrombus was detected.The case of peri-device leak from implant reduced from 4mm at implant to 2mm at 6weeks, then 1mm at 6 months.Five new peri-device leaks were detected at the 6 week TOE (range 1 – 3mm) with 4 of the leaks resolving again by the 6 month follow-up (Fig 3.) and one 2mm leak persisting. No pulmonary venous stenosis was detected.

Clinical Follow-up

25 of 26 patients were in sinus rhythm at 3 month follow-up and oral anticoagulation was discontinued and substituted with Aspirin/Clopidogrel in all. Twenty patients remain free of detectable arrhythmia at follow-up to date (mean 360 ± 256 days) based on symptom reporting, 12 month Holter monitor and implanted cardiac device interrogation.The mean CCS-SAF score at follow-up was 0.6 ± 0.8. Arrhythmia recurrence was noted in 6 patients (3 paroxysmal, 2 persistent, 1 longstanding persistent).Two patients subsequently underwent redo catheter ablation procedures for atrial tachyarrhythmia recurrence, (recommencing oral anticoagulation peri-procedure) with subsequent freedom from arrhythmia.Antiarrhythmic drug therapy was ceased post-procedure in 18 patients (14 paroxysmal at 3 months,4 persistent at 6 months) .No clinical neurological events were detected based on patient symptom reporting during follow-up to date (mean 360 ± 256 days). Routine neuro-radiological evaluation was not performed to examine for sub-clinical events. One patient (longstanding persistent) was deceased at 5 months post-procedure from suicide.The coronial report did not implicate the procedure in the cause or circumstances of the death.The post-mortem cardiac findings showed no cardiac thrombus, with almost complete endothelialization of the device surface.

Discussion

To our knowledge this is the first reported experience of concomitant percutaneous left atrial appendage device closure with catheter ablation procedures for patients with atrial fibrillation. The results demonstrate the feasibility and safety of a combined procedure with either complete or satisfactory left atrial appendage occlusion maintained at follow-up.While there is the potential for ablation – induced tissue injury at the ostium of the LAA following left pulmonary vein isolation, in practice the level of occlusion with the Watchman® device is typically distal to any observed oedematous change.Variation in the maximal measured LAA ostial dimension between the pre-procedure TOE and the post-ablation TOE was observed in more than half of the patients. The discrepancy, however, was most frequently an underestimation of the ostial size and is probably explained by additional fluid loading during the procedure associated with irrigated ablation, or given specifically to achieve a mean left atrial pressure ≥10 mmHg, as compared with a relatively hypovolaemic, fasted state during the screening TOE.

The development of "new" small peri-device leak at the initial follow-up TOE has also been observed by the authors in standalone Watchman® implantation (without concomitant ablation). It is presumed to be related to a minor mismatch between the circular device and typical elliptical orifice of the LAA that is partially masked by an injury / oedema response at the time of implant. Reassuringly the majority of these new leaks, although small, were observed to resolve with remodelling at subsequent follow up. Evidence suggests that small residual peri-device leaks are unlikely to compromise the efficacy of left atrial appendage occlusion

Figure 3: Serial TOE images at 130-135° for an individual patient who developed a new peri-device leak (arrowed) at the 6 week follow-up shown in panel A, with subsequent resolution at the 6 month study as shown in Panel B. LSPV = left superior pulmonary vein

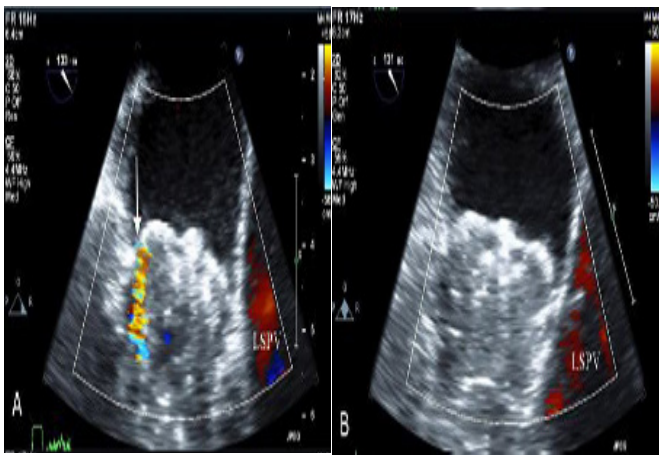


Table 1 . Demographic and Clinical Variables for Patient Group

	n= 26
Age (yrs)	63 (± 7)
Females (n)	6 (23%)
Paroxysmal AF (n)	14 (54%)
Duration of AF (yrs)	10 (± 9)
Diabetes (n)	5 (19%)
Hypertension (n)	20 (77%)
IHD (n)	4 (15%)
CHF (n)	2 (8%)
CVA (n)	11 (42%)
EF (%)	62 (± 5)
Echo LA area (cm2)	27 (± 6)

AF: Atrial Fibrillation, IHD: Ischaemic Heart Disease, CHF: Congestive Heart Failure, CVA: prior stroke / TIA, EF: Ejection Fraction, Echo LA area: transthoracic apical 4 chamber left atrial area ARB, angiotensin II receptor antagonist.

devices.[7]

The majority of the procedures were performed on patients taking warfarin with a therapeutic INR at the time of the intervention. The safety of this approach is well documented for patients undergoing catheter ablation procedures for AF.[8] This series suggests that this is also a safe approach for patients undergoing percutaneous LAA device occlusion

It might be argued that left atrial appendage device occlusion would preclude subsequent access to the left atrial appendage for the ablation of focal tachycardias which may be responsible for recurrent atrial tachyarrhythmias in this population[9] The position of the Watchman® device, in contrast to other commercially available left atrial appendage device occlusion systems, is however sufficiently distal to still permit electrical isolation of the left atrial appendage ostium.
Finally, the results from catheter ablation therapy in this cohort have been comparable to outcomes for other patients at our centre, although follow-up times remain relatively short. The majority of patients with persistent or longstanding persistent AF, however, did not discontinue antiarrhythmic drug therapy post-procedure.

Conclusions

Combined procedures of catheter ablation for atrial fibrillation and percutaneous closure of the left atrial appendage with the Watchman® device were efficacious and safe in our single centre experience.

Disclosures

- Dr Karen Phillips has received consultancy fees from Boston Scientific.

- No financial disclosures for the other authors.

References

1. Holmes DR, Reddy VY, Turi ZG, Doshi SK, Sievert H, Buchbinder M, Mullin CM, Sick P. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. Lancet 2009; 374: 534 - 542.
2. Marchlinski F, Natale A, Macle L, Daoud EG, Calkins H, Hall B, Reddy V, Augello G, Reynolds MR, Vinekar C, Liu CY, Berry SM, Berry DA. Comparison of antiarrhythmic drug therapy and radiofrequency catheter ablation in patients with paroxysmal atrial fibrillation: a randomized controlled trial. JAMA 2010;303(4):333-401.
3. Tzou WS, Marchlinski FE, Zado ES, Lin D, Dixit S, Callans DJ, Cooper JM, Bala R, Garcia F, Hutchinson MD, Riley MP, Verdino R, Gerstenfeld EP. Long-term outcome after successful catheter ablation of atrial fibrillation. Circ Arrhythm Electrophysiol. 2010 Jun;3(3):237-42.
4. Walker DT, Humphries JA, Phillips KP. Anatomical Analysis of the Left Atrial Appendage using Segmented Three- Dimensional Cardiac CT: A Comparison of Patients with Paroxysmal and Persistent Forms of Atrial Fibrillation. J Interv Card Electrophysiol. 2012;34(2):173-179
5. Reddy VY, Holmes DR, Doshi SK, NeuzilP, Kar S. Safety of percutaneous left atrial appendage closure: results from the Watchman Left Atrial Appendage System for Embolic Protection in Patients with AF (PROTECT AF) clinical trial and the Continued Access Registry.Circulation 2011;123(4):417-424
6. Dorian P, Guerra PG, Kerr CR, O'Donnell SS, Crystal E, Gillis AM, Mitchell LB, Roy D, Skanes AC, Rose MS, Wyse DG. Validation of a new simple scale to measure symptoms in atrial fibrillation: the Canadian Cardiovascular Society Severity in Atrial Fibrillation scale. Circ Arrhythm Electrophysiol. 2009;2(3):218-24
7. Viles-Gonzalez JF, Reddy VY, Petru J, Mraz T, Grossova Z, Kralovec S, Neuzil P. Incomplete occlusion of the left atrial appendage with the percutaneous left atrial appendage transcatheter occlusion device is not associated with increased risk of stroke. J Interv Card Electrophysiol. 2012;33(1):69-75.
8. Santangeli P, Di Biase L, Horton R, Burkhardt JD, Sanchez

J, Al-Ahmad A, Hongo R, Beheiry S, Bai R, Mohanty P, Lewis WR, Natale A. Ablation of atrial fibrillation under therapeutic warfarin reduces periprocedural complications: evidence from a meta-analysis. Circ Arrhythm Electrophysiol. 2012;5(2):302-11.
9. Di Biase L, Burkhardt JD, Mohanty P, Sanchez J, Mohanty S, Horton R, Gallinghouse GJ, Bailey SM, Zagrodzky JD, Santangeli P, Hao S, Hongo R, Beheiry S, Themistoclakis S, Bonso A, Rossillo A, Corrado A, Raviele A, Al-Ahmad A, Wang P, Cummings JE, Schweikert RA, Pelargonio G, Dello Russo A, Casella M, Santarelli P, Lewis WR, Natale A. Left atrial appendage: an under recognized trigger site of atrial fibrillation. Circulation. 2010;122(2):109-18