Topic Brief: Watchman Device Effectiveness

Date: 6/3/2024
Nomination Number: 1075

Purpose: This document summarizes the information addressing a nomination submitted on February 20, 2024, through the Effective Health Care Website (link to topic nomination). This information was used to inform the Evidence-based Practice Center (EPC) Program decisions about whether to produce an evidence report on the topic, and if so, what type of evidence report would be most suitable.

Issue: The nominator of this topic is a patient who is interested in new primary research on the relative risks and benefits of the FDA approved WATCHMAN device for the treatment of non-valvular atrial fibrillation (AF).[1]

Findings: The EPC program develops systematic reviews that synthesize existing primary research to inform healthcare decision-making by clinical professional groups, clinicians, healthcare organizations, patients, and others. The EPC Program does not conduct primary research. Therefore, the EPC Program will not consider this topic further.

Background

Atrial fibrillation (AF) is a common type of heart arrhythmia in which the normal beating of the two atria (upper chambers of the heart) is irregular, resulting in lower quality blood flow from the atria to the lower chambers of the heart.[2] Typically, "valvular" AF occurs in patients with mitral stenosis or artificial heart valves and places these patients at higher risk of stroke. "Non-valvular" AF is a broad category that includes patients who may have other types of heart disease[3] and is categorized by duration and length of episodes.[4] According to the American Heart Association (AHA), the lifetime risk of AF is approximately 1 in 3 among White people and approximately 1 in 5 among Black people in the United States. Additionally, almost 13% of the nearly 5.3 million cases of AF in the United States are undiagnosed.[5] Using data from 2004 to 2006, the AHA found that AF cost the United States healthcare system $26 billion annually.[6]

In many AF cases, clinicians prescribe medications such as oral anticoagulants (OAC) to prevent and treat moving blood clots that may lead to stroke.[7] In other cases, treatments may include nonsurgical options such as electrical cardioversion, radiofrequency ablation or other surgical interventions. Ninety percent of blood clots in AF begin in an area of the heart called the left atrial appendage.[8] New devices are being studied and used to prevent these blood clots from forming or escaping. The WATCHMAN device is one such Food and Drug Administration (FDA)-approved implant intended to reduce stroke risk in people with non-valvular AF.[1]

The EPC Program does not advise patients about individual treatment options.

Resources

- Recent guidelines that pertain to this topic are available: 2023 American College of Cardiology /American Heart Association /ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (see section 6.5.1 Percutaneous Approaches to Occlude the LAA)[9]

References

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Conflict of Interest: None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this brief.

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