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

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Abstract

Background: Left atrial appendage occlusion with the Watchman device is an alternative strategy for stroke risk reduction in patients with non-valvular atrial fibrillation. There are rare case reports of Watchman associated infection. Currently, there is no formal study that evaluated the incidence and outcomes of Watchman-related infections. Methods: All patients who underwent Watchman 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. Primary study outcomes included Watchman related infection, other cardiovascular device related infection, bacteremia, and mortality. Results: A total of 181 patients with an average age of 75, and a median CHA2DS2-VASc Score of 4 (interquartile range 2) and a median HAS-BLED Score of 3 (interquartile range 1), were included for 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 follow up, 38 patients (21%) died. Six developed evidence of bacteremia. Only one developed an implantable cardioverter defibrillator (ICD) infection that required complete system extraction. None of the cohort developed Watchman-related device infection during the study period. Conclusion: In a single center study spanning a 14 year period, we report no Watchman-related devices infections. This is despite the presence of patients with bacteremia, as well as an ICD infection requiring extraction. These data suggest that Watchman devices are extremely unlikely to become infected.

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Introduction

Left atrial appendage occlusion (LAAO) with a Watchman device (WD) (Boston Scientific, St. Paul, MN) is an alternative strategy to oral anticoagulation for embolic stroke risk reduction in patients with non-valvular atrial fibrillation (AF).

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 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 from a single-center cohort over a 14 year period.

Methods

This study protocol was approved by the Mayo Clinic IRB. A retrospective review of all patients who underwent WD implant from July 2004 through December 2018 was conducted. Patients had Intra-procedural trans-esophageal echocardiogram (TEE), 6 month, and 1 year TEE (with in person visits). If a device leak was noted ($>$ 5mm), a 6 month return TEE was performed. After one year post-implant, patients were followed clinically.

From this cohort of patients, we performed detailed medical chart review to identify medical co-morbidities, indication for implantation, clinical and laboratory evidence of WD infection, BSI, and mortality data. A BSI was defined by at least one 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 mean +/- standard deviation.

Results

A total of 181 patients underwent WD implantation at Mayo Clinic in Rochester, MN during the study period. Average age at implant 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. The median CHA_2DS_2-VASc Score was 4 (interquartile range 2) and the median HAS-BLED Score was 3 (interquartile range 1). Gastrointestinal bleeding (n=56, 30.7%), intracerebral hemorrhage (n=51, 28.0%), and patient preference to avoid anticoagulation (n=23, 12.6%) constituted the most common indications for WD implantation.

There were no instances of WD-related infection or endocarditis throughout the follow up period. There were 6 patients who had evidence of bacteremia post implantation. Pathogens identified included viridans group *Streptococcus* , *Escherichia coli* ,*Streptococcus agalactiae* , *Micrococcusluteus* , methicillin-susceptible *Staphylococcusaureus* , 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 of six BSI episodes occurred $>$ 3 months post implantation; one occurred

26 days post implantation. None of the 6 patients who had BSI developed significant peri-device leak, defined as greater than 5mm in size. No subsequent TEE showed evidence of device vegetation. A total of 37 patients died during follow-up with an overall mortality of 20.4%, however no death was infection related.

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 removed in an attempted cure of infection. There was one patient who required ICD extraction with subsequent BSI clearance. These findings suggest that WD infections are uncommon.

Complete endothelialization of the surface of cardiovascular devices reduces the risk of subsequent device-related infection and is thought to develop within three 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 complicating device-related infection. None of the six patients in our cohort who had BSI had evidence of peri-device leak during follow-up. Only one 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, one patient [1] in the PROTECT AF trial actually developed WD-related endocarditis that was not described in the original trial results.

Conclusion:

These findings support the low risk of device-related infections, even in the setting of BSI. Additional evaluation with specific follow-up for WD infection is warranted to further define the infectious proclivity of the WD.

Table 1. Details of bloodstream infection cases

Microbiological Isolate	Infectious source/syndrome	Days post implant	Device leak
Viridans group *Streptococcus*	Infected ICD and IE	1,897	No
Escherichia coli	Urinary tract infection	1,245	No
Streptococcus agalactiae	No source identified	1,085	No
Micrococcus luteus	No source identified	1,203	No
Methicillin-susceptible *Staphylococcus aureus*	Pneumonia	226	No
Pseudomonas aeruginosa	Urinary tract infection	26	No

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