

THE AFIB REPORT

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2011 Ablation/Maze Survey

The 2008 ablation/maze survey evaluated the short- to medium-term success rates for a total of 1045 catheter ablation, maze, and mini-maze procedures involving 677 patients. The results of the survey provided a good basis for judging the likely outcome of the various procedures aimed at curing atrial fibrillation, and also provided valuable information in regard to the success rates achieved by individual electrophysiologists and cardiac surgeons. However, the question uppermost in the mind of any afibber having undergone or contemplating a catheter ablation, maze or mini-maze procedure is “How long will a successful procedure keep me in normal sinus rhythm?” – In other words, “How long will it last?”

The 2009 ablation/maze survey (LAF Survey 16) was undertaken in order to answer that question and to, hopefully, uncover important clues as to the factors determining the long-term success of a procedure. Afibbers whose latest procedure, for the purpose of curing AF, was initially deemed successful and was done prior to November 2005, i.e. at least 4 years ago, were invited to participate in LAF Survey 16. A total of 94 responses were received and evaluated.

This 2011 ablation/maze survey (LAF Survey 17) is a follow-up on the 2009 survey and involves 55 afibbers who provided an extra two years of data.

In the survey questionnaire the term “initially successful” is defined as not being on antiarrhythmic drugs and not having experienced any AF episodes during the last 6 months of the 12-month period following the latest procedure for the purpose of curing AF (index period). The first 6 months following the procedure is considered a “blinking period” and AF episodes and episodes of other arrhythmias do not “count” during this period.

For the definition of other terms used in this report please see Appendix A.

Overview of Procedures

The procedures used to cure atrial fibrillation can be divided into two groups: – **catheterization procedures** and **surgical procedures**. Both types involve the creation of lesions on the heart wall (right and/or left atrium) in order to stop the propagation of impulses not involved in conducting the heart beat “signal” directly from the sino-atrial (SA) node to the atrio-ventricular (AV) node.

Catheterization procedures create the lesions from the inside via an ablation catheter threaded through the femoral vein and are performed by electrophysiologists (EPs). Surgical procedures create the lesions from the outside and access is either through incisions between the ribs or may involve open-heart surgery and the use of a heart/lung machine. Surgical procedures are carried out by cardiothoracic surgeons.

The overwhelming majority of catheterization procedures use radiofrequency (RF) energy to create the lesions, but some EPs prefer the use of nitrogen-cooled catheters (cryoablation) rather than RF-powered ones due to their reduced risk of creating pulmonary vein stenosis.

The original surgical procedure, the full maze or Cox procedure, used a cut-and-sew protocol for creating lesions forming a “maze” that conducted the electrical impulse from the SA to the AV node, while at the same time interrupting any “rogue” circuits. The cut and sew method has now largely been replaced by the use of RF-powered devices, but cryosurgery, microwave application, and high-intensity focused ultrasound (HIFU) have all been tried as well and are preferred by some surgeons.

The so-called mini-maze procedure also involves lesions on the outside of the heart wall, but access to the heart is through incisions between the ribs rather than via open-heart surgery. The mini-maze may involve the creation of the full maze set of lesions, but usually focuses on pulmonary vein isolation. The procedure does not involve the use of a heart/lung machine.

Most of the rogue electrical impulses that create afib originate in the area where the pulmonary veins join the left atrium. Thus, all catheterization procedures aimed at curing afib involve electrical isolation of the pulmonary veins from the left atrium wall. Depending on the origin of the afib, catheterization procedures may also involve ablations of the superior vena cava and coronary sinus (thoracic veins), linear ablation of the left atrial roof, and a standard cavotricuspid isthmus (right flutter) ablation.

Surgical procedures, except for the full maze, also focus on isolating the pulmonary veins, but in addition may involve lesion creation at specific spots located by mapping, removal of the left atrial appendage, and disconnection of the ligaments of Marshall – a potent source of vagal input.

Evaluation of Background Data

General Background of Respondents

TABLE 1

<u>Demographics</u>	<u>2011 Survey</u>	<u>2009 Survey</u>	<u>2007-2008 Surveys</u>
No. of participants	55	94	677
% male	76	83	78
% female	24	17	22
Average (median) age*, yrs	66	62	58
Median age at first episode, yrs	52	50	48
Age range at first episode, yrs	37-69	15-67	5-79
Years since diagnosis(1)	12	12	8
Years since diagnosis (range)(1)	6-24	4-24	1-45
Underlying heart disease, %	11	8	8
Enlarged left atrium, %	24	23	**
LAF confirmed by diagnosis, %	**	**	92
Median age at last proc., yrs(2)	59	58	56
Age range (last proc.), yrs	38-73	24-73	26-85
Years to last procedure(3)	4	6	**
Years to last procedure – range(3)	0-18	0-20	**
* At time of completing survey			
** Question not asked in survey			
(1) Years elapsed between first episode and completion of survey			
(2) Procedure for purpose of curing AF			
(3) Average (median) no. of years from initial diagnosis to final procedure			

There are no significant differences in demographics between the respondents to the 2011 ablation/maze survey and those participating in the 2007, 2008 and 2009 surveys. Thus, conclusions reached in the 2011 survey should be applicable to the lone AF population in general.

Afib Type

A total of 53 respondents had provided detailed information regarding their type of AF prior to their initial procedure for the purpose of curing AF. The distribution is as follows:

TABLE 2

<u>Type of AF</u>	<u>2011 Survey</u>	<u>2009 Survey</u>	<u>2007-2008 Surveys</u>
No. of respondents	53	89	584
Adrenergic, %	6	3	5
Mixed, %	49	48	44
Vagal, %	25	26	24
Total paroxysmal, %	80	78	73
Persistent, %	0	3	10
Permanent, %	20	19	17
TOTAL	100	100	100

NOTE: 5 respondents to the 2009 survey and 2 in the 2011 survey were uncertain as to which type of afib they had.

Again, there are no major differences in the afib type of respondents to the 2009 and 2011 surveys when compared to the 2007-2008 surveys except that the 2009 and 2011 surveys contain a lower percentage of respondents with persistent AF. It is not clear why this is the case. The majority of respondents to the 2009 and 2011 surveys (80%) had paroxysmal AF with mixed (random) being the most common type.

Afib Frequency

The distribution of episode frequency prior to the initial ablation/maze procedure is presented below:

TABLE 3

<u>Episode Frequency</u>	<u>Episodes/6 months</u>	<u>Respondents, %</u>
Permanent (24/7)	182	20
Daily	182	15
Twice weekly	52	27
Weekly	26	16
Twice a month	12	13
Monthly	6	4
Every 2 months	3	5
Every 3 months	2	0
Every 6 months	1	0
Once a year		0
More than 1 year between episodes		0
TOTAL		100

The majority of respondents (78%) experienced episodes at least once a week and 35% were in afib every day (including permanent afibbers). Only 9% of those seeking a cure through catheter ablation or surgical procedures experienced episodes less frequent than once a month. This indicates that most

afibbers only opt for a procedure when the frequency of episodes becomes intolerable or permanent AF becomes a reality.

Afib Duration

The distribution of episode duration prior to the initial ablation/maze procedure is presented in the following table:

TABLE 4

<u>Episode Duration</u>	<u>Average duration, hrs</u>	<u>Respondents, %</u>
Less than 30 min	0.25	2
Between 30 min and 1 hr	0.75	4
Between 1 and 3 hrs	2	20
Between 3 and 10 hrs	6	18
Between 10 and 24 hrs	17	20
Between 24 and 48 hrs	36	4
More than 48 hrs, but self-converted	48	9
More than 7 days or required cardiov.	168	0
Permanent (24/7)	24	20
Not sure	-	3
TOTAL		100

The majority of respondents (94%) experienced episodes lasting more than 1 hour and 33% had episodes lasting 24 hours or longer (including permanent afibbers).

Afib Burden

By multiplying the number of episodes with their average duration for each respondent it is possible to obtain an estimate of the afib burden experienced over a 6-month period for various types of AF. Results are presented below:

TABLE 5

<u>Average AF Burden/6 mos.</u>	<u>AF Burden, hrs</u>	<u>Time Spent in AF, %</u>
Male afibbers	364	8
Female afibbers	442	10
Vagal afibbers	204	5
Mixed afibbers	312	7
Adrenergic afibbers	144	3
Paroxysmal afibbers	312	7
Permanent afibbers	4368	100

Over a 6-month period the average paroxysmal afibber spent 7% of their time in afib (range 0 – 71%). There was no statistically significant difference in afib burden between the different types of paroxysmal afib nor was the difference between male and female afibbers statistically significant.

Afib Severity

Afib severity was rated on a scale from 1 to 5.

1. Barely noticeable
2. Mildly symptomatic
3. Symptomatic, but tolerable
4. Very symptomatic, but tolerable
5. Debilitating

TABLE 6

<u>Severity Score (1-5)</u>	% respondents with indicated score					<u>Mean Score</u>
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	
Male afibbers	5	7	24	40	24	3.7
Female afibbers	0	0	8	38	54	4.5
Vagal afibbers	0	8	31	31	31	3.8
Mixed afibbers	0	0	15	54	31	4.2
Adrenergic afibbers	0	0	33	33	33	4.0
Not sure of afib type	0	0	0	0	100	5.0
Paroxysmal afibbers	0	2	20	43	34	4.1
Permanent afibbers	18	18	18	28	18	3.1
Overall	4	5	20	40	31	3.9

The overall mean severity score was 3.9 indicating that afibbers only opt for an ablation or surgical procedure when episodes become very symptomatic. More women (92%) than men (64%) reported a severity score of 4 or 5, but this difference was not statistically significant.

Impact on Quality of Life

It may be possible to get some idea of the *impact on quality of life* (IQoL) of afib by calculating an IQoL score using the percent afib burden and the severity score. For a permanent afibber with disabling afib the impact on quality of life score would thus be 500 (severity score x % spent in afib), while for a person with no afib the IQoL score would be zero. Average IQoL scores for the various types of afib calculated using this definition are shown in Table 7.

TABLE 7

Impact on Quality of Life	
	<u>IQoL Score</u>
Male afibbers	30
Female afibbers	45
Vagal afibbers	19
Mixed afibbers	29
Adrenergic afibbers	12
Paroxysmal afibbers	29
Permanent afibbers	310

Women had a higher IQoL score (poorer quality of life) than men (45 vs. 30), but this difference was not statistically significant. However, the difference in IQoL between permanent afibbers (score of 310) and paroxysmal afibbers (score of 29) was statistically extremely significant ($p < 0.0001$). This is perhaps not surprising since experiencing very symptomatic afib for 24 hours a day every day must have a very detrimental impact on quality of life. On the other hand, paroxysmal afibbers suffer from the constant dread of not knowing when the next episode will happen. So overall, a paroxysmal afibber with debilitating episodes may be just as bad off psychologically as a permanent afibber with symptomatic but tolerable episodes. This whole area of the impact of afib on quality of life could certainly benefit from more research.

Success Rates for Procedures

Fifty-five afibbers responded to the survey and provided data for a total of 97 procedures as shown in Table 8. In addition to these 97 "free-standing" procedures, 26 patients also underwent a right atrial flutter ablation as part of their initial or final procedure for the purpose of curing afib. Adding these 26 procedures to the 8 performed separately means that 34 patients underwent a right atrial flutter ablation as part of their treatment prior to their final procedure to become free of arrhythmia.

The majority of procedures reported in this survey (96%) were radiofrequency (RF) catheter ablations. Of the 52 patients undergoing RF ablation, 33 (63%) underwent only one procedure, while 19 patients (37%) underwent 2 or more procedures for the purpose of curing AF.

The most widely reported ablation procedure was the pulmonary vein antrum isolation procedure (Natale protocol) at 26% of all RF ablations. The second most widely reported procedure was the segmental pulmonary vein ablation (Haissaguerre protocol) at 18%.

One respondent reported having undergone the full maze procedure as their initial procedure; while one respondent had the full maze following a failed catheter ablation. Two respondents reported having undergone an initial mini-maze and no further procedures.

TABLE 8

Distribution of Procedures					
	<u>Initial</u>	<u>Final</u>	<u>Additional</u>	<u>Total</u>	<u>% of Total</u>
Focal ablation	5	2	1	8	9
Pulmonary vein ablation (PVA)	10	2	1	13	14
Segmental PVI	8	5	4	17	18
Circumferential PVI	6	1	0	7	8
Antrum PVI	18	6	0	24	26
Right atrial flutter ablation(1)	0	0	8	8	8
Left atrial flutter ablation	0	0	0	0	0
Ablation for SVT	0	0	2	2	2
Unspecified	5	2	7	14	15
Cryoablation	0	0	0	0	0
Total ablation procedures	52	18	23	93	100
Surgical procedures					
Full maze	1	1	0	2	
Mini-maze	2	0	0	2	
Total surgical procedures	3	1	0	4	
Grand Total	55	19	15	97	
Adjuvant right flutter ablation(2)	18	8	0	26	
(1) Performed prior to final procedure for purpose of curing AF.					
(2) Right atrial flutter ablation carried out as part of main procedure for purpose of curing AF.					

The success rates for the different types of procedures are shown below in Table 9. Complete success is defined as being afib-free without the use of antiarrhythmics at the end of the first year following the initial procedure (ignoring the outcome of any follow-up procedures that may have been done within the first year). The most successful procedures were the pulmonary vein antrum isolation (Natale protocol) and the segmental pulmonary vein isolation (Haissaguerre protocol) with success rates of 76% and 75% for the initial procedures. The poorest performers were the circumferential pulmonary vein isolation procedure (Pappone protocol), focal ablation, and generic pulmonary vein ablation at 20% each. The overall success rate for initial RF ablations was 48%.

TABLE 9

Complete Success Rate, Initial Procedure		
	<u>No. in Group</u>	<u>Success, %*</u>
Focal ablation	5	20
Pulmonary vein ablation (PVA)	10	20
Segmental PVI	8	75
Circumferential PVI	6	20
Antrum PVI	18	76
Unspecified	5	40
Total RF procedures	52	48
Surgical procedures		
Full maze	1	100
Mini-maze	2	100
Total surgical procedures	3	100
Grand Total	55	51
* Initial procedure		

Procedure Outcome – Catheter Ablation

The original goal of the 2009 and 2011 ablation/maze surveys was to determine the “longevity” of procedures which had been initially successful defined as being afib-free without the use of antiarrhythmics during the index period following the final (or only) procedure for the purpose of curing AF. Index period, in turn, is defined as the last 6 months of the 12-month period following completion of the final procedure. In the 2011 survey, 40 respondents met this rather strict definition, while the remaining 11 did not – they were either experiencing afib episodes or using antiarrhythmics during the index period. Nevertheless, all 51 respondents were included in the evaluation of procedure outcome in order to determine the importance of an afib-free index period for the long-term prognosis.

All 51 respondents provided data until the end of the 6th year following their final procedure. Twenty-eight provided data for year 7, 16 provided data for year 8, 6 for year 9, 4 for year 10, and 1 for year 11 after their latest ablation.

The outcomes for initially successful and initially unsuccessful catheter ablations are presented in Tables 10 and 11 below.

TABLE 10

Outcome for Initially Successful Catheter Ablation(1)										
	<u>Year 1</u>	<u>Year 2</u>	<u>Year 4</u>	<u>Year 5</u>	<u>Year 6</u>	<u>Year 7</u>	<u>Year 8</u>	<u>Year 9</u>	<u>Year 10</u>	<u>Year 11</u>
Paroxysmal										
# of respondents(2)	30	30	30	29	30	16	9	3	2	1
Complete success, %	100	83	77	79	73	88	100	100	50	0
Partial success, %	0	0	0	0	0	0	0	0	0	0
Failure, %	0	17	23	21	27	7	0	0	50	100
Permanent										
# of respondents(2)	8	8	9	9	9	4	1	**	**	**
Complete success, %(3)	100	88	89	67	67	75	100	**	**	**
Partial success, %	0	0	0	0	0	0	0	**	**	**
Failure, %	0	13	11	33	33	25	0	**	**	**
Total										
# of respondents(2)	38	38	39	38	39	20	10	3	2	1
Complete success, %	100	84	79	76	72	85	100	100	50	0
Partial success, %	0	0	0	0	0	0	0	0	0	0
Failure, %	0	16	21	24	28	15	0	0	50	100

** No data available

(1) Respondents whose latest procedure was an initially successful catheter ablation (no afib and no antiarrhythmics during the last 6-month period of the year following the procedure) done at least 6 years ago.

(2) No. of respondents who reported their afib status and use of antiarrhythmics for indicated period.

(3) 78% of these procedures were performed by Prof. Haissaguerre or Dr. Natale.

TABLE 11

Outcome for Initially Unsuccessful Catheter Ablation(1)										
	<u>Year 1</u>	<u>Year 2</u>	<u>Year 4</u>	<u>Year 5</u>	<u>Year 6</u>	<u>Year 7</u>	<u>Year 8</u>	<u>Year 9</u>	<u>Year 10</u>	<u>Year 11</u>
Paroxysmal										
# of respondents(2)	10	10	9	10	10	7	5	3	2	**
Complete success, %	0	40	33	40	40	14	20	0	0	**
Partial success, %	40	20	22	20	20	29	20	33	50	**
Failure, %	60	40	44	40	40	57	60	67	50	**
Permanent										
# of respondents(2)	1	8	1	1	1	1	1	**	**	**
Complete success, %	0	0	0	0	0	0	0	**	**	**
Partial success, %	0	0	0	0	0	0	0	**	**	**
Failure, %	100	0	100	100	100	100	100	**	**	**
Total										
# of respondents(2)	11	10	10	11	11	8	6	3	2	**
Complete success, %	0	40	30	36	36	13	17	0	0	**
Partial success, %	36	20	20	18	18	25	17	33	50	**
Failure, %	64	40	50	45	45	63	67	67	50	**

** No data available

(1) Respondents whose latest procedure was an initially unsuccessful catheter ablation (afib and/or use of antiarrhythmics during the last 6-month period of the year following the procedure) done at least 6 years ago.

(2) No. of respondents who reported their afib status and use of antiarrhythmics for the indicated period.

It is clear that having an initially successful final ablation is of prime importance in determining the long-term success of the procedure. The complete success rate (no afib, no antiarrhythmics) at the end of year 6 was 72% for those whose last procedure was initially successful versus 36% for those who had not experienced an afib-free index period or who had been on antiarrhythmics during the index period.

In considering the above results, it should be kept in mind that the criterion for complete success in year 6 following the final ablation was a complete lack of afib episodes during the year without the use of

antiarrhythmics. In reality, most afibbers would be quite happy living with 1 or 2 short-lived episodes a year. Looking at it this way, 3 more ablations could be considered successful (99% reduction in afib burden) in the group of 30 paroxysmal afibbers who underwent an initially successful ablation. Thus, the complete success rate for year 6 increases from 73% to 83% for this group. Similarly, the complete success rate would increase from 40% to 60% in the group of paroxysmal afibbers who had an initially unsuccessful ablation. In addition, 3 out of 4 permanent afibbers reverted to paroxysmal afib with an average 6-month burden of 45 hours, or a 99% improvement.

The outcome of surgical procedures for the very small sample of only 4 participants is shown in Table 12.

TABLE 12

Outcome for Surgical (maze and mini-maze) Procedures(1)					
	<u>Year 1</u>	<u>Year 2</u>	<u>Year 4</u>	<u>Year 5</u>	<u>Year 6</u>
# of respondents(2)	4	3	4	4	4
Complete success, %	75	66	50	100	66 (3)
Partial success, %	0	0	0	0	0
Failure, %	25	33	50	0	33

(1) Respondents whose latest procedure was a maze or mini-maze done at least 6 years ago.
 (2) No. of respondents who reported their afib status and use of antiarrhythmics for the indicated period.
 (3) One 20-hour episode reported for year 6 (known trigger)

Based on this very small sample, it is clear that a full maze or a mini-maze procedure has an excellent chance of being successful for at least 6 years. It is also worth noting that the 4 respondents reported only one incidence of other arrhythmias (tachycardia) during years 5 and 6 following their latest maze or mini-maze procedure.

Arrhythmia Burden and Triggers

Changes in Afib Burden

Prior to the initial catheter ablation, 100% of respondents experienced paroxysmal AF episodes or were in permanent (24/7) AF. At the end of the 6th year following the last catheter ablation, 9 paroxysmal and 3 permanent afibbers who were not on antiarrhythmics still experienced afib episodes, but their afib burden and impact on their quality of life was very significantly reduced.

TABLE 13

<u>Variable(1)</u>	Reduction in afib burden			
	<u>Pre-Procedure</u>	<u>End of Year 6</u>	<u>Reduction, %</u>	<u>P-value(2)</u>
9 paroxysmal afibbers				
Episode frequency - median	26	2	92	0.007
Episode duration, hrs - median	12	3	75	0.02
Episode burden, hrs - median	180	3	98	0.008
Time spent in AF, % - median	4	0.07	98	0.02
Severity score (1-5) - mean	4	2	50	0.003
Impact on QoL(3) - mean	14	0.14	99	0.04
3 permanent afibbers				
Episode frequency - median	182	2	99	
Episode duration, hrs - median	24	5	79	
Episode burden, hrs - median	4368	10	100	
Time spent in AF, % - median	100	0.2	100	
Severity score (1-5) - mean	2.7	2.7	0	
Impact on QoL(3) - mean	270	0.5	100	
(1) All values are averages for 6-month periods (182 days) and apply to catheter ablations only.				
(2) Statistical significance (two-tailed p-value) of difference between pre-procedure values and values for year 6.				
(3) Impact on quality of life is calculated as severity score multiplied with % time spent in AF. A score of 0 corresponds to no AF, while a score of 500 corresponds to being in debilitating permanent (24/7) AF.				

It is clear that the reduction in afib frequency, duration, burden and severity from the pre-procedure status to the end of the 6th year following the last catheter ablation procedure is extremely significant as is the improvement in quality of life. The average reduction in afib burden from pre-procedure days to year 6 was 98%, and this decline was pretty well universal, with only 1 of 12 respondents reporting a minor increase (5 hrs) in burden over a 6-month period. Thus, even if an ablation is not completely successful, it is extremely likely to materially reduce afib burden and improve quality of life.

Triggers

A previous LAF survey (LAFS-14) involving 198 afibbers uncovered a number of triggers involved in initiating afib episodes. The most common were:

- Caffeine
- Alcohol
- Physical overexertion
- Heavy evening meals
- Aspartame
- Sleeping on left side
- Emotional stress
- Dehydration
- Monosodium glutamate (MSG)
- High glycemic index foods
- Cold drinks
- Tyramine-containing foods

Since these triggers can all be avoided it would be of interest to see if afib episodes occurring after the final ablation/maze procedure are associated with pre-procedure triggers. NOTE: This data is from LAFS-16.

TABLE 14

Triggers					
	<u>Year 2.%</u>	<u>Years 3-4.%</u>	<u>Years 5-6.%</u>	<u>Years 7-10.%</u>	<u>Average.%</u>
Same trigger as before final procedure					
Yes	29	36	37	20	33
Yes, most of the time	10	4	16	10	10
Yes, sometimes	19	16	21	10	18
Not certain	29	36	21	40	32
No	14	8	5	0	8
# of respondents(1)	21	25	19	10	

(1) # of respondents answering question concerning triggers

It is apparent that 43% of afibbers still experiencing afib believe that their episodes were always, or most of the time, associated with the same triggers that initiated episodes prior to the initial ablation/maze procedure for the purpose of curing AF. Only 8% were quite certain that their episodes were not associated with pre-procedure triggers, while 32% were not certain whether or not they were.

Thus, it would seem prudent for afibbers who have experienced an episode following their last procedure to avoid, as much as possible, the triggers that initiated their episodes prior to undergoing the initial ablation or maze procedure.

Other Arrhythmias

The incidence of atrial flutter, tachycardia and ectopics following the final procedure is tabulated in Table 15 below.

TABLE 15

Other Arrhythmias(1)						
	<u>Index Period</u>	<u>Year 2</u>	<u>Year 4</u>	<u>Year 6</u>	<u>Year 8</u>	<u>Mean for Years 1-8</u>
Atrial Flutter						
Complete success, %(2)	3	0	6	3	0	3
Partial success, %(3)	25	0	0	50	0	18
Failure, %(4)	29	30	15	0	20	16
Tachycardia						
Complete success, %	5	3	6	0	0	3
Partial success, %	0	50	0	0	100	18
Failure, %	14	30	31	25	40	27
Ectopics						
Complete success, %	18	35	31	24	25	27
Partial success, %	25	50	50	100	100	55
Failure, %	14	30	62	25	60	37
Total respondents	50	49	50	51	14	

(1) Respondents whose latest procedure was a catheter ablation done at least 6 years ago.
 (2) No afib episodes and no use of antiarrhythmics during indicated period.
 (3) No afib episodes, but using antiarrhythmics during indicated period.
 (4) Experiencing afib episodes with or without use of antiarrhythmics.

It is clear that afibbers whose latest ablation had been a complete success generally experienced fewer episodes of flutter, tachycardia and ectopics than did those who were still experiencing afib episodes (failures) or were keeping episodes at bay with antiarrhythmics (partial success). However, ectopics (premature atrial complexes [PACs] and premature ventricular complexes [PVCs]) were still common among even successful afibbers and very common among those controlling their episodes with antiarrhythmics. The reason for this is unclear, but it may be that ectopics experienced by successful afibbers are mainly PVCs the frequency of which would not be affected even by a successful ablation procedure. As for the high level of ectopics experienced by afibbers taking antiarrhythmics, it is possible that they are related to the inherent pro-arrhythmic effect of most antiarrhythmics.

Supplementation

The use of magnesium and potassium supplementation is tabulated in Table 16 below.

TABLE 16

Use of Supplements(1)						
	<u>Index</u> <u>Period</u>	<u>Year 2</u>	<u>Year 4</u>	<u>Year 6</u>	<u>Year 8</u>	<u>Mean for</u> <u>Years 1-8</u>
Magnesium						
Complete success, %(2)	41	41	49	56	64	47
Partial success, %(3)	25	100	100	100	0	64
Failure, %(4)	29	40	54	60	50	49
TOTAL, %	38	43	52	59	56	44
Potassium						
Complete success, %	31	30	37	44	45	36
Partial success, %	0	0	0	0	0	0
Failure, %	29	50	54	53	50	49
TOTAL, %	28	33	40	45	44	33
Total respondents	50	49	50	44	16	
(5) Respondents whose latest procedure was a catheter ablation done at least 6 years ago.						
(6) No afib episodes and no use of antiarrhythmics during indicated period.						
(7) No afib episodes, but using antiarrhythmics during indicated period.						
(8) Experiencing afib episodes with or without use of antiarrhythmics.						

There was no statistically significant difference in the use of magnesium and potassium among afib-free respondents and afibbers whose latest ablation had not been successful.

Summary

- The 2011 ablation/maze survey involved 55 respondents who had undergone a total of 97 procedures for the purpose of curing afib.
- There were no significant differences in demographics between the respondents to the 2011 survey and those participating in the 2007 and 2008 surveys (677 respondents having undergone 1045 procedures) and the 2009 survey (94 participants having undergone 161 procedures). Thus, conclusions reached in this 2011 survey should be applicable to the lone AF population in general.
- Prior to their ablation or maze procedure 78% of respondents experienced episodes at least once a week and 35% were in afib every day (including permanent afibbers). The majority of respondents (94%) experienced episodes lasting more than 1 hour and 33% had episodes lasting 24 hours or longer (including permanent afibbers).
- The average paroxysmal afibber spent about 7% of their time in afib as compared to a permanent afibber who, of course, spent 100% of their time in afib.
- The average severity score was 3.9 where a score of 1 indicates barely noticeable afib, while a score of 5 indicates debilitating episodes. There was a trend for the severity score for paroxysmal afibbers to be worse than that for permanent afibbers.
- The *Impact on Quality of Life* score showed, not surprisingly, that the impact on quality of life was considerably higher for permanent afibbers than for paroxysmal ones. Women had a higher IQoL score (poorer quality of life) than men, but this difference was not statistically significant.
- The majority of procedures reported in this survey (96%) were radiofrequency (RF) catheter ablations. Of the 52 patients undergoing RF ablation, 33 (63%) underwent only one procedure, while 19 patients (37%) underwent 2 or more procedures for the purpose of curing AF.
- The most widely reported ablation procedure was the pulmonary vein antrum isolation procedure (Natale protocol) at 26% of all RF ablations. The second most widely reported procedure was the segmental pulmonary vein isolation procedure (Haissaguerre protocol) at 18%.
- The most successful procedures were the pulmonary vein antrum isolation (Natale protocol) and the segmental pulmonary vein isolation (Haissaguerre protocol) with success rates of 76% and 75% for the initial procedures. The poorest performers were the circumferential pulmonary vein isolation procedure (Pappone protocol), focal ablation, and generic pulmonary vein ablation at 20% each. The overall success rate for initial RF ablations was 48%.
- It is clear that having an initially successful final ablation is of prime importance in determining the long-term success of the procedure. The complete success rate (no afib, no antiarrhythmics) at the end of year 6 was 72% for those whose last procedure was initially successful versus 36% for those who had not experienced an afib-free index period or who had been on antiarrhythmics during the index period. Corresponding complete success rates for year 8 were 100% and 17% respectively based on a small sample of only 16 respondents.

- In considering the above results, it should be kept in mind that the criterion for complete success in year 6 following the final ablation was a complete lack of afib episodes during the year without the use of antiarrhythmics. In reality, most afibbers would be quite happy living with 1 or 2 short-lived episodes a year. Looking at it this way, 3 more ablations could be considered successful (99% reduction in afib burden) in the group of 30 paroxysmal afibbers who underwent an initially successful ablation. Thus, the complete success rate for year 6 increases from 73% to 83% for this group. Similarly, the complete success rate would increase from 40% to 60% in the group of paroxysmal afibbers who had an initially unsuccessful ablation. In addition, 3 out of 4 permanent afibbers reverted to paroxysmal afib with an average 6-month burden of 45 hours, or a 99% improvement.
- The reduction in afib frequency, duration, burden and severity from the pre-procedure status to the end of the 6th year following the last catheter ablation procedure is extremely significant as is the improvement in quality of life. The average reduction in afib burden from pre-procedure days to year 6 was 98%, and this decline was pretty well universal, with only 1 of 12 respondents reporting a minor increase (5 hrs) in burden over a 6-month period. Thus, even if an ablation is not completely successful, it is extremely likely to materially reduce afib burden and improve quality of life.
- 43% of afibbers still experiencing afib believed that their episodes were always, or most of the time, associated with the same triggers that initiated episodes prior to the initial ablation/maze procedure for the purpose of curing AF (Data from LAFS-16). Only 8% were quite certain that their episodes were not associated with pre-procedure triggers, while 32% were not certain whether or not they were. Thus, it would seem prudent for afibbers who have experienced an episode following their last procedure to avoid, as much as possible, the triggers that initiated their episodes prior to undergoing the initial ablation or maze procedure.
- Afibbers who were free of afib without the use of antiarrhythmics generally experienced fewer episodes of flutter, tachycardia and ectopics than did those who were still experiencing afib episodes or were keeping episodes at bay with antiarrhythmics. However, ectopics (premature atrial complexes [PACs] and premature ventricular complexes [PVCs]) were still common among even successful afibbers and very common among those controlling their episodes with antiarrhythmics. The reason for this is unclear, but it may be that ectopics experienced by successful afibbers are mainly PVCs the frequency of which would not be affected even by a successful ablation procedure. As for the high level of ectopics experienced by afibbers taking antiarrhythmics, it is possible that they are related to the inherent pro-arrhythmic effect of most antiarrhythmics.

Appendix A

Definition of Terms

Types of Atrial Fibrillation

- **Paroxysmal** – Episodes occurring intermittently and tending to terminate spontaneously - usually within 48 hours.

- **Persistent** – Episodes lasting longer than 7 days and not terminating spontaneously, but can be terminated with chemical or electrical cardioversion.
- **Permanent** – Constant (chronic, 24/7) afib not amenable to effective termination by cardioversion.
- **Adrenergic** – Episodes occurring almost exclusively during daytime, often in connection with exercise or emotional or work-related stress.
- **Vagal** – Episodes tending to occur during rest, at night or after a meal. Alcohol and cold drinks are common triggers.
- **Mixed (random)** – Episodes occur anytime and do not consistently fit the adrenergic or vagal pattern.

Procedures

- **Focal ablation** – The original radiofrequency (RF) ablation procedure in which specific active foci of aberrant impulses are located and ablated.
- **Pulmonary vein ablation (PVA)** – An ablation procedure in which a ring of scar tissue is placed just inside the pulmonary veins where they enter the left atrium. The original PVA carries a high risk of pulmonary vein stenosis, so it is rarely used in its original form anymore. Thus, the term PVA is now associated with ablation around the pulmonary veins when a more specific description (SPVI, CAPVI or PVAI) is not used by the EP or the exact type of pulmonary vein isolation procedure is not known by the respondent.
- **Segmental pulmonary vein isolation (SPVI or Haissaguerre procedure)** – In this procedure electrophysiological mapping (using a multipolar Lasso catheter) is used to locate the pathways taken by aberrant impulses from the pulmonary veins and these pathways are then eliminated by ablation around the veins approximately 5 to 10 mm from the ostium of the veins.
- **Circumferential anatomical pulmonary vein isolation (CAPVI or Pappone procedure)** – In this procedure anatomical mapping (CARTO) is used to establish the exact location of the pulmonary veins. Two rings of lesions are then created in the left atrium - one completely encircling the left pulmonary veins and another completely encircling the right pulmonary veins; the two rings are usually joined by a linear lesion.
- **Pulmonary vein antrum isolation (PVAI or Natale procedure)** – This procedure is a variant of the Haissaguerre procedure. It involves locating aberrant pathways through electrophysiological mapping (using a multipolar Lasso catheter) and ablating these pathways guided by an ultrasound (ICE) catheter. The ablation is performed as close as possible to the outside edge (antrum) of the junction between the pulmonary veins and the atrial wall. All four pulmonary veins as well as the superior vena cava (if indicated) are isolated during the procedure.
- All three variants of the PVI procedure may be followed by focal ablations involving other areas of the atrium wall or creation of linear lesions in order to eliminate sources of afib located outside the pulmonary veins.
- **Right atrial flutter ablation** – This procedure involves the application of radiofrequency energy to create a block of the cavotricuspid isthmus in the right atrium so as to interrupt the flutter circuit. A right atrial flutter ablation is usually successful in eliminating the flutter, but rarely helps eliminate atrial fibrillation and may even, in some cases, initiate the development of atrial fibrillation.
- **Left atrial flutter ablation** – Left atrial flutter is a common complication of ablation for atrial fibrillation. It most often resolves on its own, but if not it may be necessary to re-enter the left atrium, locate the offending circuit, and block it via radiofrequency catheter ablation.
- **Cryoablation** – In this procedure a nitrogen-cooled or argon-cooled, rather than electrically-heated, catheter is used to create the ablation lesions.
- **Maze procedure** – The original surgical procedure, the full maze or Cox procedure, used a cut-and-sew protocol for creating lesions forming a “maze” that conducted the electrical impulse from the SA to the AV node, while at the same time interrupting any “rogue” circuits. The cut-and-sew method has now largely been replaced by the use of RF-

powered devices, but cryosurgery, microwave application, and high-intensity focused ultrasound (HIFU) have all been tried as well and are preferred by some surgeons. Creating the full set of maze lesions usually requires open-heart surgery and the use of a heart/lung machine.

- **Mini-maze procedure** – The so-called mini-maze procedure also involves lesions on the outside of the heart wall, but access to the heart is through incisions between the ribs rather than via open-heart surgery. The mini-maze may involve the creation of the full maze set of lesions, but usually focuses on pulmonary vein isolation. The procedure does not involve the use of a heart/lung machine and lesions are usually created by the application of RF energy or cryoenergy.

Statistical Terms

- **N** – The number of respondents in a sample.
- **Mean** – The average value for a group of data, i.e. the sum of the values of all data points divided by the number of data points.
- **Median** – The value in the middle of a group of data, i.e. the value above which half of all individual values can be found and below which the remaining 50% can be found.
- **Statistical significance** – In this study average values are considered different if the probability of the difference arising by chance is less than 5 in 100 using the two-tailed t-test. This is expressed as “p” being equal to 0.05 or less. Lower values of p are indicative of a greater certainty that observed differences are truly significant.

All statistical tests were carried out using the *GraphPad InStat* program (GraphPad Software Inc, San Diego, CA).

Definition of Success

- **Complete success** – No afib episodes, no antiarrhythmics, consistent sinus rhythm (success score=10)
- **Partial success** – No afib episodes, but on antiarrhythmics to maintain consistent sinus rhythm (success score=5)
- **Failure** – Afib episodes still occurring with or without the use of antiarrhythmics (success score=0)
- **Blanking period** – The first 6 months following the final procedure
- **Index period** – The last 6 months of the 12-month period following the final procedure for the purpose of curing afib
- **Initially successful** – No afib episodes and no antiarrhythmics during the index period.

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