Surgical strategies for a failed Watchman device

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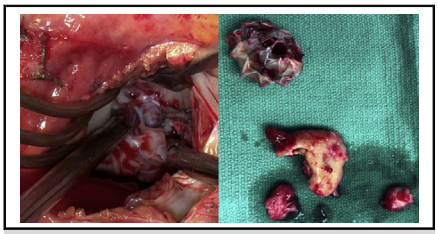


Intraoperative photographs of Watchman device explant and associated thrombi.

CENTRAL MESSAGE

Surgical extraction or exclusion of a failed Watchman device is a feasible alternative in patients who are not candidates for medical management.

See Commentaries on pages 165 and 167.

Video clip is available online.

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 substudy 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 CHA_2DS_2-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%)

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
CHA_2DS_2-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

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 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

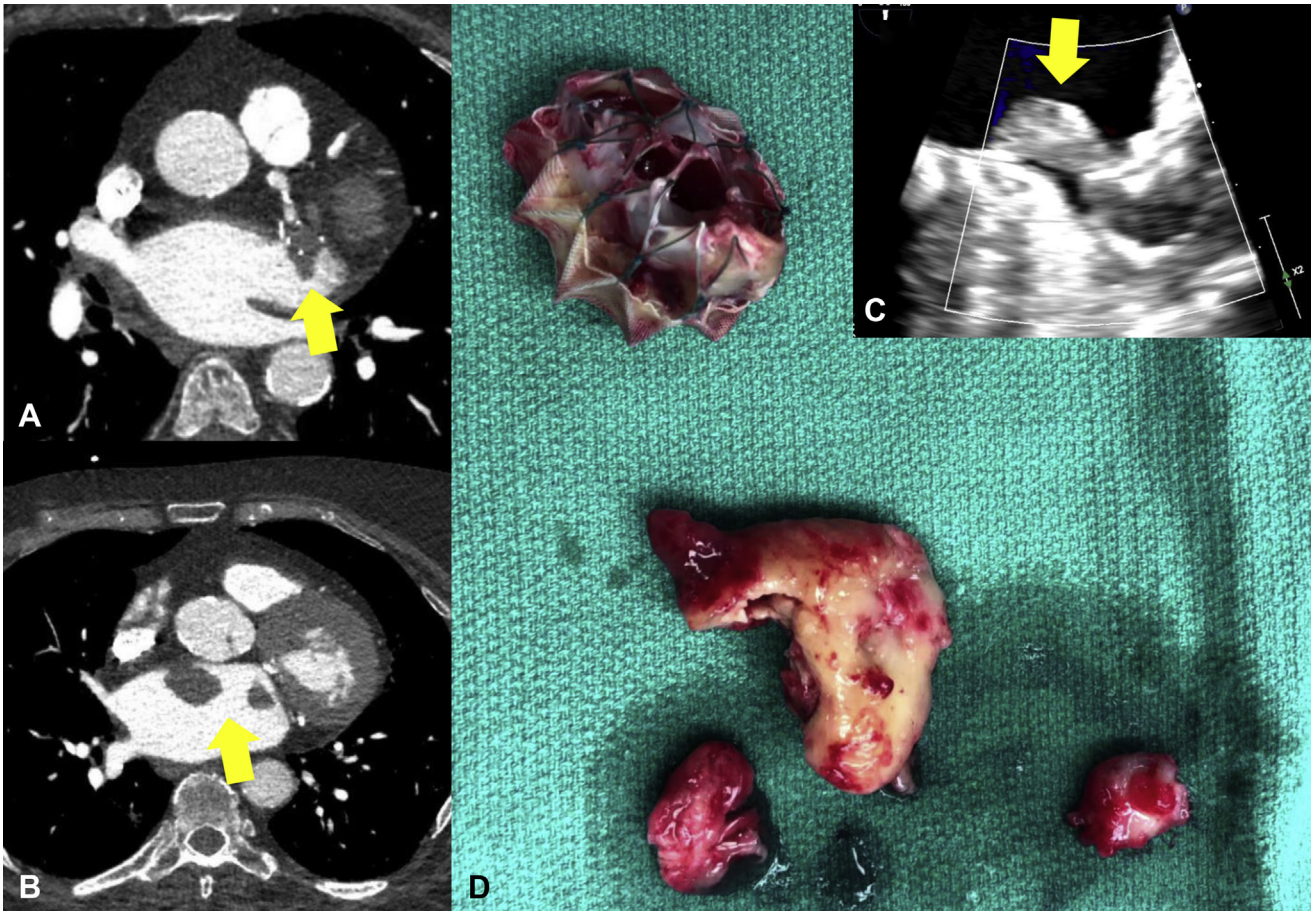


FIGURE 1. Explanted Watchman device with associated thrombi from a 77-year old woman with a history of severe aortic stenosis and atrial fibrillation status after failed ablation therapy who had a Watchman device placed in 2017 (case 1). Follow-up echocardiography and computed tomography scan (A and 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.

(Video 1).[4] 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[5] 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

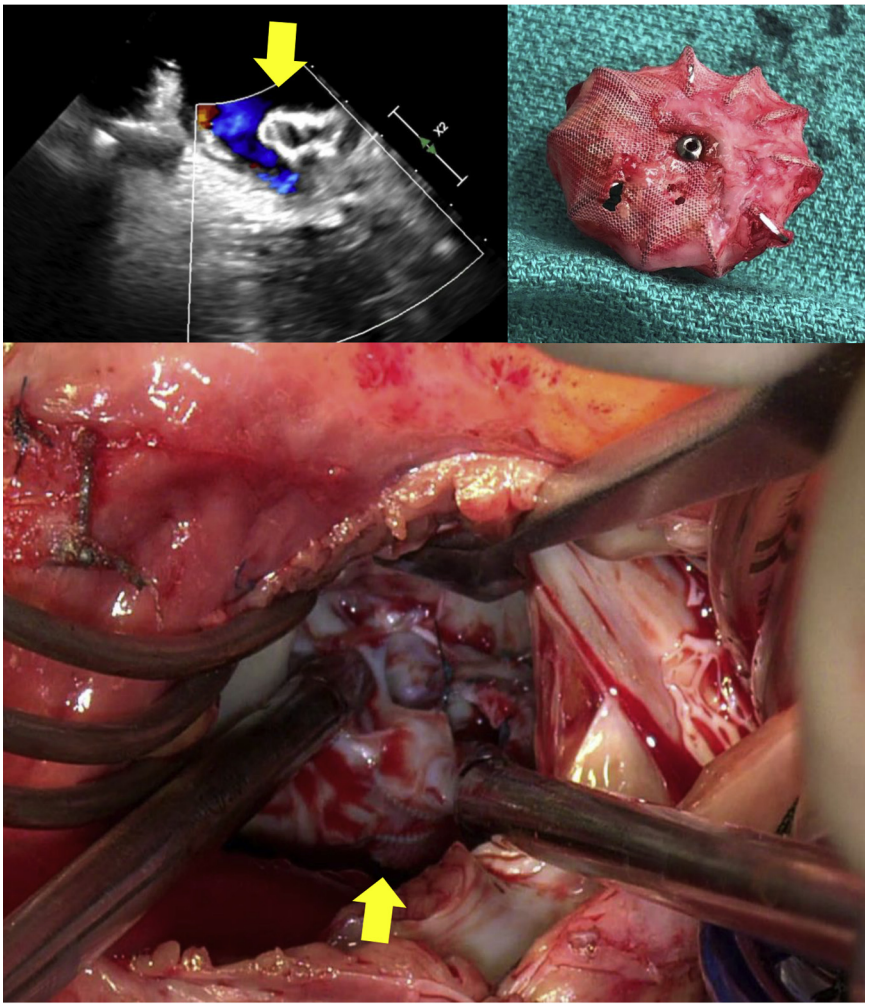
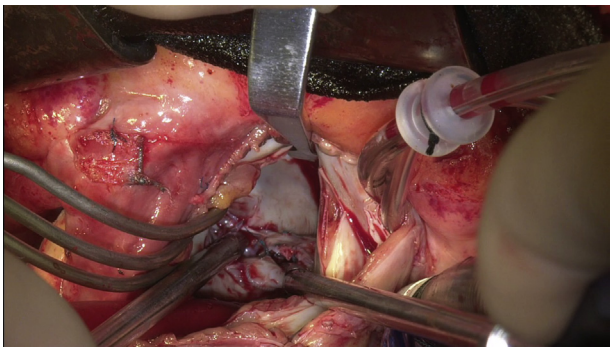


FIGURE 2. A, Preoperative echocardiography showing a malpositioned Watchman device in a 68-year-old man (case 2). B, Intraoperative photographs of the Watchman explant procedure. Approximately 50% of the device was protruding into the left atrium without associated thrombus. Although the device was completely 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.

late-stage extraction with complete endothelialization, most devices can be safely removed, providing high-risk patients with an alternative treatment to lifelong anticoagulation.

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