Atrial fibrillation (AF) is the most common arrhythmia treated in clinical practice. Lifetime risk of AF is estimated to be 24% in elderly patients. Stroke is the most devastating complication of AF, with AF patients experiencing a fivefold higher risk of stroke and a twofold increased risk of all-cause mortality. Taking all patients into consideration, the annual stroke risk is 5%, but can be as high as 15% depending on many common clinical factors. The percentage of strokes caused by AF increases with age. AF has been estimated to cause 20%–38% of all strokes, and is particularly challenging because most AF is asymptomatic. AF-related ischemic strokes are associated with significantly higher morbidity, mortality, and health care expenses compared to stroke from other etiologies. Thromboembolic cerebral ischemic events in patients with nonvalvular AF occur due to the formation of atrial thrombi, generally arising in the left atrial appendage (LAA), where it is thought that >90% of the atrial thrombi originate.

The mainstay of treatment for stroke prevention in AF is oral anticoagulation (OAC). Vitamin K antagonists (VKAs) and novel oral anticoagulants (NOACs) have been shown to be effective in reducing stroke risk. Not surprisingly based upon the mechanism of action, OAC is significantly limited by bleeding, which can be life threatening. Particularly in an elderly population, physicians must frequently balance on a tightrope between two competing desirable outcomes: stroke prevention and bleeding avoidance. The CHA2DS2-VASc score has been validated to predict the risk of stroke in AF patients, with a score of ≥2 indicative of the need for OAC. In contrast, the HAS-BLED score (one of many scoring systems) predicts the risk for AF-related OAC bleeding, with a score ≥3 being considered high risk. Muddying the waters, some criteria that predict a higher risk for AF-related stroke also predict a higher risk for AF-related OAC bleeding:
Although OAC is the gold standard therapy for stroke prevention in AF patients with a CHA₂DS₂-VASc score ≥2, the treatment rate for those who would benefit from OAC barely tops 50%. Furthermore, the “easier to take” NOACs have not significantly altered the number of patients treated, due to oft misplaced concerns about bleeding (compared to VKAs) or the high cost of these medications. Furthermore, health care providers weighing risk versus benefit of OAC in AF patients sometimes take what’s perceived as the “middle ground” in up to 30% of patients, using aspirin (instead of OAC) for stroke thromboembolic prophylaxis. This “middle ground” is actually nothing of the sort: a meta-analysis of all trials of aspirin for primary prevention of stroke in AF did not reach statistical significance, and the only trial supporting aspirin’s effectiveness specifically demonstrated a complete lack of benefit in preventing stroke in patients >75 years of age and in preventing large strokes.  

Use of OACs in AF Patients peaks at ~50%, use declines with increasing risk
For a patient unable to take OAC, an alternative therapy has entered the picture: the Watchman device for left atrial appendage closure. Watchman is a first-of-its-kind, percutaneous, self-expanding platform that occludes the left atrial appendage where clots form in AF patients. For Watchman eligibility, a patient must be an acceptable short-term candidate for warfarin OAC, but deemed unsuitable for long term OAC. Nearly all patients are able to come off warfarin 45 days after the Watchman procedure. Using cumulative, long term data from PROTECT AF and PREVAIL, efficacy and safety of Watchman have both been demonstrated. Furthermore, the 4 year data from PROTECT AF showed that Watchman outcomes improve over time, with a 60% reduction in cardiovascular / unexplained death (1.0% vs. 2.4%, p<0.005), as well as a significant reduction in all-cause mortality in the Watchman arm (3.2% vs. 4.8%, p = 0.0379). These impressive Watchman benefits are driven mainly by the avoidance of OAC-related hemorrhagic stroke and hemorrhagic stroke-related death, while providing protection from ischemic stroke:

Worldwide, more than 30,000 Watchman devices have been implanted, and the U.S. experience is growing rapidly. In October 2016, Watchman safety was highlighted at the Transcatheter Therapeutics (TCT) 2016 conference, where 3,822 consecutive U.S. cases between March 2015 and May 2016 were reviewed after the device’s FDA approval. This included a surprisingly high number of new implanters (71%) performing approximately 50% of the cases. In the entire cohort, there were 3 procedure-related strokes (0.078%) and 3 procedure-related deaths from tamponade.
(0.078%) and no device embolization. Overall procedural success was very high at 96.5%. These exemplary results confirm the findings from randomized controlled trials and registries, and demonstrate its generalizability to a real-world population.

Nationwide, nearly 1 million AF patients are not being treated with OAC and could benefit from left atrial appendage closure. Across the nation, rollout of this new exciting therapy has been limited mainly by FDA and Medicare restrictions to centers of excellence who meet all the criteria for Watchman implantation.

For more information on the Watchman procedure, call 469.814.3480.

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