WATCHMAN™
LEFT ATRIAL APPENDAGE CLOSURE DEVICE

Boston Scientific
Advancing science for life™

NCDR-LAAO REGISTRY™ CLINICAL SUMMARY

Review of the First 3 Years of Registry Data

Virtual presentation at ACC 2020 by Dr. James Freeman. *Late Breaking Clinical Trial, March 29, 2020* James V. Freeman, Paul Varosy, Yongfei Wang, Matthew Price, David Slotwiner, Fred Kusumoto, Chidambaram Rammohan, Clifford J. Kavinsky, Zoltan Turi, Joseph Akar, Christina Koutras, Jeptha Curtis, Frederick Masoudi, Yale University School of Medicine, New Haven, CT, USA

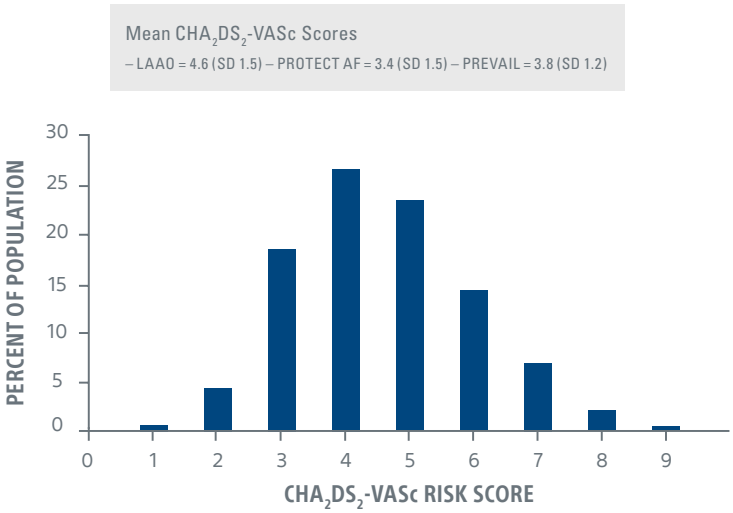
This registry analysis represents the largest real-world data to date on >38,000 WATCHMAN procedures in a high risk patient population and confirms low acute adverse event rates.*

4.8%	4.1%	4.2%	3.8%	2.8%	2.2%
PROTECT AF[1]	CAP[1]	PREVAIL[1]	CAP2[1]	EWOLUTION[2]	NCDR-LAAO[3]

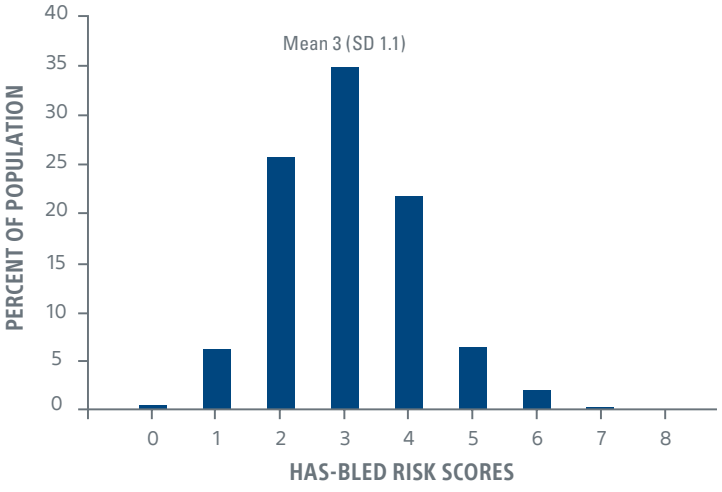
* Adverse events are defined as all major cardiac adverse events within 7 days of implant and other device/procedure-related major adverse events for PROTECT-AF, CAP, PREVAIL, CAP2 and EWOLUTION Registry.

Patients were sicker and older than patients in the WATCHMAN clinical trials with mean CHA_2Ds_2-VASc score of 4.6 and HAS-BLED of 3.

LAAO REGISTRY: CHA_2DS_2-VASc SCORES



HAS BLED SCORE DISTRIBUTION



CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE

The WATCHMAN Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who: are at increased risk for stroke and systemic embolism based on $CHADS_2$ or CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy; are deemed by their physicians to be suitable for warfarin; and have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

CONTRAINDICATIONS

Do not use the WATCHMAN Device if: Intracardiac thrombus is present. An atrial septal defect repair or closure device or a patent foramen ovale repair or closure device is present. The LAA anatomy will not accommodate a device. See Table 47 (in the DFU). Any of the customary contraindications for other percutaneous catheterization procedures (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present. There are contraindications to the use of warfarin, aspirin, or clopidogrel. The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN device is contraindicated.

WARNINGS

Device selection should be based on accurate LAA measurements obtained using echocardiographic imaging guidance (TEE recommended) in multiple angles (e.g., 0°, 45°, 90°, 135°). Do not release the WATCHMAN Device from the core wire if the device does not meet all release criteria. If thrombus is observed on the device, warfarin therapy is recommended until resolution of thrombus is demonstrated by TEE. The potential for device embolization exists with cardioversion <30 days following device implantation. Verify device position post-cardioversion during this period. Administer appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at physician discretion. For single use only. Do not reuse, reprocess or resterilize.

PRECAUTIONS

The safety and effectiveness (and benefit-risk profile) of the WATCHMAN Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated. The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying the device. Use caution when introducing the WATCHMAN Access System to prevent damage to cardiac structures. Use caution when introducing the Delivery System to prevent damage to cardiac structures. To prevent damage to the Delivery Catheter or device, do not allow the WATCHMAN Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath. If using a power injector, the maximum pressure should not exceed 100 psi. In view of the concerns that were raised by the RE-ALIGN study of dabigatran in the presence of prosthetic mechanical heart valves, caution should be used when prescribing oral anticoagulants other than warfarin in patients treated with the WATCHMAN Device. The WATCHMAN Device has only been evaluated with the use of warfarin post-device implantation.

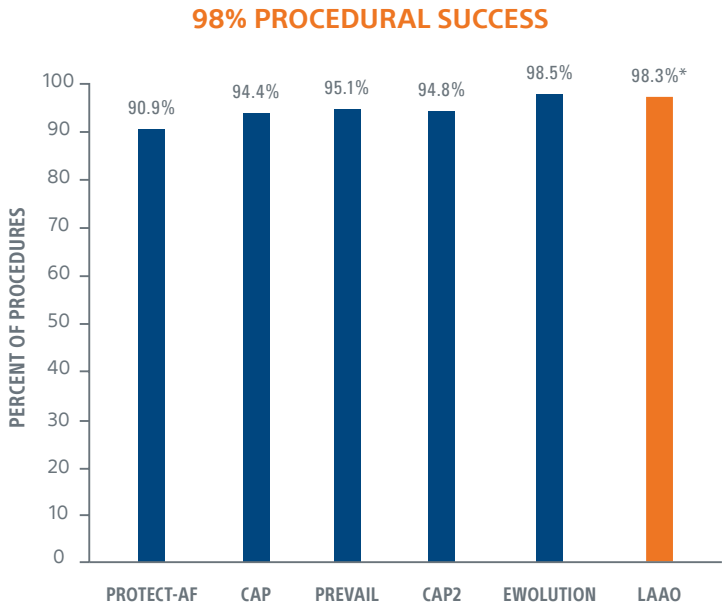
ADVERSE EVENTS

Potential adverse events (in alphabetical order) which may be associated with the use of the WATCHMAN Implant or implantation procedure include but are not limited to: Air embolism, Airway trauma, Allergic reaction to contrast media, anesthetic, WATCHMAN Implant material, or medications, Altered mental status, Anemia requiring transfusion, Anesthesia risk, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, Bruising, hematoma or seroma near the catheter insertion site, Cardiac perforation, Chest pain/discomfort, Confusion post procedure, Congestive heart failure, Contrast related nephropathy, Cranial bleed, Death, Decreased hemoglobin, Deep vein thrombosis, Device embolism, Device fracture, Device thrombosis, Edema, Embolism, Excessive bleeding, Fever, Fistula, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia , Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardial erosion, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Renal failure, Respiratory insufficiency/failure , Surgical removal of the device, Stroke – Hemorrhagic, Stroke – Ischemic, Systemic embolism, TEE complications (throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular or vascular damage, Vasovagal reactions.

There may be other potential adverse events that are unforeseen at this time.

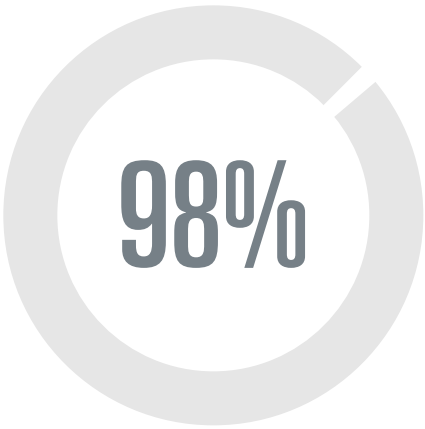
Eikelboom JW, Connolly SJ, Brueckmann M, et al. N Engl J Med 2013;369:1206-14. 92289690 C.2

98.3% were successfully implanted, higher than in the pivotal trials and consistent with the more recent EWOLUTION Registry.

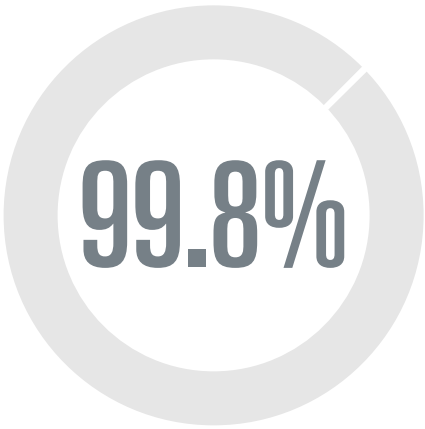


*Acute procedural success= rate of success among procedures in which a device was deployed. Among those with an acutely successful procedure 70 (0.2%) had device margin residual leak ≥5mm.

PROCEDURAL SUCCESS



CLOSED WITH LEAK <5MM



NCDR-LAAO Registry Description

A total of 38,158 procedures from 495 hospitals performed by 1,318 physicians in the United States were included between January 2016 and December 2018.

1 *WATCHMAN FDA Panel Sponsor Presentation.* Oct 2014

2 Boersma, et al, *Heart Rhythm, Vol 14, No 9.* September 2017

3 Freeman, *JACC, March 2020, Vol 75, No. 13, 2020*