THE AFIB REPORT

Your Premier Information Resource for Lone Atrial Fibrillation!

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Welcome to our 9th year of publication and our 5th annual ablation/maze survey. Not entirely unexpected, the analysis of the results of the 2008 Ablation/Maze Survey turned out to be a challenge, to say the least. With almost 700 respondents reporting the results of over 1000 procedures and providing 60 pages of supporting information, it took some time to sort through it all and bring the data into a format whereby analysis was possible. It has been worth the struggle – and I'm pleased to share my very interesting findings with you.

I firmly believe that trigger identification and avoidance, lifestyle changes, dietary changes (paleo and Zone diets are good choices), judicious supplementation (especially with potassium, magnesium, and taurine) and generally being kind to oneself are the first choices in the battle with the "beast". Antiarrhythmic drugs may be considered next, but as they are often ineffective (86% of survey respondents who took antiarrhythmics or beta- or calcium-channel blockers still experienced episodes) and can have severe side effects, they are unlikely to be a viable long-term solution. This leaves ablation or the maze/mini-maze procedures as the final alternatives for eliminating afib.

This first part of the survey covers radiofrequency ablation procedures only. The second part, to be published in the February 2009 issue, will cover the maze and mini-maze procedures, cryoablation, and AV node and pacemaker installation. With 677 respondents and 1045 individual procedures evaluated, this survey is no doubt one of the largest ever done in the "real world". In other words, a survey in which the information is provided by the patients who underwent the procedures rather than by the EPs or institutions performing them. The survey includes procedures performed at over 168 different centers so should give a good picture of the overall situation, but as in any survey some real "gems" – or "horrors" may well have been missed. Please also bear in mind that success and failure are based on the absence or presence of ***symptomatic*** *episodes only.*

Part 1 of the survey covers RF ablations for the purpose of curing atrial fibrillation and flutter, and involves 461 afibbers (who knew the outcome of their last procedure performed 6 months or longer prior to completing the survey) who underwent a total of 729 RF procedures. The average final complete success rate was 56%, but was significantly higher in top-ranked institutions (65%), and correspondingly lower in other institutions (32%).

However, it is indeed encouraging to see that the complete success rate has doubled from the average 24% observed in the 1998-2004 period to 48% for the year 2007 and first four months of 2008. This remarkable improvement in single procedure success is reflected in an overall average increase in final (complete) success rate from 47% in the period 1998-2004 to 66% in the period 2007-2008

In conclusion, when other measures have failed, as they did for me, an RF ablation performed at one of the 15 top-ranked institutions is a good option for a full return to normal life. Having the procedure with a less skilled EP is still a gamble.

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

Hans

2008 Ablation/Maze Survey

The 2008 Ablation/Maze Survey produced 323 responses, 162 of which were updates to responses submitted in earlier surveys. Combining the 516 respondents to earlier surveys with the 161 new respondents contributing their experience in 2008 results in a total database of 677 patients having undergone a total of 1045 procedures.

The survey results are discussed in three sections. The first covers definition of terms and the general background of the respondents. The second section deals with the details and results of radiofrequency (RF) catheter ablation procedures, while the third section to be published in the February 2009 issue covers the details and results of other procedures (cryoablation, maze procedure, mini-maze procedure, and AV node ablation and pacemaker implantation).

PART 1 – DEFINITIONS AND BACKGROUND

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.
- **AV node ablation + pacemaker –** In this procedure the AV node (the ventricular beat controller) is isolated from any extraneous impulses through cauterization of surrounding tissue, and the ventricles are fed their "marching order" through an implanted pacemaker. The procedure does not eliminate atrial fibrillation, but makes it substantially less noticeable. Patients who have undergone AV node ablation and pacemaker installation are entirely dependent on the pacemaker and are usually on warfarin for life.

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 0.5 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

The success of the procedures is (unless otherwise noted) judged at least 6 months after the completion of the procedure. It is defined in two ways:

Subjectively – The afibber's own opinion as to whether the procedure was completely successful, partially successful, or not successful at all

Objectively – The following criteria are used to define success objectively:

- Complete success – No afib episodes, no antiarrhythmics, consistent sinus rhythm
- Partial success – No afib episodes, but on antiarrhythmics to maintain consistent sinus rhythm
- Failure – Afib episodes still occurring with or without the use of antiarrhythmics
- Uncertain – Cases where insufficient data was available or where less than 6 months had gone by since the procedure.

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" 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

Distribution of Procedures

Six hundred and seventy-seven afibbers responded to the survey and provided data for a total of 1045 procedures distributed as follows:

TABLE 1

	Number of Procedures				
RF Ablation Procedures	1st	2nd	3rd	Further	Total
Focal ablation	52	26	7	0	85
Pulmonary vein ablation (PVA)	191	71	15	1	278
Segmental pulmonary vein ablation	65	37	10	0	112
Circumferential pulmonary vein ablation	55	23	5	2	85
Pulmonary vein antrum isolation	127	37	13	3	180
Right atrial flutter ablation	50	17	6	0	73
Left atrial flutter ablation	5	6	4	0	15
Ablation for supraventricular tachycardia	4	2	2	0	8
Ablation procedure unknown	62	32	9	13	116
Total RF ablation procedures	611	251	71	19	952
Other Procedures					
Cryoablation	8	4	0	0	12
Maze procedure	20	3	1	2	26
Mini-maze procedure	29	3	6	2	40
AV node ablation + pacemaker	9	3	1	2	15
Total other procedures	66	13	8	6	93
GRAND TOTAL	677	264	79	25	1045
% undergoing procedure	100	39	12	4	

The majority of procedures (90%) were radiofrequency (RF) ablation procedures. Thirty-nine percent of the 677 respondents underwent a second procedure, 12% a third procedure, and 4% underwent further procedures. The most widely used AF ablation procedure was the generic pulmonary vein ablation (PVA) followed by the pulmonary vein antrum isolation (Natale), the segmental PVI (Haissaguerre), and the circumferential PVI (Pappone).

General Background of Respondents

TABLE 2

Demographics	Male	Female	Total
Gender distribution, %	78	22	100
Average (median) age*, yrs	58	59	58
Median age at diagnosis, yrs(1)	47	49	48
Age range at diagnosis, yrs(1)	5-74	10-79	5-79
Years since diagnosis(1)	8	8	8
Years since diagnosis (range)	1-45	1-44	1-45
Underlying heart disease, %	9	7	8
LAF confirmed by diagnosis, %	92	90	92
Median age at last proc., yrs(1)	56	56	56
Age range (last proc.), yrs(1)	26-81	26-85	26-85

* At time of completing survey
(1) From 2007 ablation/maze survey

There are no significant differences between males and females as far as demographic variables are concerned.

Afib Type and Burden

A total of 584 respondents had provided detailed information regarding their type of AF (adrenergic, mixed, vagal) prior to their procedure. The distribution was as follows:

TABLE 3

Type of AF	Male	Female	Total
No. of respondents	453	131	584
Adrenergic, %	5	4	5
Mixed, %	43	48	44
Vagal, %	25	24	24
Total paroxysmal, %	72	76	73
Persistent, %	10	10	10
Permanent, %	17	15	17
TOTAL	100	100	100

NOTE: 93 respondents were uncertain as to which type they had

The majority of the 2008 respondents (73%) had paroxysmal AF, while 10% had persistent, and 17% had permanent AF. Mixed (random) AF was the most common paroxysmal type for both sexes followed by vagal and adrenergic.

Although not specifically dealt with in this survey, the 2007 survey did provide data concerning the frequency of episodes and the total burden (frequency x duration) experienced among 478 afibbers.

The majority of respondents (79%) experienced episodes at least once a week and 40% were in afib every day (including permanent afibbers). Only 6% of those seeking a cure through ablation or surgical procedures had 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 median duration of paroxysmal episodes was 9 hours with a wide range of from a few minutes to 120 hours. There was no statistically significant difference in afib burden between paroxysmal afibbers taking antiarrhythmics or blockers and those taking no medications on a continuous basis.

The total average (median) burden over a 3-month period was 208 hours for mixed afibbers, 163 hours for vagal afibbers, and 104 hours for adrenergic.

PART 2 – RADIOFREQUENCY ABLATION

Demographics

A total of 552 afibbers underwent a RF ablation of the left atrium for the purpose of curing afib as their first procedure. The majority of the 481 respondents who knew their type of afib had the paroxysmal form (74%), 10% had persistent afib, while the remaining 16% were in permanent afib. Among the 352 paroxysmal afibbers who were aware of the initiating circumstances for their episodes, 58% characterized themselves as mixed, 35% were vagal, and 7% were adrenergic.

Twenty-three percent of respondents were female. Six percent of respondents had been diagnosed with heart disease.

Initial Procedure Results

Only afibbers who had undergone their first RF ablation at least 6 months prior to completing the survey questionnaire were considered in this evaluation in order to avoid making premature conclusions as to success. Thus, 475 afibbers who knew the outcome of their first ablation were included. Results are presented in the table below.

TABLE 4

	# in Group	Complete Success,%	Partial Success,%	Failure,%
Ablation Results				
Adrenergic	20	44	6	50
Mixed	188	35	6	58
Vagal	99	33	3	64
Paroxysmal - not sure	49	24	7	69
Total paroxysmal	356	33	6	61
Persistent	42	46	8	46
Permanent	70	42	5	53
Not sure	7	29	14	57
Grand total	475	34	5	61
Other Possible Variables				
Underlying heart disease	30	20	7	73
Outcome for males	367	36	4	61
Outcome for females	108	28	10	62

The overall rate of complete success (no afib, no antiarrhythmics) for a first RF ablation was 34%. The rate of partial success (no afib, but on antiarrhythmics) was 5%, and the overall failure rate was a disappointing 61%. There were no statistically significant differences in success or failure rates between the three types of paroxysmal AF (adrenergic, mixed and vagal). The failure rate for afibbers with underlying heart disease was somewhat higher than the average; however, this difference was not statistically significant, nor was the difference in complete success between male and female ablatees.

The overall complete success rate (34%) for the initial RF ablation is clearly disappointing. However, as previous surveys have shown, success rates are mostly dependent on the skill and experience of the EP performing the procedure. The possible influence of episode duration and frequency on procedure outcome was evaluated in the 2007 ablation/maze survey. Episode duration, somewhat surprisingly, did not play a statistically significant role in determining the outcome of the first ablation. The risk of failure did, however, increase with increasing episode frequency. Afibbers who experienced episodes every week or more frequently had a 65% risk of failure, while those with less frequent episodes had a failure

risk of 49%. This difference is statistically significant (p = 0.03) and may indicate that ablation should be considered if episode frequency approaches once a week. However, in assessing the validity of any possible correlation such as this, it should always be kept in mind that the overriding factor in any evaluation of ablation success is the EP performing the procedure.

Second and Third Procedure Results

Only afibbers who had undergone their 2nd and 3rd afib ablations at least 6 months prior to completing the survey and were certain of the outcome were included in this tabulation in order to avoid making premature conclusions as to success. Results are presented in the table below.

TABLE 5

	# in Group	Complete Success,%	Partial Success,%	Failure,%
Procedure outcome				
1st procedure	475	34	5	61
2nd procedure	193	34	5	61
3rd procedure	46	35	17	48
Total/Average	714	34	6	60

The percentage of complete success of the 2nd and 3rd procedures is not significantly different from that of the first procedure, thus supporting the claim by many EPs that a follow-up procedure is not materially different from the initial procedure. The remainder of this section will thus combine the results for all RF afib ablation procedures for which the outcome is known (after a 6-month wait period) including the 4th, 5th and 6th procedures.

It is of interest to note that the rate of partial success (no afib, but on antiarrhythmic drugs) is substantially higher after the 3rd procedure than after the 1st and 2nd procedures (17% vs. 5%). This difference is statistically highly significant and may indicate that the chance of antiarrhythmics working is greater after multiple ablations.

Procedure Outcome – RF Ablation

Outcome of Procedures

TABLE 6

	Complete Success, %				
Procedure	1998-2004 Success,%	2005 Success,%	2006 Success,%	2007-2008 Success,%	1998-2008 Success,%
Focal ablation	11	30	33	33	19
PV ablation (PVA)	19	37	26	43	28
Segmental PVI	32	43	43	41	40
Circumferential PVI	30	20	18	67	34
Antrum PVI (PVAI)	52	63	63	59	59
Unspecified	11	18	11	38	18
Total/Average	24	39	33	48	34
# of procedures in year	276	148	140	165	729

The average complete success rate for 729 individual left atrium RF ablation procedures (including 4th, 5th, and 6th) performed during the period 1998-2008 was 34%. Complete success rates have doubled from the average 24% observed for the 1998-2004 period to 48% for the year 2007 and first 4 months of 2008. This remarkable improvement in single procedure success is reflected in an overall average

increase in final (complete) success rate from 47% in the period 1998-2004 to 66% in the period 2007-2008.

The most successful procedure is clearly the pulmonary vein antrum isolation procedure (Natale method) with an average single procedure success rate of 59%. The second most successful procedure was the segmental PVI (Haissaguerre method) as practiced in Bordeaux and several other clinics with an average single procedure success rate of 40%. The circumferential PVI (Pappone method) had an overall success rate of 34%, but improved markedly in the last year or so to reach an average complete success rate of 67%. This remarkable improvement could be due to the introduction of more reliable mapping procedures, the increasing experience of the EPs performing the procedure, but could also be due to a preference for selecting paroxysmal afibbers for the procedure. In the period 2007-2008, 95% of patients undergoing the circumferential procedure had the paroxysmal form of AF. In contrast, only 65% of patients undergoing the pulmonary vein antrum isolation procedure had paroxysmal. Similarly, only 62% of afibbers treated with the segmental procedure had paroxysmal AF.

The usage pattern of the different procedures in relation to the type of afib ablated is further explored in Table 7.

TABLE 7

Success Rate – Single Procedure, 2005-2008

		Procedure Use, %			Complete Success Rate, %		
Procedure	# in Group	Paroxysmal	Persistent	Permanent	Paroxysmal	Persistent	Permanent
Focal ablation	28	71	7	21	35	100	0
PV ablation (PVA)	129	79	12	9	36	38	18
Segmental PVI	85	74	12	14	40	40	58
Circumferential PVI	50	90	6	4	36	67	0
Antrum PVI (PVAI)	99	65	7	28	69	57	46
Unspecified	51	76	6	18	21	100	0
Total/Average		75	9	15	41	51	32
# in group	442	333	41	68	137	21	22

It is clear that the circumferential PVI is primarily used in paroxysmal afib and has an average success rate for this type (36%). The PVAI procedure, on the other hand, has an excellent success rate for both paroxysmal (69%) and permanent (46%) afib, and only 65% of patients undergoing this procedure had paroxysmal afib. The best success rate for permanent afib (58%) was observed for the segmental PVI, no doubt, because 67% of the procedures were carried out by the Bordeaux team of Profs. Haissaguerre and Jais. Similarly, the 46% success rate for single procedure PVAI for permanent afib is, no doubt, due to the fact that 66% of the procedures were carried out by Dr. Natale. The average success rate for persistent afib was surprisingly high at 51%. I have no explanation for this other than the fact that most procedures for persistent afib were carried out at top-ranked institutions.

Adverse Events

The 2008 ablation/maze survey did not specifically enquire about adverse events. However, the 2006 survey did and since the incidence of adverse events is an important consideration in deciding on an ablation, I have repeated the results of the 2006 survey.

The table below shows the incidence of adverse events that occurred during or shortly following 358 RF ablation procedures performed during the period 1998-2006. Fifty-nine percent of all procedures were not accompanied by an adverse event, while 41% were associated with one or more events.

TABLE 8

	1998-2004			2005-2006			1998-2006		
Event, %	Complete Success	Partial Success	Failure	Complete Success	Partial Success	Failure	Complete Success	Partial Success	Failure
No adverse event	74	63	55	69	30	48	71	50	52
One or more, %	26	38	45	31	70	52	29	50	48
Total, %	100	100	100	100	100	100	100	100	100

It is clear that the risk of adverse events is substantially higher in the case of a failed ablation (48%) than in the case of a successful one (29%). This difference is statistically very significant (p=0.002). About 70% of all adverse events reported were fully resolved at the time the survey was completed.

The following table shows the distribution of events. The percentage of events relates to the number of procedures (not the total number of events). Thus, the sum of adverse events and no adverse events may not always equal 100% since some procedures were accompanied by more than one adverse event.

TABLE 9

	1998-2004			2005-2006			1998-2006			
	Comp. Succ.	Part. Succ.	Fail.	Comp. Succ.	Part. Succ.	Fail.	Comp. Succ.	Part. Succ.	Fail.	Total Evnts
None, %	74	63	55	69	30	48	71	50	52	59
Hematoma, %	13	13	19	14	10	21	13	12	20	17
TIA, %	2	0	1	0	0	1	1	0	1	1
Stroke, %	0	0	2	0	0	0	0	0	1	1
PV stenosis, %	2	0	6	0	10	0	1	4	4	3
Pericarditis, %	0	0	3	3	10	1	1	4	3	2
Tamponade< %	0	0	2	0	0	0	0	0	2	1
Fistula, %	2	0	0	0	0	0	1	0	0	0
Left atrial tach/flutter, %	2	31	12	8	20	21	5	27	15	12
Right atrial flutter, %	2	0	8	3	30	8	2	12	8	6
Minor reversible event, %	5	0	3	7	10	1	6	4	3	4
Life-threatening, %	0	0	1	0	0	0	0	0	1	0
Permanent damage, %	0	0	2	0	0	0	0	0	1	1
Adverse events, %	26	44	59	34	90	55	30	62	57	47

Over the period 1998-2006 hematoma in the groin and thigh area was the most common adverse effect at 17%.

Fortunately, this adverse event was short-lived and was completely resolved at the time the survey was submitted. The second most common adverse event was the development of post-procedural left atrial tachycardia/flutter. This complication arose in 44 of 358 procedures (12%). The left atrial tachycardia/flutter resolved on its own in about 40% of cases, but 6 (14%) ablatees underwent another ablation to deal with it. Post-procedure right atrial flutter was reported by 22 ablatees (6%) and 8 (36%) subsequently underwent an ablation to eliminate it.

In the remaining 64% the right atrial flutter was temporary and resolved itself prior to completion of the survey. NOTE: One hundred and fourteen (32%) of all ablation procedures included a right atrial flutter ablation as a precautionary measure.

Minor reversible events occurred during 4% of all procedures, pulmonary vein stenosis during 2.5%, and stroke and TIA accounted for 0.6% and 0.8% respectively. Tamponade (piercing of the heart wall) occurred during 3 procedures and thus accounted for 0.8% of events, pericarditis (inflammation of the heart wall) followed 8 procedures (2.1%), and one ablatee experienced a non-fatal fistula (0.3%). One respondent sustained permanent damage to the mitral valve, and another experienced a life-threatening event.

Afib Episodes after Procedure(s)

Questions about the occurrence of afib episodes after each procedure were not included in the 2008 survey, so the results from the 2006 survey are repeated below.

TABLE 10

	# in Group	Complete Success, %	Partial Success, %	Failure, %
Continuing afib episodes				
None	156	69	33	8
Less than 1 month	83	12	27	21
One month	21	7	3	3
Two months	30	6	7	7
Three months	21	3	3	5
More than 3 months	155	2	27	56
Total	466	100	100	100

Complete success was associated with only an 11% incidence of continuing afib episodes after the first, often unstable month. Failure, on the other hand, was associated with a 68% incidence of continuing episodes after the first month. This difference was extremely significant ($p < 0.0001$). It is also evident that experiencing episodes beyond 3 months post-procedure is a strong indicator of ultimate failure. While only 2% of successfully ablated afibbers experienced episodes beyond 3 months, 56% of those ultimately unsuccessful did. These findings support the observation made by Italian researchers that patients who continue to have episodes beyond the first month post-procedure only have a 10% probability of eventual cure[1].

Recovery Time

A question about recovery time was not included in the 2008 ablation/maze survey, so the results from the 2006 survey are repeated below.

TABLE 11

	# in Group	Complete Success,%	Partial Success,%	Failure,%	Average,%
Time to full recovery					
Less than 1 month	96	28	29	33	31
1-2 months	84	26	25	28	27
2-3 months	54	24	8	14	17
More than 3 months	75	21	38	25	24
Total	309	100	100	100	100

About 58% of all ablatees recovered fully in less than 2 months, but 24% took longer than 3 months to return to their pre-ablation level of stamina.

Patient Outcome

Four hundred and sixty-one patients had undergone only RF ablation procedures in order to cure their AF, knew the outcome of their final procedure, and had gone at least 6 months since that last procedure. The average (median) observation period after the most recent ablation was 18 months with a range of 6 months to 11 years.

Two hundred and fifty-six of the 461 respondents (56%) were no longer experiencing afib episodes and were no longer taking antiarrhythmic drugs (compete success). Ten percent were also afib-free, but only with the help of antiarrhythmics (partial success), while the remaining 156 (34%) were still experiencing episodes with or without the use of antiarrhythmics. Thus, the overall outcome after an average 1.5 procedures per patient was as follows:

	Objective Judgment	Subjective Judgment
Complete success	56%	64%
Partial success	10%	20%
Failure	34%	16%
TOTAL	100%	100%

The subjectively judged success rate is clearly higher than actually warranted by the actual outcome. It is likely that some afibbers considered their procedure a success even though they still experienced episodes, but generally of lesser frequency and/or shorter duration. Many also were less sensitive to former triggers adding to the feeling of success.

In interpreting the objective judgment numbers, it should be kept in mind that they are applicable to the 11-year period 1998-2008. If only the latest period 2007-2008 is considered, then the percentages become:

	Objective Judgment
Complete success	66%
Partial success	8%
Failure	26%
TOTAL	100%

Trigger Avoidance

While 79% of successful ablatees no longer needed to avoid previous triggers, only 23% of those having undergone an unsuccessful procedure were so lucky. Nevertheless, it would seem that any ablation, whether successful or not, does help to reduce trigger sensitivity.

TABLE 12

	# in Group	Complete Success,%	Partial Success,%	Failure,%	Average,%
Trigger avoidance					
No longer necessary	264	79	51	23	57
Still necessary	85	5	16	42	18
Much less sensitive	72	10	18	24	16
Uncertain	39	6	14	11	8
Total	460	100	100	100	100

Changes in Heart Rate

The 2008 ablation/maze survey did not enquire about post-procedural changes in heart rate. However, the 2007 survey did and produced the following results. Changes in resting heart rate after RF ablation were quite common among paroxysmal and persistent afibbers.

TABLE 13

	# in Group	Complete Success,%	Partial Success,%	Failure,%	Average,%
Heart rate change					
Increase	137	67	56	41	57
No change	67	23	36	33	28
Decrease	36	10	8	26	15
Total	240	100	100	100	100

The most frequent post-procedural change was an increase in heart rate (experienced by 57%). This increase was most common among afibbers who had undergone successful procedure(s) (67%) and least common among those whose procedures had failed to cure the afib (41%). This difference was statistically significant (p=0.04). A decrease in heart rate was fairly rare among successfully ablated afibbers (10%), but more common (26%) among those whose procedure had failed.

The reason for the increase in heart rate after an ablation is that a significant portion of vagal nerve endings is damaged during the RF ablation procedure. Because the vagal nerves imbedded in the myocardium serve as "speed controllers" counteracting the adrenergic influence, a reduction in the number of effective vagal nerves would be expected to lead to an increased heart rate. Thus, it is possible that a more "aggressive" ablation, as indicated by a higher heart rate after the procedure, is more likely to be successful. However, this is speculation on my part and obviously assumes that the "aggression" is directed at the right spots on the atrium walls and pulmonary vein ostia.

It is generally assumed that the increase is temporary, however, this may not always be the case. A mini-survey (2006 survey) of 25 afibbers who had experienced a significant increase (average of 20 bpm) in post-procedure resting heart rate revealed that for 13 out of 25 respondents (52%) the heart rate was still significantly elevated a year or more after the last procedure. From personal experience I know that a substantial increase in heart rate (to 90 bpm or higher) can be very uncomfortable, so it is to be hoped that afib researchers will eventually address this problem.

Post-Procedural Arrhythmias

One hundred and forty-seven afibbers provided data as to whether they had experienced episodes of ectopics (PACs and PVCs), supraventricular tachycardia (SVT) including inappropriate sinus tachycardia, or flutter beyond 6 months following their final left atrium ablation procedure for the purpose of curing afib. When completing the survey they had five choices in answering the questions:

1. Do you still experience ectopics?
2. Do you still experience tachycardia?
3. Do you still experience flutter?

The five possible answers were:

- Yes
- No
- No, but did experience episodes for **some time** following the procedure
- No, **never** did experience episodes after the procedure
- Not sure

The answers were evaluated against the following two variables:

- Success of left atrium ablation procedure
- Previous or concomitant right atrial flutter ablation

The results are presented in Tables 14 to 16.

TABLE 14

Post-Procedure Ectopics

	# in group	Never,%	No, %	Sometimes,%	Yes,%	Not sure,%
Outcome of ablation(1)						
Complete success	103	2	29	8	50	12
Failure	34	0	21	0	71	9
Right flutter ablations						
No previous flutter ablation	73	3	22	7	59	10
Right flutter ablation(2)	74	4	24	7	50	15

(1) Outcome of final RF ablation in the left atrium
(2) Right atrial flutter ablation as part of left atrium ablation, or separate procedure preceding final left atrium ablation

It is clear that continuing to experience episodes of ectopic beats (PACs and PVCs) even 6 months following a left atrium ablation procedure is very common with 50% of ablatees having undergone a successful procedure, and 71% of those whose procedure had failed experiencing ectopics. This difference is statistically significant and shows that an increase in ectopic episodes goes hand in hand with a failed procedure. It is also clear that even a successful ablation does not solve the problem of ectopics, but merely prevents them from precipitating afib. The idea has been advanced that the ectopic beats originate in the pulmonary veins, but cannot initiate afib, because the electrical impulse generated by them is unable to cross the barrier (lesions) isolating the veins from the left atrium. I posed this possibility to Prof. Pierre Jais and his reply was, "*In my opinion, you cannot feel ectopics from the isolated veins. There is no atrial contraction associated with the isolated beat*". It is thus likely that the source of the ectopics is the atrium wall itself and that an additional ablation may be required in order to deal with them. However, I should point out that many afibbers have found that supplementation with magnesium/potassium/taurine significantly reduces ectopics.

There was no indication that having a right atrial flutter ablation prior to or during the left atrium ablation reduced the incidence of ectopics.

TABLE 15

Post-Procedure Tachycardia

	# in group	Never,%	No,%	Sometimes,%	Yes, %	Not sure,%
Outcome of ablation(1)						
Complete success	103	7	70	10	12	2
Failure	34	6	41	3	44	6
Right flutter ablations						
No previous flutter ablation	73	4	66	7	19	4
Right flutter ablation(2)	74	9	59	9	22	0

(1) Outcome of final RF ablation in the left atrium
(2) Right atrial flutter ablation as part of left atrium ablation, or separate procedure preceding final left atrium ablation

Tachycardia is a less common post-procedural complication than ectopics and unless actually diagnosed may be mistaken for flutter or vice versa. Again, it is clear that a failed left atrium ablation is associated with a substantially higher risk of experiencing post-procedural tachycardia than if the procedure is successful (44% vs. 12%). Having undergone a right atrial flutter ablation as part of or prior to the left atrium ablation did not affect the incidence of post-procedure tachycardia.

TABLE 16

		Post-Procedure Flutter				
	# in group	Never,%	No, %	Sometimes,%	Yes, %	Not sure,%
Outcome of ablation(1)						
Complete success	103	11	72	5	7	6
Failure	34	0	32	3	41	24
Right flutter ablations						
No previous flutter ablation	73	7	62	5	14	12
Right flutter ablation(2)	74	9	62	5	15	8

(1) Outcome of final RF ablation in the left atrium
(2) Right atrial flutter ablation as part of left atrium ablation, or separate procedure preceding final left atrium ablation

The incidence of post-procedure flutter is substantially higher in the case of a failed left atrium ablation than in the case of a successful one (41% vs. 7%). Unfortunately, I have no data to enable me to determine whether the flutter originated in the left or right atrium. However, the finding that having undergone a right atrial flutter ablation made no difference to the incidence of post-procedural flutter may indicate that most of the post-procedure flutter was left atrial flutter.

Other RF Ablation Procedures

Ablation for Supraventricular Tachycardia

Eight afibbers had undergone an ablation for supraventricular tachycardia (SVT), 4 as their first procedure and 4 following a left atrium ablation procedure. All but one (performed after a left atrium AF ablation) were successful.

Left Atrial Flutter Ablation

Five respondents had received a diagnosis of left atrial flutter as being the likely cause of their afib and underwent an ablation for this condition as their first procedure. Four of the respondents knew the outcome of the procedure and had gone at least 6 months since the procedure. One of the procedures was partially successful (no afib, but still on antiarrhythmics), but the other 3 were not. Two of the three went on to have PVIs, both of which successfully eliminated their afib.

It is estimated that about 10% of afibbers undergoing a PVI develop left atrial flutter or tachycardia following the procedure. If the flutter or tachycardia develops within the first week following the procedure, it is usually transient and requires no treatment. However, it may develop as much as 2-3 months post-procedure and, in this case, treatment is usually required. Treatment may involve re-isolation of the pulmonary veins or the placement of linear ablation lesions to interrupt the flutter circuit.

Ten respondents underwent a left atrial flutter ablation subsequent to a PVI. There is insufficient data to determine the success of these ablations as far as elimination of the flutter is concerned.

Right Atrial Flutter Ablation

Seventy-three respondents had undergone a right atrial flutter ablation either as an initial procedure (50 respondents) or as a follow-up after a PVI, mini-maze or unsuccessful right atrial flutter ablation (23 respondents). In addition, 254 left atrium ablation procedures included a routine right atrial flutter

ablation, while 379 did not. The need for a subsequent right atrial flutter ablation was 0.8% in the group having undergone the routine flutter ablation versus 1.8% in the group that did not. This difference was not statistically significant.

Forty-seven of the 50 respondents who underwent a right atrial flutter ablation as their first procedure reported the outcome at least 6 months after their procedure. Five of the procedures were completely successful in eliminating the afib (11%) and 4 (9%) were partially successful (still on antiarrhythmics). Thus, in 80% of cases an initial right atrial flutter ablation failed to eliminate the underlying AF (with or without antiarrhythmics). Somewhat surprisingly, 11% of afibbers underwent a second, and even a third, right atrial flutter ablation in further attempts to cure their afib.

In this regard, it should be mentioned that only 2 of the original 50 initial procedures were carried out at top-ranked RF ablation institutions and both were followed by standard PVI ablations. All told, 56% of initial right atrial flutter ablations were followed by standard RF pulmonary vein ablations.

Atrial flutter and AF are similar in that they both involve abnormal, sustained, rapid contractions of the heart's upper chambers (atria). In atrial flutter the atria contract 220 to 350 times a minute in an orderly rhythm. In AF the rate of contraction may be as high as 500 beats/minute and the rhythm is totally chaotic. The two arrhythmias can both occur as a result of an enlarged atrium or in the aftermath of open-heart surgery, but the mechanism underlying them is quite different. Nevertheless, they can coexist in the same patient and one may convert to the other.

Because the location of the origin of atrial flutter, at least in the common type, is so well known and consistent from patient to patient radio frequency catheter ablation can be used with considerable success to permanently eradicate atrial flutter. Unfortunately, this procedure is unlikely to cure AF, which may often coexist with atrial flutter. There is also some evidence that atrial flutter patients who have a successful ablation increase their risk of later developing AF by 10-22%. So undergoing RF ablation for atrial flutter may not remove the necessity of dealing with AF.

Because of the close connection between AF and atrial flutter, it was quite common, in the early days of ablation, to perform an atrial flutter ablation in the hope that it would cure the AF. The atrial flutter ablation involves only the right atrium so there is no need to pierce the septum to the left atrium as is done in a PVI.

After the 1998 discovery that 80-90% of paroxysmal episodes originate in the left atrium near the pulmonary veins, the use of the right atrial flutter ablation in an attempt to cure AF became less common, but the procedure is still used as a first attempt in patients with a combination of AF and flutter. It is, of course, also used in patients suffering from right atrial flutter only.

Quality of Life

Although the main concern of the medical profession when it comes to lone atrial fibrillation is stroke risk, the overwhelming concern of the patient is quality of life. As all afibbers know, being in permanent afib or awaiting the next episode in a state of anxiety has a devastating effect on ones quality of life and radically changes the life of those nearest and dearest to us.

Considering quality of life improvement rather than strictly success or failure of RF ablation procedures, it becomes clear that even a failed ablation may improve life quality. The average complete success rate found in this survey (after an average 1.5 procedures) is 56%. Adding to this partial success (where afib is kept at bay with antiarrhythmics) brings the percentage of afibbers whose lives have been improved through RF ablation to 66%. Further considering that, according to the 2007 ablation/maze survey, about 70% of ablatees whose procedure failed still reduced their afib burden by at least 50%

brings one to the conclusion that RF ablation, whether successful or not, is likely to improve quality of life in close to 90% of those undergoing the procedure. A significant portion of the remaining 10% may however, see a worsening of their condition or may experience a serious adverse event.

Performance Rating

Previous ablation/maze surveys have all arrived at the conclusion that the most important factor in determining the outcome of a RF ablation is the skill and experience of the EP performing it. In order to provide some guidance in regard to the likelihood of undergoing a successful left atrium AF ablation at a particular institution, I have developed a Performance Rating scheme. This rating takes into account the success rates reported by afibbers treated at specific institutions and by specific EPs. The rating is calculated using the following rating scores:

Success Score

- Completely successful left atrium ablation score = 10
- Partially successful left atrium ablation score = 5
- Failed ablation (continuing afib episodes) score = 0

Please note that in this evaluation of 729 single RF left atrium afib ablation procedures, a procedure is not considered a failure unless followed by another RF left atrium afib ablation or continued afib episodes. The subsequent occurrence of left or right atrial flutter or tachycardia is treated here as an adverse event and not as an ablation failure.

It is clear that a performance rating is not very indicative in cases where just one or two procedures have been performed. Thus, performance ratings have only been established for institutions that had reports on 6 or more procedures. The results from 28 institutions with 6 or more procedures are presented in the table below.

TABLE 17

Rank	No. of Procedures	Rating	Institution
1	7	7.1	Cleveland Clinic, Weston, FL
2	83	6.4	Cleveland Clinic, OH
3	55	5.9	California Pacific Medical Center, San Francisco *
4	14	5.7	Mayo Clinic, Rochester, MN
5	8	5.0	Freeman Hospital, Newcastle, UK
6	11	5.0	Medical University of South Carolina (MUSC)
7	20	5.0	University of Pennsylvania
8	6	5.0	Johns Hopkins University Hospital
9	73	4.7	Hopital Cardiologique du Haut Leveque, Bordeaux, FR
10	7	4.3	Loyola Medical Center, Maywood, IL
11	14	4.3	Good Samaritan Hospital, Los Angeles
12	6	4.2	Aurora/Sinai Medical Center, Milwaukee, WI
13	11	3.6	Sequoia Hospital, Redwood City, CA
14	13	3.5	University of Michigan
15	14	3.2	NYU Medical Center, NY
16	11	2.7	Centinela Hospital, Inglewood, CA
17	22	2.3	Royal Jubilee Hospital, Victoria, BC
18	10	2.0	University of California at San Diego
19	11	1.8	St. Paul's Hospital, Vancouver, BC
20	9	1.7	University of Alabama, Birmingham
21	12	1.7	St. Bartholomew's, London, UK
22	7	1.4	Hollywood Hospital, Perth, Australia
23	7	1.4	Northwestern Memorial Hospital, Chicago, IL
24	7	1.4	Southampton Hospital, UK
25	9	1.1	Massachusetts General Hospital, Boston
26	6	0.8	Scottsdale Healthcare, Osborn, AZ
27	13	0.8	Brigham and Women's Hospital, Boston, MA
28	14	0.4	Texas Heart Institute, Houston

* Includes procedures carried out by Drs. Natale and Hao at Marin General Hospital

The first 15 institutions (performance rating of 3.0 or higher) in the above table account for close to 50% of all left atrium RF ablation procedures performed; their performance is evaluated in detail in Table 18 (ranked by complete success rate).

TABLE 18

Single Procedure Success – Top-Ranked Institutions

Rank	Institution	# of Procedures	Rating	Success Rate, % Complete	Partial	Failure
1	Cleveland Clinic, OH	83	6.4	61	6	33
2	Cleveland Clinic, FL	7	7.1	57	29	14
3	California Pacific(1)	55	5.9	56	5	38
4	Mayo Clinic, MN	14	5.7	50	14	36
5	Freeman Hospital	8	5.0	50	0	50
6	Bordeaux	73	4.7	47	1	52
7	MUSC	11	5.0	45	9	45
8	U of Pennsylvania	20	5.0	45	10	45
9	Good Samaritan	14	4.3	43	0	57
10	Loyola	7	4.3	43	0	57
11	Sequoia	11	3.6	36	0	64
12	Johns Hopkins	6	5.0	33	33	33
13	Aurora/Sinai	6	4.2	33	17	50
14	U of Michigan	13	3.5	31	8	62
15	NYU	14	3.2	29	7	64
Grand Total – Top-ranked		342	5.3	50	6	44
Other Institutions		387	2.4	21	5	74
All Institutions		729	3.7	34	6	60

(1) Includes procedures carried out by Drs. Natale and Hao at Marin General

The electrophysiologists performing the procedures in the above 15 institutions are as follows:

Institution	Electrophysiologists
Cleveland Clinic, OH	Drs. Andrea Natale*, Robert Schweikert**, Walid Saliba, Patrick Tchou, Oussama Wazni
Cleveland Clinic, FL	Dr. Sergio Pinski
California Pacific	Drs. Andrea Natale, Steven Hao
Mayo Clinic, Rochester, MN	Drs. Douglas Packer, Thomas Munger, Paul Friedman, Peter Brady
Freeman, Newcastle, UK	Dr. Stephen Furniss***
Bordeaux, France	Drs. Michel Haissaguerre, Pierre Jais
MUSC	Dr. Marcus Wharton
University of Pennsylvania	Drs. David Callans, Frank Marchlinski, David Lin
Good Samaritan, Los Angeles	Drs. Anil Bhandari, Neala Hunter, David Cannom, Mark Girski
Loyola Medical, Maywood, IL	Drs. David Wilber, Albert Lin
Sequoia, Redwood City, CA	Drs. Rob Patrawala, Roger Winkle
Johns Hopkins	Drs. Hugh Calkins, Ronald Berger
Aurora/Sinai, Milwaukee, WI	Dr. Jasbir Sra
University of Michigan	Drs. Fred Morady, Hakan Oral, Frank Pelosi, Eric Good
NYU Medical Center	Dr. Larry Chinitz

NOTE: 90% of the procedures performed at the Cleveland Clinic, OH were done by Dr. Natale or Dr. Schweikert

* Now at St. David's Medical Center, Austin, TX and California Pacific Medical Center, San Francisco
** Now at Akron General Medical Center, OH
*** Now at Eastbourne General Hospital, East Sussex, UK

The average performance rating for the top-ranked institutions is 5.3 as compared to 2.4 for the remaining institutions (387 single procedures). In evaluating the results for the top-ranked institutions

it should be kept in mind that some may have a greater load of "difficult cases" than do others. Table 19 shows the relative proportion of paroxysmal, persistent, and permanent afibbers treated at the top-ranked institutions.

The statistics presented in Table18 are indeed sobering. Undergoing a single RF ablation procedure of the left atrium at an institution not included in the top 15 is associated with an average complete success rate of 21%, a partial success rate of 5%, and a failure rate of 74%.

Despite this overall bleak picture for "other" institutions, there would appear to be some good performers in this group, bearing in mind that the number of procedures upon which this conclusion is based is extremely limited.

Electrophysiologist	# of Procedures	Complete Success
Dr. Jonathan Steinberg [1]	5	80%
Dr. Chun Hwang [2]	4	50%
Dr. Yaariv Khaykin [3]	3	100%
Dr. David Fitzgerald [4]	3	67%

[1] St. Luke's Hospital, NYC
[2] Utah Valley Hospital, Provo, UT
[3] Southlake Hospital, Newmarket, ON, Canada
[4] Wake Forest University Medical Center, Winston-Salem, NC

TABLE 19

Types of afib treated – Top-ranked institutions

	# of Procedures	Paroxysmal,%	Persistent,%	Permanent,%
Cleveland Clinic, OH	83	69	7	24
Cleveland Clinic, FL	7	100	0	0
California Pacific *	55	63	2	35
Mayo Clinic, MN	14	100	0	0
Freeman Hospital	8	100	0	0
Bordeaux	73	70	15	15
MUSC	11	100	0	0
U of Pennsylvania	20	85	10	5
Good Samaritan	14	54	23	23
Loyola	7	86	0	14
Sequoia	11	64	18	18
Johns Hopkins	6	100	0	0
Aurora/Sinai	6	67	0	33
U of Michigan	13	85	8	8
NYU	14	100	0	0
Grand Total – Top-ranked	342	74	8	18
Other Institutions	387	80	9	11
All Institutions	729	77	9	14

* Includes procedures carried out by Drs. Natale and Hao at Marin General

It is clear that a significant percentage of procedures performed at the Cleveland Clinic in Ohio (31%), Hopital Cardiologique du Haut Leveque in Bordeaux (30%), California Pacific Medical Center in San Francisco (37%), Good Samaritan Hospital in Los Angeles (46%), and Sequoia Hospital in Redwood City, CA (36%) involved patients with permanent or persistent afib. In contrast, the cases treated at Freeman Hospital in Newcastle, UK, the Cleveland Clinic in Weston, FL, Medical University of South

Carolina, NYU Medical Center, Johns Hopkins, and the Mayo Clinic in Rochester did not include any permanent or persistent afibbers.

Final Outcome

The ultimate measure of success for the individual patient is, of course, whether or not they are cured of afib irrespective of how many procedures it takes. In other words, the crucial question to an afibber seeking a solution is, "If I go to institution X what are my chances of getting cured?"

This part of the evaluation includes 461 individual patients whose last reported procedures were RF ablations in the left atrium for the purpose of curing AF. All patients reported their afib status 6 months following their last procedure. The patients underwent a total of 729 procedures at 168 different institutions. A substantial number of the 200 repeat ablations were performed at institutions other than the ones doing the original procedure, so as far as this evaluation is concerned, a total of 531 patients were treated. Results of the evaluation are presented in Table 20.

TABLE 20

Final Performance Rating – Top-Ranked Institutions

Rank	Institution	# of Procedures	# of Patients	Repeat Rate, %	Success Rate, % Complete	Partial	Failure
1	Cleveland Clinic, OH	83	72	15	72	7	21
2	Bordeaux	73	47	55	72	2	26
3	California Pacific	55	46	20	67	7	26
4	Cleveland Clinic, FL	7	6	17	67	33	0
5	Freeman Hospital	8	6	33	67	0	33
6	Mayo Clinic, MN	14	11	27	64	18	18
7	MUSC	11	8	38	63	13	25
8	Good Samaritan	14	10	40	60	0	40
9	U of Pennsylvania	20	16	25	56	13	31
10	Loyola	7	6	17	50	0	50
11	Sequoia	11	8	38	50	0	50
12	Aurora/Sinai	6	4	50	50	25	25
13	Johns Hopkins	6	5	20	40	40	20
14	U of Michigan	13	9	44	44	11	44
15	NYU	14	8	63	38	13	50
Grand Total – Top-ranked		342	262	30	65	8	27
Other Institutions		387	269	44	32	7	61
All Institutions		729	531	37	48	8	44

NOTES:
Ranking is by highest % of patients achieving complete elimination of afib without use of antiarrhythmics.
Repeat rate is calculated as # of repeat ablations divided by # of initial procedures performed at the institutions.
First repeat procedure on patients who came to the institution from another one is not counted as a repeat.

The average complete success rate for the 15 top-ranked institutions is 65% with a failure rate of 27%. This compares to a complete success rate of 32%, and a failure rate of 61% at other than top-ranked institutions. The average repeat rate is 30% at top-ranked institutions versus 44% at other institutions.

In evaluating the results of the final performance rating it should be kept in mind that they, in order to optimize the statistical power of the survey, reflect the 11-year period 1998-2008. Techniques and outcomes have improved markedly from the period 1998-2004 to the period 2007-2008. For example, the final success rate for the three top-rated RF ablation centers (Cleveland Clinic (Ohio), Hopital

Cardiologique du Haut Leveque (Bordeaux), and California Pacific Medical center (San Francisco)) has increased almost 10% to average 82% for the period 2007-2008. A very encouraging trend indeed!

The repeat rate of 55% at Hopital Cardiologique Haut Leveque in Bordeaux is particularly high. This is likely due to the fact that most patients treated in Bordeaux have traveled long distances to get there and probably do not fancy repeating the trip. Thus, the Bordeaux team, at least until recently, used to perform a touch-up procedure as soon as one week following the initial procedure if the patient showed any signs at all that the ablation had not been successful. Over half of the repeat procedures done in Bordeaux were performed within the first month following the initial procedure. Since the first 3 months following an ablation is usually considered a blanking period where irregular heart activity is common without necessarily predicting ultimate failure, it is likely that some of the repeat procedures may not have been necessary, but were done anyway in order to ensure, as far as possible, that the patient returned home cured.

Comparison with Other Surveys

At least 6 surveys of PVI procedure success rates have now been published. The most recent one done by J.D. Fisher and colleagues at the Montefiore Medical Center in New York compiled the results of ablations performed in major centers around the world and reported in 200 peer-reviewed medical articles and covered a total of 23,000 AF patients.[2] Another large study, the Cappato Study, published in 2005 involved 8745 patients treated at 90 different institutions world-wide.[3] The outcome experience at the Cleveland Clinic, Ohio was presented for 323 patients who underwent a PVI for drug-resistant AF.[4] The University of Michigan experience (755 patients) was presented in a 2006 paper by *Oral, et al*[5], while Johns Hopkins Hospital outlined their PVI outcomes for 200 PVI procedures in a 2006 study authored by *Cheema, et al*.[6] Finally, also in 2006, a group of Danish electrophysiologists outlined their results of a study involving 100 patients who underwent a PVI using either the Haissaguerre or Pappone method.[7]

A comparison of the results from these surveys and the 2008 ablation/maze survey is presented in Tables 21 and 22. Table 21 summarizes the results of initial procedures, while Table 22 summarizes final outcome, that is, outcome after repeat ablations as required.

TABLE 21

		Outcome after initial procedure				
		No. of	Initial Success Rate, %			Observ.
Survey	Institution	Procedures	Complete	Partial	Failure	period, mos.
TOP-RANKED INSTITUTIONS						
Bhargava[3]	Cleveland Clinic, OH	323	71	0	29	6
Afibbers.org	Cleveland Clinic, OH	72	63	7	31	6
Afibbers.org	15 top-ranked	342	50	6	44	6
OTHER INSTITUTIONS						
Nilsson[6]	Copenhagen Univ.	100	17	0	83	3
Afibbers.org	Other	387	21	5	74	6

There are, unfortunately, only two studies, other than the afibbers.org survey (2008 ablation/maze survey), that have provided data for initial procedure outcome. Complete success after one ablation varies from 17% to 71% with the afibbers.org survey finding a rate of 50% for top-ranked institutions and 21% for other institutions.

TABLE 22

Survey	Institutions	Outcome after final procedure # of Patients	Final Success Rate, % Complete	Partial	Failure	Repeat Rate, %	Observ. period,mos.
TOP-RANKED INSTITUTIONS							
Bhargava[4]	Cleveland Clinic, OH	323	83	0	17	12	12
Afibbers.org	Cleveland Clinic, OH	72	72	7	21	15	6
Oral[5]	Univ. Michigan	755	73	?	?	?	12
Cappato[3]	Top-ranked (world)	3244	64	16	20	27	12
Fisher[2]	Major (world)	23000	63	12	25	25	6
Afibbers.org	15 top-ranked	262	65	8	27	30	6
OTHER INSTITUTIONS							
Cheema[6]	Johns Hopkins	200	41	11	48	32	12
Nilsson[7]	Copenhagen Univ.	100	44	?	?	74	12
Afibbers.org	Other	269	32	7	61	61	6

The final outcome results are somewhat better documented with a recent world-wide survey of major institutions involving 23,000 patients finding an average complete success rate of 63%, a partial success rate of 12%, a failure rate of 25%, and a repeat rate of 25%. This compares well with our results for top-ranked institutions of a 65% complete success rate, an 8% partial success rate, a 27% failure rate, and a 30% repeat rate.

Summary

- The 2008 ablation/maze survey included 611 respondents who had undergone a total of 952 RF ablation procedures. The outcome of 729 of these procedures was known (status reported at least 6 months following the procedure).

- The overall objectively-rated complete success rate (no afib, no drugs) for 461 afibbers after an average of 1.5 procedures per patient was 56%, partial success was achieved in 10% of cases, and 34% of all afibbers who underwent one or more RF ablations continued to experience AF episodes.

- The subjective judgment of success by ablatees was somewhat more favourable with 64% feeling that the end result was total success, 20% claiming partial success, and 16% judging their procedures as a failure.

- The objectively rated complete success rate for a single RF ablation procedure was 34%, that of partial success 5%, and that of failure 61% when averaged over the years 1998-2008. For the more recent period 2007-2008, the complete success rate for a single RF ablation procedure averaged 48%. This remarkable improvement in single procedure success is reflected in an overall average increase in final (complete) success rate from 47% in the period 1998-2004 to 66% in the period 2007-2008.

- Forty-one percent of 358 RF ablation procedures were accompanied by an adverse event, the most common (17%) being temporary hematoma in the thigh area. Left atrial tachycardia was also a fairly common adverse effect (12%), but resolved by itself in about 50% of cases. Stroke and TIA were rare at 0.6% and 0.8% respectively. About two-thirds of all adverse events were fully resolved at the time the survey was completed. Successful ablations were much less likely to be accompanied by an adverse event than were unsuccessful ones. NOTE: This data is from the 2006 ablation/maze survey.

- There were no significant differences in success and adverse event rates between a first and subsequent RF ablations, perhaps indicating that the technical difficulty in performing them is pretty much the same.

- The majority (79%) of respondents experienced AF episodes at least weekly prior to their ablation. [From 2007 survey]

- There was no evidence that age at diagnosis and ablation, gender, years of afib, or type of paroxysmal afib affected the outcome to a significant degree. However, more frequent episodes were associated with a lower success rate. [From 2007 survey]

- The most successful procedure for the period 2005-2008 was the pulmonary vein antrum isolation procedure (Natale method) with a single procedure complete success rate of 62% (paroxysmal, persistent and permanent combined). The segmental PVI (Haissaguerre method) was the second-most successful procedure with an average complete success rate of 42%.

- A significant majority (69%) of afibbers who had a completely successful ablation experienced no AF episodes at all after the procedure. Only 8% of those "doomed to failure" experienced no episodes at all after their procedure. Only 2% of completely successful ablatees experienced episodes for more than 3 months after the procedure, while 56% of unsuccessful ablatees did so. Thus, if AF episodes continue beyond 3 months the procedure is almost certainly a failure. On the other hand, if no AF episodes occur during the first month then the procedure is likely to be a success. [From 2007 survey]

- Almost 60% of ablatees recovered fully in less than 2 months, but 24% took longer than 3 months to return to their pre-ablation level of stamina. NOTE: This data is from the 2006 ablation/maze survey.

- Most (96%) of afibbers who had a completely successful ablation did not continue with warfarin, but 13% of them continued to use natural stroke prevention remedies such as fish oil, nattokinase, vitamin E and ginkgo biloba. Seventeen percent took a daily aspirin for stroke prevention. In contrast, 36% of ablatees with a failed procedure continued on warfarin. [From 2007 survey]

- While 79% of successful ablatees no longer needed to avoid previous triggers, only 23% of those having undergone an unsuccessful ablation were so lucky. Nevertheless, it would seem that any ablation, whether successful or not, does help to reduce trigger sensitivity.

- The incidence of post-procedure ectopics (PACs and PVCs) even 6 months or more following the procedure was high at 50% for completely successful ablations and 71% for failed procedures, a difference that is statistically significant. There was no indication that having undergone a right atrial flutter ablation prior to or during the left atrium ablation reduced the incidence of ectopics.

- The incidence of post-procedure tachycardia (SVT and inappropriate sinus tachycardia) was 12% for completely successful and 44% for failed ablations. Having undergone a right atrial flutter ablation as part of or prior to the left atrium ablation did not affect the incidence of post-procedure tachycardia.

- The incidence of post-procedure flutter was 7% for a completely successful ablation and 41% for an unsuccessful one. Having undergone a prior right atrial flutter ablation made no difference to the post-procedure incidence of flutter perhaps indicating that most of the post-procedure flutter was left atrial flutter.

- Even an unsuccessful ablation resulted in a significant reduction in episode frequency in 74% of cases and in 75% of cases was associated with a significant decrease in episode duration. Overall, 70% of unsuccessfully ablated patients experienced a 50% or better decrease in their afib burden. [From 2007 survey]

- Considering a 50% or greater reduction in afib burden (frequency x duration) as an indicator of improvement, it is estimated that close to 90% of RF ablations were ultimately successful in improving quality of life. [From 2007 survey]

- A post-ablation increase in heart rate was a common occurrence. This phenomenon was more prevalent among successful ablatees (67%) than among those whose ablation had failed (41%). This may indicate that a more aggressive approach (increased destruction of vagal nerve endings) is associated with a better outcome. [From 2007 survey]

Conclusion

I have made every effort to ensure that the calculations and conclusions made in this survey are correct. I have observed good internal consistency in the data and am comforted by the fact that the success rates found in this 2008 LAF Ablation/Maze Survey agree reasonably well with those found in published studies. The LAF survey is based on a total of 729 procedures performed on 461 individual patients, not an overly large number, but enough to draw reasonably valid conclusions in general terms. Where the survey results become less "solid" are in the evaluation of the success rates of individual electrophysiologists and institutions. The ratings of the Cleveland Clinic and the Hopital Cardiologique, Bordeaux are probably reasonably indicative since they involve a reasonably large number of patients, but ratings based on just 5 or 6 patients are clearly much less reliable, and it is quite possible that larger samples would produce different results.

Nevertheless, there is still a considerable gap in outcomes between top-ranked institutions and other centers. By far the best chance of success can be had at the top-ranked institutions, particularly one of the top three. That said, it is also clear that most, probably as many as 90%, of RF ablations result in a significant improvement in quality of life whether they are completely successful or not. This also means that 10% of all afibbers embarking on the ablation path can expect no improvement and in a significant proportion, a worsening of afib or a major adverse event.

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