

Atrial Fibrillation Key Assumptions

Atrial Fibrillation Disease Course

1. Heart rhythm may be normal sinus rhythm (NSR) or atrial fibrillation (AF)
2. Patients with AF may have spontaneous conversion to NSR
3. AF patients in NSR may have recurrent episodes of AF

AF and Stroke

1. Patients with AF are at increased risk of stroke
2. Stroke risk is described by CHADS₂ score for patients with AF
3. Stroke risk may be lower in AF patients with NSR induced by LA catheter ablation or mini-Maze procedure, and may differ from stroke risk in AF patients managed by rate control or rhythm control
4. Stroke outcomes include no disability, mild disability, moderate/severe disability and death
5. Patients with stroke have increased risk of subsequent stroke

AF and Stroke Prevention

1. Stroke prevention treatment with warfarin, aspirin (ASA), dabigatran, and WATCHMAN[®] procedure reduce risk of stroke
2. Stroke prevention will follow the ACC/AHA/ESC guidelines for management of patients with AF

Stroke Prevention after LA Catheter Ablation

1. Alternate strategies for discontinuation of warfarin anticoagulation after LA catheter ablation for patients who are in NSR will be analyzed
2. Sensitivity analysis to duration of anticoagulation and the risk of stroke for patients who are in NSR will be conducted

Stroke Prevention and Hemorrhage

1. Warfarin, ASA, and dabigatran are associated with an increased risk of hemorrhage
2. Hemorrhage may be extracranial or intracranial (ICH)
3. ICH outcomes include no disability, mild disability, moderate/severe disability and death

AF and Death

1. AF patients have an elevated risk of non-stroke and non-hemorrhagic probability of death
2. AF patients with stroke- or ICH-associated disability have increased risk of death
3. AF patients treated with warfarin or ASA have a reduced risk of cardiovascular, non-stroke death that is different for each agent
4. Patients with mild or moderate/severe disability following stroke or intracranial hemorrhage have an increased risk of death

AF Management Strategies Key Assumptions

LA Catheter Ablation Strategy Assumptions

1. Initial LA catheter ablation with PVI and possibly other lines or targets of ablation is successful in returning patients to NSR
2. AF may recur during the initial 3 months (i.e., “blinking period”)
3. The rate of recurrent AF in the remaining three 3-month cycles of the first year is constant and will be estimated from the 1-year recurrent AF rate
4. Patients with recurrent AF after initial LA catheter ablation with PVI will have a repeat LA catheter ablation procedure with other lines or targets of ablation which is successful in returning patients to NSR
5. Patients with recurrent AF after the repeat LA catheter procedure with other lines are managed with a rate control strategy
6. In the model, patients may only have 1 repeat LA catheter procedure
7. The rate of recurrent AF following LA catheter ablation after the first year may differ from the 1-year recurrence rate
8. LA catheter ablation has potential risks of stroke, tamponade, atrial-esophageal fistula, and other complications

Rhythm Control Strategy Assumptions

1. Patients managed with rhythm control will be initially treated with amiodarone
2. The majority of patients on rhythm control will initially convert to NSR, but have a high rate of recurrent AF
3. Patients treated with rhythm control with amiodarone are at risk for amiodarone pulmonary toxicity
4. Amiodarone pulmonary toxicity may be reversible, irreversible or fatal
5. Amiodarone toxicity also includes thyroid toxicity

Rhythm Control -> LA Catheter Ablation Assumptions

1. Initial treatment with rhythm control strategy
2. Failure (6 months of AF) is criteria for referral for LA catheter ablation
3. Amiodarone is discontinued following LA catheter ablation

Rate-Control Strategy Assumptions

1. Patients will be treated with atenolol/digoxin
2. Many patients with rate control will initially convert to NSR
3. Patients with rate control have high rate of recurrent AF
4. Patients treated with atenolol or digoxin have a risk of reversible toxicity

WATCHMAN Procedure Assumptions

1. Complications following WATCHMAN procedure include pericardial effusion, major non-stroke hemorrhage, and procedure-related ischemic stroke