

# Infection Rate and Outcomes of Watchman Devices: Results from a Single-Center 14-Year Experience

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## Keywords

Watchman device · Endocarditis · Bacteremia

## Abstract

The Watchman device (WD) is a commonly used alternative strategy to oral anticoagulation for stroke risk reduction in patients with atrial fibrillation who have an increased bleeding risk. There are rare case reports of WD-related infection. Currently, there is no formal study that has systematically evaluated the incidence and outcomes WD-related infections. The objective of this study was to evaluate the incidence, risk factors, and outcomes for WD-associated infections in a single-center cohort over a 14-year period. All patients who underwent WD implantation over a 14-year study period (July 2004 through December 2018) comprised our cohort. Baseline characteristics, procedural data, and post-implantation events were identified through a retrospective chart review. Primary study outcomes included WD-related infection, other cardiovascular device-related infection, bacteremia, and mortality. A total of 181 patients (119 males; 65.7%) with a mean age of 75 years at implantation were included in the analysis. A total of 534.7 patient years of follow-up was accrued, with an average of 2.9 years per patient. The

most common indications for implantation included gastrointestinal bleeding (56 patients; 30.9%) and intracerebral bleeding (51 patients; 28.2%). During the follow-up period, 37 (20.4%) patients died. Six developed evidence of bacteremia. Only 1 developed an implantable cardioverter defibrillator infection that required a complete system extraction. None of the cohort developed a WD-related device infection during the study period. We concluded that there is a low risk of WD-related infection even in the setting of a blood stream infection.

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## Introduction

Left atrial appendage occlusion with a Watchman device (WD) (Boston Scientific, St. Paul, MN, USA) is an alternative strategy to oral anticoagulation for embolic stroke risk reduction in patients with nonvalvular atrial fibrillation (AF) who have an increased risk of bleeding.

There are rare case reports of WD-associated infection [1–3]. While the original Watchman trials reported on adverse outcomes broadly, they did not directly report on

**Table 1.** Details of bloodstream infection cases

Microbiological isolate	Infectious source/ syndrome	Time post im- plantation, days	Device leak
Viridans group <i>Streptococcus</i>	Infected ICD and IE	1,897	No
<i>E. coli</i>	Urinary tract infection	1,245	No
<i>S. agalactiae</i>	No source identified	1,085	No
<i>M. luteus</i>	No source identified	1,203	No
Methicillin-susceptible <i>S. aureus</i>	Pneumonia	226	No
<i>P. aeruginosa</i>	Urinary tract infection	26	No

the incidence of WD-related infections or outcomes in the setting of blood stream infections (BSI) [4–6].

We sought to evaluate the incidence, risk factors, and outcomes for WD-associated infections in a single-center cohort over a 14-year period.

## Methods

A retrospective review of all patients who underwent WD implantation from July 2004 through December 2018 was conducted. All patients were enrolled in a regimented follow-up protocol. Intra-procedural transesophageal echocardiogram (TEE) was performed. At 6 weeks postimplantation, all patients presented for an in-person visit with TEE. If a device leak (>5mm) was noted on that TEE, then patients returned at 6 months after implantation for the same evaluation. At 1 year postimplantation, they again presented for an in-person visit with a TEE. After 1 year postimplantation, the patients were followed clinically. For 6 months after implantation, the patients were instructed to take prophylactic antibiotics for dental procedures involving manipulation of the gingiva.

From this cohort of patients, we performed a detailed medical chart review to identify medical comorbidities, indications for implantation, clinical and laboratory evidence of WD infection, BSI, and mortality data. A BSI was defined by at least 1 positive blood culture correlating to a clinical syndrome of infection. Valvular and WD-related endocarditis was defined by modified Duke criteria [7].

Categorical variables are reported as percentages, and continuous variables are reported as means  $\pm$  SD.

## Results

A total of 181 patients underwent WD implantation at the Mayo Clinic in Rochester, MN, USA, during the study period. The average age at implantation was 75 years ( $\pm 7.9$ ). Patients were followed for a total of 534.7 patient years, with an average follow-up time of 2.9 years.

A total of 84 (46.4%) patients had persistent AF, while 97 (53.6%) had paroxysmal AF. A total of 159 (87.8%) patients had hypertension and 57 (31.5%) had diabetes mellitus. The median CHA<sub>2</sub>DS<sub>2</sub>-VASc score was 4 (IQR = 2) and the median HAS-BLED score was 3 (IQR = 1). Gastrointestinal bleeding ( $n = 56$ ; 30.7%), intracerebral hemorrhage ( $n = 51$ ; 28.0%), and patient preference for avoidance of anticoagulation ( $n = 23$ ; 12.6%) constituted the most common indications for WD implantation, with other indications including cerebral amyloid angiopathy, genitourinary bleeding, ischemic stroke despite anticoagulation, pulmonary hemorrhage, epistaxis, retinal bleeding, extremity bleeding, and recurrent atrial thrombi.

There were no instances of WD-related infection or endocarditis throughout the follow-up period. There were 6 patients who had evidence of bacteremia postimplantation. Pathogens identified included viridans group *Streptococcus*, *Escherichia coli*, *Streptococcus agalactiae*, *Micrococcus luteus*, methicillin-susceptible *Staphylococcus aureus*, and *Pseudomonas aeruginosa*. Infectious syndromes included an implantable cardioverter defibrillator-associated endocarditis, sepsis secondary to a urinary source, and sepsis secondary to a pulmonary source (Table 1). Five out of 6 BSI episodes occurred >3 months after implantation; 1 occurred 26 days after implantation. None of the 6 patients who had BSI developed a significant peri-device leak (defined as >5 mm in size). In the setting of BSI, subsequent TEE were performed and none showed evidence of device vegetation. All 6 patients ultimately recovered from their BSI with clear blood cultures after appropriate antibiotics. A total of 37 patients died during follow-up, with an overall mortality of 20.4%; however, no death was infection related. Of the 6 patients who developed a BSI, 2 died during follow-up, i.e., one while in hospice and the other from myasthenic crisis.

## Discussion

This is the first systematic evaluation of a single cohort over a 14-year study period to report on WD infection or associated endocarditis, and no cases of WD-related infections were identified. Despite a small subset of patients developing BSI, there was no evidence of WD infection and no WD was removed in an attempt to cure infection. There was 1 patient who required ICD extraction with subsequent BSI clearance. These findings suggest that WD infections are uncommon.

Complete endocardialization of the surface of cardiovascular devices reduces the risk of a subsequent device-related infection and is thought to develop within 3 months of device implantation [8]. In theory, a WD with peri-device leak, and therefore more turbulent flow surrounding it, might be more susceptible to a complicating device-related infection. None of the 6 patients in our cohort who had BSI had evidence of a peri-device leak during follow-up. Only 1 of them developed BSI within 3 months of implantation.

One patient in our cohort developed an ICD infection due to viridans group *Streptococcus*. The patient underwent device extraction and a prolonged course of antibiotics with clearance of BSI. Despite sustained BSI due to ICD infection, the WD never developed infection.

No device-related infection was described in the original Watchman trials [4–6]. It is concerning, however, whether monitoring for this complication was done in these trials; for example, 1 patient [1] enrolled in the PROTECT AF trial actually developed WD-related endocarditis that was not described in the original trial results. This study is limited by its retrospective nature, data from a single center, and the inherent rarity of endocarditis.

To our knowledge, our cohort is the first to specifically describe infection/related surveillance after WD implantation. This cohort provides relative reassurance that the WD has a low risk of device infection, even in the setting of BSI. A total of 534 years of patient follow-up is a reasonably long period of time and adds credence to this declaration. Future surveillance will be needed to demonstrate the persistence of these findings and better delineate how peri-device leak or the time to implantation might impact the susceptibility to device-related infection.

## Statement of Ethics

This study was conducted ethically and in accordance with the World Medical Association Declaration of Helsinki. The protocol was approved by the Mayo Clinic Institutional Review Board (IRB 17-000314). Given the retrospective nature of this work, no formal consent from the subjects was obtained.

## Conflict of Interest Statement

R.C.W.: Mayo Clinic, Fellow.

T.M.: Mayo Clinic, Resident.

F.A.: Mayo Clinic, Resident.

S.P.: Creighton University, Fellow.

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## Author Contributions

R.C.W.: study conception, data acquisition, data analysis and interpretation, drafting and revision of this paper, and approval of the final product.

T.M., F.A., and S.P.: data acquisition and analysis, drafting of this paper, and approval of the final product.

S.J.A., L.M.B., D.R.H. Jr., and D.C.S.: study conception, interpretation of data, revision of this paper, and approval of the final product.

C.V.S.: study conception, interpretation of the data, drafting and revision of this paper, and approval of the final product.

## References

- 1 Khumri TM, Thibodeau JB, Main ML. Transesophageal echocardiographic diagnosis of left atrial appendage occluder device infection. *Eur J Echocardiogr*. 2008;9(4):565-6.
- 2 Jensen J, Thaler C, Saxena R, Calcaterra D, Sanchez J, Orlandi Q, et al. Transesophageal Echocardiography to Diagnose Watchman Device Infection. *CASE (Phila)*. 2020 Feb;4(3):189-94.
- 3 Boukobza M, Smaali I, Duval X, Laissy JP. Convexity Subarachnoid Hemorrhage, Pseudomonas Aeruginosa (PA) Infective Endocarditis and Left Atrial Appendage Occluder (LAAO) Device Infection. A Case Report. *Open Neuroimaging J*. 2017 May;11(1):26-31.
- 4 Boersma LV, Ince H, Kische S, Pokushalov E, Schmitz T, Schmidt B, et al.; EWOLUTION Investigators. Efficacy and safety of left atrial appendage closure with WATCHMAN in patients with or without contraindication to oral anticoagulation: 1-Year follow-up outcome data of the EWOLUTION trial. *Heart Rhythm*. 2017 Sep;14(9):1302-8.
- 5 Osmancik P, Herman D, Neuzil P, Hala P, Taborsky M, Kala P, et al.; PRAGUE-17 Trial Investigators. Left Atrial Appendage Closure Versus Direct Oral Anticoagulants in High-Risk Patients With Atrial Fibrillation. *J Am Coll Cardiol*. 2020 Jun;75(25):3122-35.
- 6 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 Dec;70(24):2964-75.
- 7 Durack DT, Lukes AS, Bright DK; Duke Endocarditis Service. New criteria for diagnosis of infective endocarditis: utilization of specific echocardiographic findings. *Am J Med*. 1994 Mar;96(3):200-9.
- 8 Schwartz RS, Holmes DR, Van Tassel RA, Hauser R, Henry TD, Mooney M, et al. Left atrial appendage obliteration: mechanisms of healing and intracardiac integration. *JACC Cardiovasc Interv*. 2010 Aug;3(8):870-7.