Surgical strategies for a failed Watchman device

Sarah T. Palmer, MD, Matthew A. Romano, MD, Steven F. Bolling, MD, and Shinichi Fukuhara, MD, Ann Arbor, Mich

Transcatheter closure of the left atrial appendage (LAA) using a Watchman device (Boston Scientific, Plymouth, Minn) is an approved alternative to oral anticoagulation to reduce the risk of stroke in patients with atrial fibrillation that are considered at high risk for bleeding complications.1 Device malposition and/or incomplete LAA seal are known inherent modes of device failure. These events may be underreported, because most of these nonfatal complications can be managed by continued antithrombotic therapy. These scenarios may exacerbate thrombus formation, however, with the reported incidence of device-related thrombus as high as 3.9%.2 The PREVAIL trial, a landmark Watchman device study, failed to demonstrate that LAA occlusion was noninferior to warfarin at preventing adverse events at 18 months.1 Although another landmark trial, the PROTECT-AF trial, demonstrated noninferiority of Watchman LAA occlusion versus warfarin alone, its sub-study revealed that a peri-device flow rate at 12 months as high as 32%.3 Moreover, none of those studies reported the number of patients requiring a surgical intervention and associated outcomes.

Surgical device removal or exclusion is rarely considered except in situations with devastating device-related complications. There are limited data regarding the optimal approach and the feasibility of surgical device explant. We present a case series of Watchman device failures and discuss strategies for extraction or alternative approaches to LAA occlusion.

CLINICAL SUMMARY

We evaluated 5 cases of Watchman failure necessitating surgical intervention. Essential clinical data are summarized in Tables 1 and 2. Written informed consent for publication was obtained from each patient. All patients had a failed transcatheter radiofrequency ablation procedure and underwent Watchman implantation. The mean patient age was 74.4 years and 2 patients were male. The mean CHA2DS2-VASc score was 7.6. Of note, all developed bleeding complications, including 3 gastrointestinal (60%) 1 retroperitoneal (20%), and 1 hemorrhagic stroke (20%) while being maintained on oral anticoagulation in the presence of device failure. Modes of failure were peri-device leak in 3 patients (60%) device dislodgement in 1 patient (20%), and peri-device thrombus formation refractory to medical therapy in 1 patient (20%) (Figure 1).

Watchman device removal/exclusion was the primary indication in 3 cases: case 1, a nonresponder to anticoagulation with multiple thrombi in the setting of peri-device leak; case 2, device dislodgement and anticoagulation intolerance due to gastrointestinal bleeding; and case 3, a peri-device leak with hemorrhagic stroke. It was the secondary indication in cases 4 and 5, with severe mitral regurgitation and peri-device leak, one of which was an incidental intraoperative finding. Three devices (60%)
were explanted (Figure 2; Video 1), with subsequent LAA closure either using an AtriClip (AtriCure, Mason, Ohio) or performing primary endocardial suture closure with a running double layer of polypropylene. In case 3, the Watchman device was excluded through a thoracoscopic approach with a 45-mm Pro-V AtriClip (AtriCure)

### TABLE 1. Relevant clinical characteristics at index Watchman implantation

| Characteristic                          | Patient 1          | Patient 2          | Patient 3          | Patient 4          | Patient 5          |
|----------------------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Age (y)/sex                            | 77/female          | 68/male            | 78/male            | 74/female          | 75/female          |
| CHA2DS2-VASc score                     | 8                  | 6                  | 9                  | 9                  | 6                  |
| Previous radiofrequency ablation procedure | Yes                | Yes                | Yes                | Yes                | Yes                |
| Year of Watchman device implant        | 2017               | 2018               | 2017               | 2019               | 2016               |
| Device size (mm)                       | 33                 | 24                 | 24                 | 24                 | Unknown            |
| Index Watchman device placement procedure | Initial attempt with suboptimal compression/residual flow; fully retrieved; second attempt successful | Uneventful | Initial attempt with 27 mm with suboptimal positioning; second attempt successful | Uneventful | Unknown |
| Antithrombotic regimen before surgery  | Warfarin           | Aspirin + rivaroxaban | Warfarin           | Dual antiplatelet therapy | Warfarin           |
| Preceding stroke                       | No                 | No                 | Yes                | No                 | No                 |

### TABLE 2. Relevant clinical characteristics at Watchman explantation/exclusion

| Characteristic                                              | Patient 1          | Patient 2          | Patient 3          | Patient 4          | Patient 5          |
|-------------------------------------------------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Clinical indication for Watchman explant or exclusion        | Peri-device leak and multiple thrombi formation refractory to medical therapy in the setting of multiple gastrointestinal bleeding episodes | Device dislodgement in the setting of gastrointestinal bleeding | Peri-device leak in the setting of hemorrhagic stroke | Intraoperatively incidentally detected peri-device leak in the setting of severe mitral regurgitation | Peri-device leak in the setting of severe mitral regurgitation |
| Echocardiographic findings                                  | Large thrombi attached to the device as well as the left atrial wall | Closure device protruding into the left atrium with partial dehiscence | Peri-device leak | Peri-device leak | Peri-device leak |
| Procedure for the Watchman device and left atrial appendage | Explantation with clip | Explantation with primary closure | Thoracoscopic exclusion with clip | Explantation with clip | Device left in situ due to severe incorporation; bovine pericardial patch exclusion |
| Watchman age (y)                                           | 3                  | 2                  | 1                  | 2                  | 4                  |
| Other concurrent procedures                                | Full biatrial Maze + aortic valve replacement | Full biatrial Maze | Left atrial Maze | Full biatrial Maze + mitral replacement | Full biatrial Maze + mitral replacement |
| Postexplant/exclusion echocardiographic findings of the left atrial appendage | No flow or residual stump | No flow or residual stump | No flow or residual stump | No flow or residual stump | No flow or residual stump |
| Current antithrombotic agent regimen                       | None               | Aspirin            | Aspirin            | Aspirin + rivaroxaban | Warfarin           |
| Latest follow-up                                          | Doing well at 3 mo | Doing well at 3 mo | Doing well at 2 y | Doing well at 3 mo | Doing well at 6 mo |
In case 5, the device was excluded with bovine pericardium owing to severe endothelialization and the inability to be explanted. Overall, 3 of 4 (75%) attempted device extractions were successful without major LAA damage. All patients underwent a concurrent Maze procedure with or without valve replacement. Anticoagulation therapy was discontinued immediately postoperatively or within 6 months for cases 1 to 3.

**DISCUSSION**

We have described a series of Watchman device-related complications requiring surgical intervention. The first point to consider is when to treat a failed device. Intolerance of anticoagulation, such as bleeding in the presence of a peri-device leak or residual stump, warrants intervention. This scenario may exacerbate additional thromboembolic risk in addition to atrial fibrillation, given the presence of a thrombogenic foreign body in the LAA. It is likely that only a small subset of these patients are referred to surgery; most patients are managed by continued antithrombotic therapy, which, ironically, contradicts the original concept of the Watchman device.

The second point to consider is how to treat a failed device. We strongly advocate device removal when technically possible. O’Hara and colleagues presented the first reported surgical Watchman extraction due to recurrent device-related thrombus in which the LAA was resected with the device. In contrast, in our series, 3 different surgical strategies—Watchman explant, thoracoscopic Watchman exclusion with external clipping, and bovine pericardial patch exclusion—were used based on the need for other simultaneous procedures. A thoracoscopic approach is used in patients who are not undergoing reoperation, do not require a concomitant procedure, have no atrial thrombus present, and have no protrusion of the device (ie, must have a neck on which to place a clip). Despite

**FIGURE 1.** Explanted Watchman device with associated thrombi from a 77-year old woman with a history of severe aortic stenosis and atrial fibrillation status after failed ablation therapy who had a Watchman device placed in 2017 (case 1). Follow-up echocardiography and computed tomography scan (A and B) and transesophageal echocardiography (C) revealed the presence of multiple large thrombi in her left atrium that were associated with her device. She underwent an aortic valve replacement, biatrial Maze, and extraction of the left atrial thrombus and Watchman device (D), with closure of her left atrial appendage using a 45-mm AtriClip.
late-stage extraction with complete endothelialization, most devices can be safely removed, providing high-risk patients with an alternative treatment to lifelong anticoagulation.

References
1. Reddy VY, Doshi SK, Kar S, Gibson DN, Price MJ, Huber K, et al; PREVAIL and PROTECT AF Investigators. 5-year outcomes after left atrial appendage closure: from the PREVAIL and PROTECT AF trials. *J Am Coll Cardiol*. 2017;70:2964-75.
2. Lempereur M, Aminian A, Freixa X, Gafour S, Kefer J, Tzikas A, et al. Device-associated thrombus formation after left atrial appendage occlusion: a systematic review of events reported with the Watchman, the Amplatzer cardiac plug, and the Amulet. *Catheter Cardiovasc Interv*. 2017;90:E111-21.
3. Viles-Gonzalez JF, Kar S, Douglas P, Dukkipati S, Feldman T, Horton R, et al. The clinical impact of incomplete left atrial appendage closure with the Watchman device in patients with atrial fibrillation: a PROTECT AF (Percutaneous closure of the left atrial appendage versus Warfarin therapy for prevention

**Figure 2.** A, Preoperative echocardiography showing a malpositioned Watchman device in a 68-year-old man (case 2). B, Intraoperative photographs of the Watchman explant procedure. Approximately 50% of the device was protruding into the left atrium without associated thrombus. Although the device was completely endothelialized, it was successfully extracted without major injury to the left atrial appendage tissue. The orifice of the left atrial appendage was then closed with a running 4-0 Prolene suture in 2 layers. C, The explanted Watchman device was completely intact on removal.

**Video 1.** Demonstration of various complications associated with Watchman device and surgical strategies. Video available at: https://www.jtcvs.org/article/S2666-2507(20)30400-4/fulltext.
of stroke in patients with atrial fibrillation) substudy. J Am Coll Cardiol. 2012; 59:923-9.

4. Romano MA. Minimally invasive thoracoscopic exclusion of the left atrial appendage following Watchman device with an AtriCure ProV LAA exclusion device. Innovations. 2019;14:509-11.

5. O’Hara C, O’Hara GE, Jacques F, Champagne J, Lemyre M, Charbonneau L, et al. Run with the hare and hunt with the hounds: Watchman device surgical resection in the setting of recurrent device related thrombi in a patient with bleeding diathesis. JACC Cardiovasc Interv. 2016;9:e223-5.