

Table 1. Preliminary analysis of effectiveness, by AF management strategy.

Measure	Rate Control	Rhythm Control		Catheter Ablation			mini-Maze
		Amiodarone	Dronedarone	Paroxysmal	Mixed	Total	
Freedom from AF							
Short-term (6-12 mo)	N=2; 27-58% UM: 42%	N=4; 52-60% UM: 57%	N=3; 25-36% UM: 32%	N=7; 62-89% UM: 84%	N=7; 45-80% UM: 64%	N=14; 45-89% UM: 74%	N=1; 89%
Long-term (16-24 mo)	NR	N=1; 43%	NR	N=1; 89%	N=1; 82%	N=2; 82-89% UM: 86%	N=1; 82%
1 st Line (6-12 mo)	N/A	N/A	N/A	N=1; 88%	NR	N=1; 88%	NR
AF Burden							
Median min in AF @ 12 mo	NR	NR	NR	N=1; 4	NR	N=1; 4	NR
Mean # episodes at 12 mo	NR	NR	NR	N=1; 1	NR	N=1; 1	NR
Repeat Ablation							
Rate (%) at 12 mo	N/A	N/A	N/A	TBD	TBD	N=8; 12-59% UM: 38%	NR
Mean # ablations/pt	N/A	N/A	N/A	TBD	TBD	N=7; 1.2-2.6 1.8	NR
Rehospitalizations							
	TBD	TBD	*	*	*	*	TBD
Stroke†							
	N=3; 0.5-0.7% UM: 0.6%	NR	N=2; 0.5-2% UM: 1.2%	N/A	N/A	N=9; 0-3.5% UM: 0.7%	NR
Quality of Life (Δ scores @ 3-12 mo)							
SF-36 physical	N=2; 4-7 UM: 5.5	N=1; 8	NR	N/A	N/A	N=5; 7-10 UM: 8.6	NR
SF-36 mental	N=2; 5-6 UM: 5.5	N=1; 4	NR	N/A	N/A	N=5; 7-10 UM: 8.4	NR
Symptom frequency	NR	NR	NR	N/A	N/A	N=2; (-8)-(-11) UM: -9.5	NR
Symptom severity	NR	NR	NR	N/A	N/A	N=2; (-8)-(-12) UM: -10	NR

NOTE: Paroxysmal category based on ≥70% of study population with paroxysmal AF; all others categorized as “mixed”

UM: Unweighted mean

*Dronedarone: 1 RCT, rate of first hospitalization 15% vs. 22% for placebo. Catheter ablation: multiple studies using different measures suggest reduced rates of hospitalization vs. AADs

†Annualized to account for differential follow-up

Table 2. Preliminary analysis of harms, by AF management strategy.

Measure	Rate Control	Rhythm Control		Catheter Ablation	mini-Maze
		Amiodarone	Dronedarone		
Mortality					
Peri-operative	N/A	N/A	N/A	N=21; 0-0.7% UM: 0.03%	N=8; 0-3.0% UM: 0.7%
Cardiovascular†	N=1; 8.2%	N=1; 0.6%	N=2; 2-3% UM: 2.2%	TBD	TBD
All-cause†	N=8; 0-11% UM: 3.0%	N=8; 0-21% UM: 3.6%	N=5; 0-5% UM: 2.0%	TBD	TBD
Procedure-related complications	N/A	N/A	N/A	N=37 <i>PV Stenosis</i> 0-28%; UM: 3.6% <i>Cardiac Tamponade</i> 0-5%; UM: 1.2%	N=8 <i>Thoracotomy Complications</i> 0-7%; UM: 2.1% <i>Phrenic Nerve Injury</i> 0-4%; UM: 1.0%
Drug adverse events					
Pulmonary toxicity‡	‡	N=10; 0-2% UM: 0.3%	N=7; 0-0.1% UM: 0.04%	N/A	N/A
Thyroid toxicity‡	‡	N=10; 0-12% UM: 4.3%	N=7; 0-14% UM: 2.2%	N/A	N/A
Other	‡	‡	‡	‡	‡

UM: Unweighted mean

†Annualized to account for differential follow-up

‡Will be evaluated in more detail in report

Table 3. Preliminary analysis of effectiveness and harms, by stroke prevention strategy.

Measure	Warfarin/OAC*	Aspirin*	Dabigatran	WATCHMAN
Effectiveness†				
Thrombotic Stroke	2.0%	4.3%	N=2; 0.92-1.34% UM: 1.13%	N=1; 2.2%
Hemorrhagic Stroke	0.5%	0.3%	N=2; 0.10-0.12% UM: 0.11%	N=1; 0.14%
Total Stroke	2.4%	4.5%	N=2; 1.01-1.44% UM: 1.23%	N=1; 2.34%
Harms†				
Major Hemorrhage (Non-Stroke)	2.2%	1.3%	N=2; 2.71-3.11% UM: 2.91%	N=1; 2.3%
Total Safety Events§	N=1; 4.4%	N/A	N/A	N=1; 7.4%

OAC: Oral anticoagulant

UM: Unweighted mean

*From patient-level meta-analyses (*Ann Intern Med* 1994; *JAMA* 2002; *Ann Intern Med* 1999)

†Annualized to account for differential follow-up

§For drug-device comparison only