

THE AFIB REPORT

Your Premier Information Resource for Lone Atrial Fibrillation!

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13th YEAR



Welcome to our 8th ablation survey. Previous surveys dealt mainly with the immediate success of catheter ablations or surgical procedures. This 2013 survey and the previous two surveys (2009 and 2011), however, focus on the long-term success. Long-term success in the case of catheter ablations for lone AF is a relative term since these procedures did not become common until about 10 years ago.

A total of 54 respondents who had undergone their final procedure prior to November 2005 participated in the 2013 survey. The majority of procedures reported (99%) were radiofrequency catheter ablations. Of the 54 respondents undergoing RF ablation, 32 (59%) underwent a single procedure, while 22 (41%) underwent 2 or more procedures for the purpose of curing AF. The most widely used and most successful procedure for paroxysmal AF was the pulmonary vein antrum isolation procedure developed by Dr. Andrea Natale and the segmental pulmonary vein isolation procedure (Haissaguerre protocol), which was also especially successful among permanent afibbers.

The most important variable determining long-term success was whether or not a respondent had an **initially successful** procedure, i.e. remained in sinus rhythm without the use of antiarrhythmics during the last 6 months of the 12-month period following their final procedure (index period). The long-term prognosis for an afib-free future without the use of antiarrhythmic drugs after an initially successful catheter ablation is excellent with 88% of paroxysmal afibbers and 80% of permanent afibbers being in this enviable state 8 years after their final procedure. In comparison, in the initially unsuccessful group only 40% of paroxysmal afibbers and 50% of permanent afibbers achieved this status.

At year 4 the afib burden and percent time spent in afib were reduced by an average (median) of 98% over the pre-ablation burden among paroxysmal afibbers whose ablation had not been successful. This was reflected in a 97% reduction in impact on quality of life. The reduction in afib burden and percent time spent in afib were also reduced in year 8 as compared to pre-ablation values; however, the reduction (80%) was no longer statistically significant, but the reduction in impact on quality of life (88%) remained statistically significant. These findings may indicate that, while an unsuccessful ablation still results in a significantly lower afib burden and improved quality of life in paroxysmal afibbers at the 4 year mark, the beneficial effects of the ablation may begin to wear off at the 8 year mark.

Only 3 permanent afibbers had provided data for pre-ablation and year 8. Average reductions in afib burden and percent time spent in afib were close to 100% and reduction in impact on quality of life was 99%.

Finally, if you need to restock your supplements, please remember that by ordering through my on-line vitamin store you will be helping to defray the cost of maintaining the web site and bulletin board. You can find the store at <http://www.afibbers.org/vitamins.htm> - your continuing support is greatly appreciated.

Wishing you and yours a Happy Holiday Season with good health and lots of NSR in the coming New Year,

Hans

2013 Ablation Survey

SUMMARY

The 2013 ablation/maze survey involved 54 respondents who had undergone a total of 76 procedures for the purpose of curing afib.

There were no significant differences in demographics between the respondents to the 2013 survey and those participating in the 2008 survey (677 respondents having undergone 1045 procedures) or the 2009 survey (94 participants having undergone 161 procedures). Thus, the 2013 survey respondents would appear to be a representative sample of the general lone atrial fibrillation population.

Prior to their initial ablation procedure 85% of respondents experienced episodes at least once a week and 42% were in afib every day (including permanent afibbers). The majority of respondents (90%) experienced episodes lasting more than 1 hour and 39% had episodes lasting 24 hours or longer (including permanent afibbers). Only 7% of those seeking a cure through catheter ablation 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.

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. There was a trend ($p=0.056$) for female afibbers to spend more time (14% on average) in afib than did male afibbers (7%).

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 (90%) than men (64%) reported a severity score of 4 or 5, but this difference was not statistically significant.

Paroxysmal, female afibbers had a statistically significant higher *Impact on Quality of Life* (IQoL) score than paroxysmal, male afibbers (54 vs. 13); this is not surprising as paroxysmal female afibbers on average spent more time in afib (14%) than did male paroxysmal afibbers (7%) and also had more severe episodes. The difference in IQoL between permanent afibbers (score of 350) and paroxysmal afibbers (average score of 14) was also statistically extremely significant ($p<0.0001$).

All but one of the 76 procedures reported in this survey (99%) were radiofrequency (RF) catheter ablations. Of the 54 patients undergoing RF ablation as their final or initial procedure, 32 (59%) underwent only one procedure, while 22 patients (41%) underwent 2 procedures for the purpose of curing AF.

The most widely reported ablation procedure was the pulmonary vein antrum isolation procedure (Natale protocol) at 31% of all RF ablations. The second most widely reported procedure was the segmental pulmonary vein isolation procedure (Haissaguerre protocol) at 20%.

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 56% for the initial procedures. The poorest performers were the circumferential pulmonary vein isolation procedure (Pappone protocol), at 29%, focal ablation at 17% and generic pulmonary vein ablation at 22%. The overall success rate for initial RF ablations was 44%.

It is clear that having an initially successful final ablation is of prime importance in determining the long-term success of the procedure. The average (mean) complete success rate (no afib, no

antiarrhythmics) at the end of year 8 was 86% for those whose last procedure was initially successful versus 42% 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 10 were 91% and 17% respectively based on a small sample of only 15 respondents.

Of the 40 respondents who were afib-free (without the use of antiarrhythmics) in year 4 only 2 (5%) reverted to having afib episodes by year 8. One more afibber (9% of the 11 for whom data was available in year 10) reverted to having afib in year 10 indicating that status at year 4 is a good indicator of long-term prognosis.

Forty-three per cent 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.

At year 4 the afib burden and percent time spent in afib were reduced by an average (median) of 98% over the pre-ablation burden among paroxysmal afibbers whose ablation had not been successful. This was reflected in a 97% reduction in impact on quality of life. The reduction in afib burden and percent time spent in afib were also reduced in year 8 as compared to pre-ablation values; however, the reduction (80%) was no longer statistically significant, but the reduction in impact on quality of life (88%) remained statistically significant. These findings may indicate that, while an unsuccessful ablation still results in a significantly lower afib burden and improved quality of life in paroxysmal afibbers at the 4 year mark, the beneficial effects of the ablation may begin to wear off at the 8 year mark.

Only 3 permanent afibbers had provided data for pre-ablation and year 8. Average reductions in afib burden and percent time spent in afib were close to 100% and reduction in impact on quality of life was 99%.

It is clear that afibbers whose latest ablation had been a complete success experienced fewer episodes of other arrhythmias than did those who were still experiencing afib episodes (failures) or were keeping episodes at bay with antiarrhythmics (partial success). On average (over the 8-year evaluation period) 34% of afibbers having undergone a completely successful ablation experienced other arrhythmias as compared to 71% ($p=0.003$) among those with a partially successful ablation, and 63% ($p=0.05$) among afibbers with a failed ablation. The presence of other arrhythmias (mostly ectopics) was 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 other arrhythmias (mostly ectopics) experienced by afibbers taking antiarrhythmics, it is possible that they are related to the inherent pro-arrhythmic effect of most antiarrhythmics.

The two most important, statistically significant, factors associated with being afib-free in year 8 were not having afib episodes during the index period and having, as the final or only ablation, a pulmonary vein antrum isolation procedure (Natale protocol). There was a trend for having undergone the final or only procedure at a top-ranked institution to be associated with a favourable 8-year outcome, as was having been on antiarrhythmics prior to the initial procedure and not having needed antiarrhythmics during the index period.

The most important factors associated with an afib-free index period were:

- Having undergone the final or only ablation procedure at a top-ranked institution;
- Having, as the final or only ablation, a pulmonary vein antrum isolation procedure (Natale protocol) or a segmental pulmonary isolation procedure (Haissaguerre protocol);
- Being male;
- Not experiencing atrial fibrillation or atrial flutter during the blanking period;
- Not experiencing atrial flutter during the index period;
- Not needing beta- or calcium channel blockers during the blanking and index periods.

Acknowledgement: A heartfelt thanks to those who took the time to participate in this survey. Your efforts are appreciated by all.

Survey Details

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 2013 ablation survey (LAF Survey 18) is a follow-up on the 2009 survey and involves 54 afibbers who provided an extra four years of data. The 2013 survey covers only catheter ablation procedures as the response from afibbers having undergone surgical procedures was inadequate.

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.

Evaluation of Background Data

General Background of Respondents

TABLE 1

Demographics	2013 Survey	2009 Survey	2007-08 Surveys
# of participants	54	94	677
% male	81	83	78
% female	19	17	22
Average age at first episode, yrs	50	50	48
Age range at first episode, yrs	19-67	15-67	5-79
Years since diagnosis[1]	17	12	8
Years since diagnosis (range)[1]	8-28	4-24	1-45
Underlying heart disease, %	9	8	8
Enlarged left atrium, %	22	23	**
LAF confirmed by diagnosis, %	**	**	92
Average age at last procedure, yrs	57	58	56
Age range at last procedure, yrs	22-72	24-73	26-58
Years to last procedure[2]	7	6	**
Years to last procedure (range)[2]	0-20	0-20	**

*** Question not asked in survey*

[1] Years elapsed between first episode and completion of survey

[2] Average (median) # of years from initial diagnosis to final procedure

There are no significant differences in demographics between the respondents to the 2013 ablation/maze survey and those participating in the 2007, 2008 and 2009 surveys. Thus, conclusions reached in the 2013 survey should be applicable to the lone AF population in general.

Afib Type

A total of 51 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

Type of AF	2013 Survey	2009 Survey	2007-08 Surveys
# of respondents	51	89	584
Adrenergic, %	2	3	5
Mixed, %	51	48	44
Vagal, %	23	26	24
Total paroxysmal, %	76	78	73
Persistent, %	2	3	10
Permanent, %	22	19	17
TOTAL	100	100	100

NOTE: 5 respondents to the 2009 survey and 3 in the 2013 survey were uncertain as to which type of AF they had.

Again, there are no major differences in the afib type of respondents to the 2009 and 2013 surveys when compared to the 2007-2008. The majority of respondents to the 2009 and 2013 surveys (78%) had paroxysmal AF with mixed (random) being the most common type.

Afib Frequency

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

TABLE 3

Episode Frequency	Episodes/6 months	Respondents, %
Permanent (24/7)	182	20
Daily	182	22
Twice weekly	52	26
Weekly	26	17
Twice a month	12	4
Monthly	6	4
Every 2 months	3	7
TOTAL	-	100

The majority of respondents (85%) experienced episodes at least once a week and 42% were in afib every day (including permanent afibbers). Only 7% of those seeking a cure through catheter ablation 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 procedure is presented in the following table:

TABLE 4

Episode Duration	Average Duration, hrs	Respondents, %
Less than 30 min	0.25	2
Between 30 min and 1 hour	0.75	7
Between 1 and 3 hours	2	19
Between 3 and 10 hours	6	15
Between 10 and 24 hours	17	15
Between 24 and 48 hours	36	4
More than 48 hours, but self-converted	48	11
More than 7 days or required cardioversion	168	2
Permanent (24/7)	24	20
Not sure	-	5
TOTAL	-	100

The majority of respondents (90%) experienced episodes lasting more than 1 hour and 39% 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

Average AF Burden/6 mos	AF Burden, hrs	Time Spent in AF, %
Paroxysmal male afibbers	156	4
Paroxysmal female afibbers	624	14
Vagal afibbers	260	6
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 0.1 – 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 ($p=0.056$), although there was a trend for female paroxysmal afibbers to carry a heavier burden.

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
% respondents with indicated score

Severity Score (1-5)	1	2	3	4	5	Mean Score
Male afibbers	2	7	27	37	27	3.8
Female afibbers	-	-	10	40	50	4.4
Vagal afibbers	-	8	31	15	46	4.0
Mixed afibbers	-	-	19	58	23	4.0
Adrenergic afibbers	-	-	100	-	-	3.0
Paroxysmal afibbers	-	2	26	40	31	4.0
Persistent afibbers	-	-	-	-	100	5.0
Permanent afibbers	9	18	18	36	18	3.4
Overall	2	6	24	39	30	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 (90%) 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. The average (median) IQoL score for the entire group of respondents was 40. IQoL scores for various categories of afib, calculated using this definition, are shown in Table 7.

TABLE 7

Respondents	IQoL Score
Paroxysmal male afibbers	13
Paroxysmal female afibbers	54
Vagal afibbers	40
Mixed afibbers	18
Adrenergic afibbers	10
Paroxysmal afibbers	14
Permanent afibbers	350

Paroxysmal female afibbers had a statistically significant higher IQoL score (poorer quality of life) than paroxysmal male afibbers (54 vs. 13); this is not surprising as paroxysmal female afibbers, on average, spent more time in afib (14%) than did male paroxysmal afibbers (4%) and also had more severe episodes. The difference in IQoL score was also noted in LAFS-16 where female paroxysmal afibbers had a score of 51 vs. 13 for male paroxysmal afibbers ($p=0.006$). The difference in IQoL between permanent afibbers (score of 350) and paroxysmal afibbers (score of 14) was also 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.

Procedure Outcome

Fifty-four afibbers responded to the survey and provided data for a total of 76 procedures as shown in Table 8. In addition to these 76 “free-standing” procedures, 31 patients also underwent a right atrial flutter ablation as part of their initial or final procedure for the purpose of curing afib. Adding these 31 procedures to the 8 performed separately means that 39 patients underwent a right atrial flutter ablation as part of their treatment to become free of arrhythmia.

The majority of procedures reported in this survey (99%) were radiofrequency (RF) catheter ablations. Of the 54 patients undergoing RF ablation, 32 (59%) underwent only one procedure, while 22 patients (41%) 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 31% of all RF ablations. The second most widely reported procedure was the segmental pulmonary vein ablation (Haissaguerre protocol) at 20%.

TABLE 8
Distribution of Procedures

Procedure	Initial	Final	Total	% of Total
Focal ablation	6	6	12	16
Pulmonary vein ablation (PVA)	8	1	9	12
Segmental PVI	9	6	15	20
Circumferential PVI	7	1	8	11
Antrum PVI	17	7	24	31
Unspecified	6	1	7	9
Cryoablation	1	0	1	1
Total ablation procedures	54	22	76	100
Adjuvant right flutter ablation[1]	20	11	31	-

[1] 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 56% for the initial procedures. The poorest performers were the circumferential pulmonary vein isolation procedure (Pappone protocol) at 29%, focal ablation at 17% and generic pulmonary vein ablation at 22%. The overall success rate for initial RF ablations was 44%.

TABLE 9
Complete Success Rate, Initial Procedure

Procedure	# in Group	Success, %*
Focal ablation	6	17
Pulmonary vein ablation (PVA)	8	22
Segmental PVI	9	56
Circumferential PVI	7	29
Antrum PVI	17	76
Unspecified	6	17
Cryoablation	1	0
Total catheter ablation procedures	54	44

* Defined as being AF-free without use of antiarrhythmics 1 year from date of initial ablation.

The outcome of the final procedure (which was the initial procedure in 59% of cases) for various categories of afib and respondent characteristics is presented in Table 10 below.

TABLE 10
Outcome of Final Procedure

Ablation Results	# in Group	Complete Success, %	Partial Success, %	Failure, %
Adrenergic	1	100	0	0
Mixed	26	77	19	4
Vagal	12	75	8	17
Paroxysmal – not sure	3	67	33	0
Total paroxysmal	42	76	17	7
Persistent	1	0	0	100
Permanent*	11	91	0	9
Overall success	54	78	13	9

* 78% of procedures done by Pr. Haissaguerre or Dr. Natale

The goal of the 2013 ablation survey 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 2013 survey, 42 respondents met this rather strict definition, while the remaining 12 did not – they were either experiencing afib episodes or using antiarrhythmics during the index period. Nevertheless, all 54 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 54 respondents provided data until the end of the 8th year following their final procedure – 33 provided data for year 9, 17 provided data for year 10, and 3 provided data for year 11 after their latest ablation.

The outcomes, by year, for all ablations as well as for initially successful (no afib, no antiarrhythmics during index period) and initially unsuccessful (afib episodes or use of antiarrhythmics during index period) catheter ablations are presented in Tables 11A, 11B, and 11C below.

TABLE 11A
Overall Procedure Outcome

	Year 1, %	Year 4, %	Year 8, %	Year 9, %	Year 10, %	Year 11, %
Paroxysmal						
# of respondents[1]	42	42	42	27	15	2
Complete success, %	76	57	63	59	67	50
Partial success, %	7	4	4	7	7	0
Failure, %	17	22	16	33	27	50
Persistent & Permanent						
# of respondents[1]	12	12	12	6	2	1
Complete success, %[2]	83	85	64	67	50	0
Partial success, %	0	0	0	0	0	50
Failure, %	17	8	21	33	50	0
Total						
# of respondents[1]	54	54	54	33	17	3
Complete success, %	78	74	76	61	65	33
Partial success, %	6	4	4	6	6	33
Failure, %	17	22	20	33	29	33

[1] # of respondents who reported their afib status and use of antiarrhythmics for indicated period

[2] 78% of procedures done by Pr. Haissaguerre or Dr. Natale

TABLE 11B
Outcome for Initially Successful Ablation Procedure[1]

	Year 1, %	Year 4, %	Year 8, %	Year 9, %	Year 10, %	Year 11, %
Paroxysmal						
# of respondents[2]	32	32	32	19	10	2
Complete success, %	100	81	88	79	90	50
Partial success, %	0	0	0	0	0	0
Failure, %	0	19	13	21	10	50
Persistent & Permanent						
# of respondents[2]	10	10	10	5	1	0
Complete success, %[3]	100	100	80	80	100	0
Partial success, %	0	0	0	0	0	0
Failure, %	0	0	20	20	0	0
Total						
# of respondents[2]	42	42	42	24	11	2
Complete success, %	100	86	86	79	91	50
Partial success, %	0	0	0	0	0	0
Failure, %	0	14	14	21	9	50

[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 procedure) done at least 8 years ago

[2] # of respondents who reported their afib status and use of antiarrhythmics for indicated period

[3] 80% of procedures done by Pr. Haissaguerre or Dr. Natale

TABLE 11C
Outcome for Initially Unsuccessful Ablation Procedure[1]

	Year 1, %	Year 4, %	Year 8, %	Year 9, %	Year 10, %	Year 11, %
Paroxysmal						
# of respondents[2]	10	10	10	8	5	0
Complete success, %	0	30	40	13	20	0
Partial success, %	30	20	20	25	20	0
Failure, %	70	50	40	63	60	0
Persistent & Permanent						
# of respondents[2]	2	2	2	1	1	1
Complete success, %	0	50	50	0	0	0
Partial success, %	0	0	0	0	0	100
Failure, %	100	50	50	100	100	0
Total						
# of respondents[2]	12	12	12	9	6	1
Complete success, %	0	33	42	11	17	0
Partial success, %	25	17	17	22	17	100
Failure, %	75	50	42	67	67	0

[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 procedure) done at least 8 years ago

[2] # of respondents who reported their afib status and use of antiarrhythmics for 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 average (median) complete success rate (no afib, no

antiarrhythmics) at the end of year 8 was 86% for those whose last procedure was initially successful versus 42% for those who had not experienced an afib-free index period or who had been on antiarrhythmics during the index period. This difference is statistically significant ($p=0.01$).

It will no doubt be of interest to many afibbers that, of the 40 respondents who were afib-free (without the use of antiarrhythmics) in year 4, only 2 (5%) reverted to having afib episodes by year 8. One more afibber (9% of the 11 afibbers for whom data was available in year 10) reverted to having afib in year 10, indicating that status at year 4 is a good indicator of long-term prognosis.

Arrhythmia Burden and Triggers

Changes in Afib Burden

Prior to the initial catheter ablation, all respondents experienced symptomatic paroxysmal AF episodes or were in permanent (24/7) AF. At the end of the 4th year following the last catheter ablation 6 paroxysmal afibbers who were not on antiarrhythmics provided data allowing a comparison between pre-ablation afib burden and year 4 afib burden. Their afib burden and percent time spent in afib were reduced by an average (median) of 98% ($p=0.03$). This was reflected in a 97% reduction in impact on quality of life ($p=0.04$) as shown in Table 12A below.

The reduction in afib burden and percent time spent in afib were also reduced in year 8 as compared to pre-ablation values; however, the reduction (80%) was no longer statistically significant ($p=0.06$) but the reduction in impact on quality of life (88%) remained statistically significant ($p=0.05$). NOTE: It is of course likely that the differences would be statistically significant if a larger sample size had been available.

These findings may indicate that, while an unsuccessful ablation still results in a significantly lower afib burden and improved quality of life in paroxysmal afibbers at the 4 year mark, the beneficial effects of the ablation may begin to wear off at the 8 year mark.

Only 3 permanent afibbers had provided data for pre-ablation and year 8. Average reductions in afib burden and percent time spent in afib were close to 100% ($p<0.0001$) and reduction in impact on quality of life was 99% ($p=0.0004$).

TABLE 12A
Change in AF Burden – Year 4

6 paroxysmal afibbers[1]	Pre-ablation	Year 4	Reduction, %	P-value[2]
Episode frequency – median	52	13	75	0.03
Episode duration, hrs – median	21	4	81	0.1
Episode burden, hrs – median	806	11	99	0.03
Time spent in AF, % - median	19	0.3	98	0.03
Severity score (1-5) – mean	4	3	25	0.05
Impact on QoL[3] – mean	102	3	97	0.04

[1] All values are averages for 6-month periods (182 days) and apply to catheter ablation only.

[2] Statistical significance (two-tailed p-value) of difference between median pre-procedure values and values for year 4.

[3] Impact on Quality of Life is calculated as severity score multiplied with % time spent in AF.

A score of zero corresponds to no AF, while a score of 500 corresponds to being in debilitating permanent (24/7) AF. NOTE: No data available for permanent afibbers in year 4.

TABLE 12B
Change in AF Burden – Year 8

6 paroxysmal afibbers[1]	Pre-ablation	Year 8	Reduction, %	P-value[2]
Episode frequency – median	52	36	31	0.4
Episode duration, hrs – median	21	6	71	0.3
Episode burden, hrs – median	806	158	80	0.06
Time spent in AF, % - median	19	3.6	81	0.06
Severity score (1-5) – mean	4	3	25	0.02
Impact on QoL[3] – mean	102	12	88	0.05
3 permanent afibbers[1]				
Episode frequency – median	182	1	99	<0.0001
Episode duration, hrs – median	24	18	25	0.8
Episode burden, hrs – median	4368	18	100	<0.0001
Time spent in AF, % - median	100	0.4	100	<0.0001
Severity score (1-5) – mean	3.6	4.3	(19)	0.4
Impact on QoL[3] – mean	366	3.3	99	0.0004

[1] All values are averages for 6-month periods (182 days) and apply to catheter ablation only. Pre-ablation burden is for burden prior to 1st ablation for AF.

[2] Statistical significance (two-tailed p-value) of difference between median pre-procedure values and values for year 8.

[3] Impact on Quality of Life is calculated as severity score multiplied with % time spent in AF. A score of zero corresponds to no AF, while a score of 500 corresponds to being in debilitating permanent (24/7) AF.

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: The following data is from LAFS-16.

TABLE 13
Triggers – Same Trigger as Before Final Ablation

	Year 2, %	Years 3-4, %	Years 5-6, %	Years 7-10, %	Average, %
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 other arrhythmias (atrial flutter, tachycardia and ectopics) following the final procedure is tabulated in Table 14 below.

TABLE 14
Other Arrhythmias[1]

	Index Period	Year 4	Year 8	Average
Complete success[2]	36%	40%	27%	34%
Partial success[3]	67%	50%	100%	71%
Failure[4]	67%	67%	55%	63%
Total respondents	54	54	54	-

[1] Respondents whose latest procedure was a catheter ablation done at least 8 years ago.

[2] No AF episodes and no use of antiarrhythmics during indicated period.

[3] No AF episodes, but using antiarrhythmics during indicated period.

[4] Experiencing AF episodes with or without the use of antiarrhythmics.

It is clear that afibbers whose latest ablation had been a complete success experienced fewer episodes of other arrhythmias than did those who were still experiencing afib episodes (failures) or were keeping episodes at bay with antiarrhythmics (partial success). On average (over the 8 year evaluation period) 34% of afibbers having undergone a completely successful ablation experienced other arrhythmias as compared to 71% (p=0.003) among those with a partially successful ablation and 63% (p=0.05) among afibbers with a failed ablation. The presence of other arrhythmias (mostly ectopics) was 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 other arrhythmias (mostly ectopics) experienced by afibbers taking antiarrhythmics, it is possible that they are related to the inherent pro-arrhythmic effect of most antiarrhythmics.

Factors Affecting Year 8 Outcome

The factors that may affect long-term outcome of catheter ablations were evaluated for 54 respondents who knew their afib status at the end of year 8. The respondents were divided into two groups – group 1 consisted of 41 afibbers who had not used antiarrhythmics and who had not experienced any episodes during year 8 (complete success: 100%); group 2 consisted of 13 afibbers who either experienced episodes during year 8 (failure: 85%), or had remained free of episodes through the use of antiarrhythmics (partial success: 15%).

Table 15 compares a number of factors that could potentially explain the significant outcome differences between the two groups. In considering this analysis it should be kept in mind that differences that are found to be statistically non-significant (NS or $p>0.05$) may well prove to be significant in studies involving a larger number of participants.

TABLE 15
Comparative Data at Year 8

	Group 1 Success	Group 2 Failure	Significance of Difference
Number of participants	41	13	-
Demographics			
Percent male	83	77	NS
Percent female	17	23	NS
Average (mean) age at 1 st episode, years	51	48	NS
Underlying heart disease, %	7	15	NS
Enlarged left atrium, %	22	23	NS
AF burden prior to 1st procedure[1]			
Episode frequency (# in 6-month period)	52	52	NS
Episode duration (median), hours	6	6	NS
AF burden (hrs spent in AF in 6 months)	156	432	NS
AF burden (% time spent in AF in 6 months)	4	10	NS
AF severity (mean – scale of 1 to 5)	3.7	4.1	NS
Impact on QoL (mean – range of 0-500)	74	49	NS
Arrhythmias during blanking period			
No arrhythmias, %	22	0	NS
Atrial fibrillation, %	20	38	NS
Atrial flutter, %	7	38	p=0.005
Tachycardia, %	10	38	p=0.02
Ectopics (PACs and PVCs), %	34	46	NS
Arrhythmias during index period			
No arrhythmias, %	65	17	p=0.003
Atrial fibrillation, %	10	42	p=0.01
Atrial flutter, %	0	33	p=<0.0001
Tachycardia, %	5	33	p=0.006
Ectopics (PACs and PVCs), %	23	33	NS
Timing of procedures			
Average (mean) age at 1 st procedure	57	56	NS
Years from 1 st episode to initial procedure	6	7	NS
Average (mean) age at last procedure	58	56	NS

Years from 1 st procedure to last procedure	7	8	NS
Average number of procedures	1.4	1.5	NS
Months (average) between procedures	19	14	NS
Type of last or only procedure			
Circumferential PVI, %	12	0	NS
Pulmonary vein antrum isolation, %	49	15	p=0.03
Segmental PVI, %	22	15	NS
Generic PVA, %	5	31	p=0.009
Focal ablation, %	10	31	p=0.07
Other catheter ablation procedures, %	2	8	NS
Right atrial flutter ablation, % ^[2]	53	62	NS
Procedures done at top institutions, % ^[3]	73	46	p=0.07
Medications prior to initial procedure			
Antiarrhythmics, %	71	15	p=0.08
Beta or calcium channel blockers, %	26	0	NS
Medications during blanking period			
Antiarrhythmics, %	0	0	NS
Beta or calcium channel blockers, %	23	27	NS
Medications during index period			
Antiarrhythmics, %	7	27	p=0.06
Beta or calcium channel blockers, %	16	27	NS
Supplementation			
With the “essential trio”, % ^[4]	47	27	NS

[1] Paroxysmal afibbers only

[2] Right atrial flutter ablation done as part of AF ablation

[3] % of procedures done at top 15 institutions as determined in 2008 Ablation/Maze Survey

[4] Supplementation with one or more of the “essential trio” components (magnesium, potassium, and taurine) during the 1st year following last procedure.

There are no statistically significant differences in general background variables between the two groups. Afib burden and severity prior to the initial procedure are also not significantly different between the two groups indicating that the long-term outcome of an ablation is independent of how bad the afib status was prior to the initial procedure.

The difference in the frequency of arrhythmias observed during the index period is however, not surprisingly, statistically extremely significant, again confirming that the absence of afib episodes during the index period is of crucial importance in predicting a favourable long-term outcome. It is also evident that experiencing atrial flutter or tachycardia during the index period heralds a poor 8-year outcome as does experiencing these arrhythmias during the blanking period.

Age at time of procedures and duration of afib prior to procedures did not affect year 8 outcome and the number of procedures and the time span between them did not affect long-term outcome either.

The type of ablation procedure did, however, affect year 8 outcome. Forty-nine per cent of afibbers in group 1 had undergone a pulmonary vein antrum isolation (PVAI) procedure while only 15% had done so in group 2. This difference was statistically significant (p=0.03). In contrast, 31% of members of group 2 had undergone a “generic” pulmonary vein ablation (PVA) while only 5% of members of group 1 had done so. This difference again was statistically significant (p=0.009). Focal ablations were also associated with a poorer long term outcome. There was a trend (p=0.07) for ablations done at top-ranked institutions to have a better long-term outcome with 73% of group 1 members having undergone their ablation at such an institution as compared to only 46% of group 2 having done so. This

observation is strongly supportive of the results of previous ablation surveys, which have all concluded that the all-important factor in short-term (1 year) success is the experience and expertise of the EPs performing the procedures.

Finally, there was a trend for long-term outcome being better among afibbers who had been on antiarrhythmics prior to their initial procedure ($p=0.08$) while afibbers who had needed antiarrhythmics during the index period tended to have a poorer year 8 outcome ($p=0.06$).

Clearly, a very important factor in predicting the long-term (8 year) outcome of a catheter ablation is the absence of arrhythmias (atrial fibrillation, flutter and tachycardia) during the index period (last 6 months of the 12-month period following the final procedure for the purpose of curing AF). The factors that significantly influence afib occurrence during the index period are listed in Table 16.

TABLE 16
Comparative Data for Index Period

	Group 1 Success	Group 2 Failure	Significance of Difference
Number of participants	42	12	-
Demographics			
Percent female	12	42	0.02
Arrhythmias during blanking period			
Atrial fibrillation, %	17	46	0.02
Atrial flutter, %	10	31	0.04
Arrhythmias during index period			
Atrial flutter, %	2	25	0.008
Type of last or only procedure			
Segmental or antrum PVI procedure, %	74	17	0.0002
Procedures done at top institutions, % ^[1]	76	33	0.005
Medications during blanking period			
Beta or calcium channel blockers, %	19	50	0.03
Medications during index period			
Beta or calcium channel blockers, %	10	50	0.001

[1] Procedures done at top 15 institutions as determined in 2008 Ablation/Maze Survey

It is again clear that the skill and expertise of the EPs doing the procedures are the key factors in determining whether or not the index period will be free of afib episodes. Seventy-six per cent of successful procedures (group 1: no afib and no antiarrhythmics during index period) were done at top-ranked institutions and 74% involved either a PVAI or a segmental PVI. In contrast, only 33% of failed procedures (group 2: afib episodes or use of antiarrhythmics during index period) were done at top-ranked institutions and only 17% involved a PVAI or segmental PVI procedure. Both of these differences are statistically extremely significant ($p=0.005$ and $p=0.0002$).

Female afibbers were more likely to be found in group 2 (42%) than in group 1 (12%) and this difference was statistically significant ($p=0.02$). Experiencing atrial fibrillation or atrial flutter during the blanking period was also associated with a greater chance of not experiencing an afib-free index period, as was experiencing atrial flutter during the index period itself ($p=0.008$). Finally, needing beta-blockers or

calcium channel blockers during the blanking period and the index period was also associated with a significantly reduced chance of being afib-free during the index period.

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.

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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