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Erik Fladmo
University of North Dakota

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Embolus Prevention: Anticoagulant Therapy In Comparison To Watchman's Procedure In Patients With Atrial Fibrillation

Erik Fladmo PA-S

Department of Physician Assistant Studies, University of North Dakota School of Medicine & Health Sciences



Abstract

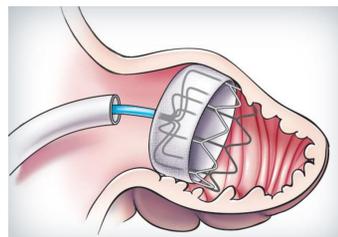
- Atrial fibrillation or A-fib is a common cardiac disease that occurs as individuals get older.
- A risk factor of atrial fibrillation is blood clot formation and dislodgement or 'embolus' in the left atrium.
- Current treatment methods to prevent clot formation include anticoagulants, as well as a left atrial appendage closure device, The Watchman's device is the only FDA approved left atrial appendage closure device.
- Study results confirm the rising efficacy and cost effectiveness of Watchman's device versus long term anticoagulant therapy as well as their adverse effects regarding placement and post procedure; however further randomized control trials are needed to compare both therapies particularly novel oral anticoagulants head to head rather than through extrapolation.
- Long term effects of Watchman's device need to be studied.

Introduction

- Anticoagulant therapy has been a mainstay treatment for patients who have a-fib for prevention of blood clots.
- With use of an oral and or non-oral anticoagulant the patient's risk for developing a thrombus or embolus is markedly diminished.
- Risks involved by taking oral or non-oral anticoagulants: prolonged bleeding, increased bruising, hemorrhagic stroke.
- In 2015 the FDA approved the Watchman's procedure. This procedure entails the insertion of a closure device into the left atrial appendage of the left atrium to block blood clots before they exit due to a-fib. The purpose of this study will be to review both long term anticoagulant therapy and the Watchman device as prophylactic treatments, as well as the difference between the two regarding their purpose, in addition to comparing their of costs, risks, and benefits.

STATEMENT OF THE PROBLEM

- Many patients who take anticoagulants run the risk of bleeding and increased costs due to appointments and medication refills. Watchman's device, a relatively new treatment in preventing embolus or blood clots in the heart, needs to be considered for patients who suffer from atrial fibrillation.



RESEARCH QUESTIONS

- For prevention of embolus formation from atrial fibrillation in the adult and older adult population, would anticoagulant therapy or Watchman procedure be a better choice?
- When comparing Watchman's procedure and long-term anti-coagulant therapy for eligible patients, which choice would be the best economically for the patient?

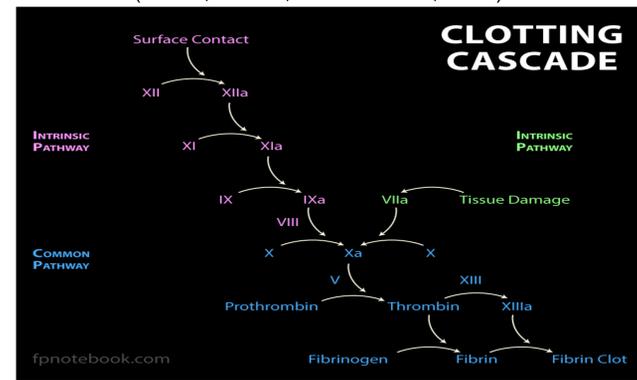
Literature Review

- A-fib, according to Markides & Shilling (2003) is caused by combined micro-reentry action potential with enhanced automaticity in the heart. The heart fibrillates and loses regular contraction.
- According to Pellman, Sheikh, Diego, & Jolla (2017) blood coagulates in a fibrillating heart forming embolism.



Understanding AFib: A heart dancing without rhythm. (2018). Scope Stanford Medicine. Retrieved from <https://scopeblog.stanford.edu/2018/09/27/understanding-afib-a-heart-dancing-without-rhythm/>

- A-fib is diagnosed by 12-lead EKG (Gutierrez & Blanchard, 2016).
- Use of anticoagulation is based on CHADS2 and CHA2DS2-VASc for eligible patients (Markides & Schilling, 2003).
- Markides & Schilling (2003) show that anticoagulants can prevent clots, however there is an increased risk in bleeding and hemorrhagic stroke.
- There are many anticoagulants on the market today, each has an effect on different areas of the coagulation cascade (Harter, Levine, & Henderson, 2015).



Clotting Pathway (2019). Family Practice Notebook. Retrieved from <https://fpnotebook.com/HemeOnc/Exam/CltngPthwy.htm>

- Most common anticoagulants to prevent embolus are Aspirin, Warfarin, and Factor Xa inhibitors ala Eliquis.
- Antiplatelets compared to Warfarin showed less protection and increased relative risk of 1.44 for stroke, PE, MI, and vascular death (Katritsis, Gersh, & Camm, 2015).

- Warfarin a commonly used anticoagulant needs constant monitoring due to narrow therapeutic index. Patients need to be very compliant for the full benefit of preventing blood clots (Katritsis, Gersh, & Camm, 2015).
- Factor Xa inhibitors have fixed dosing, lower interactions, and they do not require monitoring in clinic via INR (Katritsis, Gersh, & Camm, 2015).



F.D.A. Clears Anticlotting Drug by Bristol and Pfizer (2012). The New York Times. Retrieved from <https://www.nytimes.com/2012/12/29/business/fda-approves-eliquis-from-bristol-and-pfizer.html>

- Factor Xa inhibitors cost more as compared to Warfarin (Katritsis, Gersh, & Camm, 2015).
- Direct thrombin inhibitors are as effective as warfarin in preventing stroke and embolus with fewer intracranial bleeds 0.30% vs. 0.74% per year (Gutierrez & Blanchard, 2016).
- The Watchman Device prevents potential clots in patients with A-fib by blocking the left atrial appendage or LAA where 90% of emboli form (Sharma, Park, & Lakkireddy, 2018).
- FDA approved since March 2015. Placement of the device is made under general anesthetic.
- Watchman device has been shown to be superior to warfarin in preventing hemorrhagic stroke (HR: 0.20, 95% CI: 0.07 to 0.56; (p=0.0022). As well as disabling/fatal stroke, cardiovascular or unexplained death (Reddy et al. 2017).
- When Watchman(OR 0.21 CI 0.05-0.99) and Newer oral anticoagulants (NOACs) (OR 0.46 CI 0.30-0.82) were compared overall results showed superiority over Warfarin in hemorrhaging stroke (Koifman et al., 2016).
- NOACs showed a higher likelihood of hemorrhagic stroke as compared to Watchman's device though (OR 0.44, CI 0.09-2.14) (Koifman et al., 2016).
- Watchman cost is higher than warfarin/NOAC initially, however at 10 years LAAC has more quality-adjusted life years with lower totaling costs (Reddy et al.,2018). LAAC was shown to be the most cost-effective treatment strategy for prevention of stroke in a-fib (Reddy et al.,2018).

Comparison of Therapies for Nonvalvular A-Fib		
	Total Costs	Total QALYs
5 Years		
LAA Closure	\$20,892	3,455
Warfarin	\$10,764	3,387
NOACs	\$20,924	3,448
10 Years		
LAA Closure	\$25,425	5,855
Warfarin	\$26,834	5,601
NOACs	\$39,260	5,751
15 Years		
LAA Closure	\$29,075	7,309
Warfarin	\$41,326	6,843
NOACs	\$53,431	7,077
20 Years		
LAA Closure	\$31,198	8,031
Warfarin	\$49,946	7,392
NOACs	\$61,701	7,682

Study Affirms Cost-Effectiveness of Watchman LAA Closure Device for Stroke Reduction. by IctMDthe heart beat, December 14, 2015 retrieved from <https://www.ictmd.com/news/study-affirms-cost-effectiveness-watchman-laa-closure-device-stroke-reduction/> Copyright June, 2016

Discussion

- Anticoagulation therapy and Watchman's device both have risks upon implementation regarding A-fib.
- Watchman's procedure has pre and post surgical risk.
- Procedures have improved with practice via a decrease in complications 8.7% to 4.2%, and since FDA approval (Sharma, Park, & Lakkireddy, 2018).
- Indirect comparison shows NOACs and Watchman are superior to Warfarin for hemorrhagic stroke prevention (Koifman et al., 2016).
- Watchman's device decreases/eliminates risk of bleed, decreased cost, and constant monitoring (Harter, Levine, & Henderson, 2015).
- Hemorrhage is still the most feared adverse effect with anticoagulants (Harter, Levine, & Henderson, 2015).
- There are very few studies comparing Watchman's device to NOACs. Based on indirect comparison both NOACs and Watchman Device are superior to Warfarin in hemorrhagic stroke prevention.
- According to Koifman et al., 2016 NOACs have a higher rate of hemorrhagic stroke (OR 0.44, CI 0.09-2.14) as compared to Watchman's device. Watchman's device displayed higher occurrence of ischemic stroke as compared to NOACs though.
- Ischemic strokes have been shown to be non-disabling and result in functional independence overall (Reddy et al., 2016).
- Cost effectiveness of Watchman's device is shown at 5 years post procedure as compared to NOACs and warfarin.

Clinical Application

- There is not an end all medicine/application to prevent stroke in patients with a-fib.
- Watchman's device has a decreased rate of bleeding, hemorrhagic stroke, and shows non-inferiority to anticoagulants (warfarin) and ease of compliance are all benefits that a patient needs to be educated on when considering embolus prevention/anticoagulation prevention in A-fib.
- Watchman's procedure and implementation has become more refined and practitioners are better trained as well.
- More RCT are needed for comparison to NOACs to fully encompass efficacy vs. adverse effects.

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