THE AFIB REPORT

Your Premier Information Resource for Lone Atrial Fibrillation!

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I know this issue is late in arriving and I apologize. The analysis of the 2006 ablation/maze survey proved to be a daunting task due to the volume and complexity of the data I was dealing with. However, it has been worth the struggle and I am pleased to now 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 yourself 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 main alternatives for eliminating afib.

*This first part of the survey covers radiofrequency ablation procedures only. Part 2, to be published in the February 2007 issue, will cover the maze and mini-maze procedures, cryoablation, and other less common procedures. With 335 respondents and nearly 500 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 covers procedures performed at over 80 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.*

This part covers RF ablations performed in 76 institutions and involves 277 afibbers who underwent a combined total of 408 procedures. The results are certainly more promising than those reported in the 2005 survey. Ultimate complete success rates now average 72% for the 10 top-ranked institutions and 80% for the top 3 (Bordeaux, Cleveland Clinic and Marin General Hospital). The average complete success rate for other institutions, unfortunately, remains low at 37% with a failure rate of 48%. The rate of adverse events is still high at 41%, but fortunately, 70% of these events resolve on their own within the first month post-procedure. The survey clearly shows that afib episodes continuing beyond the first month after the procedure is a strong indicator of ultimate failure, while a significantly increased heart rate post-procedure may be indicative of likely success. It appears that even a failed ablation is likely to reduce the number of episodes and their duration, but some unlucky afibbers may experience a worsening of their condition or even a life-altering adverse event.

In conclusion, when other measures have failed, as they did for me, an RF ablation performed at one of the 10 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 your family a Happy Holiday Season and lots of NSR in the coming New Year,

Hans

2006 Ablation/Maze Survey

2006 Ablation/Maze Survey – Part 1

The evaluation of the 2006 ablation/maze survey turned out to be a very major undertaking. With 335 afibbers responding to almost 100 questions about their ablation, maze or other procedures close to 35,000 data points had to be extracted, arranged and evaluated. This issue of *The AFIB Report* evaluates the results of radiofrequency ablation. Results of maze, mini-maze and other procedures will be presented in the next issue.

The volume of data is clearly good as far as being able to draw valid conclusions, but less desirable as far as being able to present the data and conclusions in a readable and comprehensible format. I am fairly certain that this survey is the largest ablation survey 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 that performed them. Please note that the survey only relates to symptomatic episodes of atrial fibrillation.

This report has been divided into five major sections: –

- Definition of Terms
- Evaluation of Background Data
- Initial Procedure Results
- Procedure Outcome
- Patient Outcome
- Performance Rating

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 occurring anytime and do not consistently fit the adrenergic or vagal pattern.

Procedures

- **Focal ablation** – The original radiofrequency 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.
- **Cryoablation –** In this procedure a nitrogen-cooled, rather than electrically-heated, catheter is used to create the ablation lesions.
- **Maze procedure** – This procedure involves open-heart surgery. After making a foot long incision and cracking open the ribs, scar tissue is surgically created (by cutting and sewing) on the surface of the heart to make pathways connecting the sinus node and the AV node and to eliminate the possibility of aberrant impulses initiating atrial fibrillation. The patient is usually hooked up to a heart/lung machine during the full maze procedure.
- **Mini-maze procedure –** This procedure is similar to the maze procedure in that scar tissue is created on the outside of the heart rather than on the inside as is done in ablation procedures. Access to the heart is through two or more small incisions between the ribs and it is not necessary to stop the heart during the procedure. Lesions are created via radiofrequency ablation rather than by cutting and sewing.
- **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, cause 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.
- **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

- **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 after the last reported ablation (initial or touch-up). It is defined in two ways:

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

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
- Failure – Afib episodes still occurring
- Uncertain – Cases where insufficient data was available or where less than 6 months had gone by since the procedure.

Evaluation of Background Data

Distribution of Procedures

Three hundred and thirty-five afibbers responded to the survey and provided details of a total of 493 procedures distributed as follows:

TABLE 1

	Number of Procedures				
Procedure	1st	2nd	3rd	Further	Total
Focal ablation	23	11	1	0	35
Pulmonary vein ablation (PVA)	64	24	4	0	92
Segmental pulmonary vein ablation	41	24	7	0	72
Circumferential pulmonary vein ablation	42	13	2	4	61
Pulmonary vein antrum isolation	66	20	3	0	89
RF procedure not specified	41	15	2	1	59
Total RF ablation procedures	277	107	19	5	408
Cryoablation	4	2	0	0	6
Maze procedure	10	1	2	0	13
Mini-maze procedure	18	1	2	1	22
Right atrial flutter	18	5	2	1	26
Left atrial flutter	2	3	2	1	8
AV node ablation + pacemaker	6	2	1	1	10
Total non-AF procedures	58	14	9	4	85
GRAND TOTAL	**335**	**121**	**28**	**9**	**493**

The majority of procedures (83%) were radio frequency (RF) ablation procedures aimed at curing atrial fibrillation. Thirty-seven per cent of the 335 respondents underwent a second procedure, 9% a third procedure, and 3% 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	77%	23%	100%
Average (median) age*	57	57	57
Age range (present)	27-78	26-86	26-86
AF confirmed by diagnosis	95%	97%	95%
Underlying heart disease	11%	8%	10%
Mitral valve prolapse	6%	8%	7%
Mitral valve regurgitation	11%	13%	11%
Median age at diagnosis	47	49	48
Age range (at diagnosis)	5-74	8-79	5-79
Median age at last procedure	56	56	56
Age range (last procedure)	26-85	26-78	26-85

* at time of completing survey

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

Afib Type

A total of 279 respondents had provided detailed information regarding their type of AF (adrenergic, mixed, vagal). The distribution was as follows:

TABLE 3

Type of AF	Male, %	Female, %	Total, %
Adrenergic	8	3	7
Mixed	48	53	49
Vagal	24	31	25
Total paroxysmal or persistent	80	87	81
Permanent	20	13	19
TOTAL	**100**	**100**	**100**

The majority of respondents (81%) had paroxysmal or persistent AF, while 19% were in permanent AF. The proportion of permanent afibbers in this sample would thus seem to be somewhat higher than in our total database (14% among 625 afibbers), while the prevalence of vagal AF is somewhat lower (34% of total database). Mixed (random) AF was the most common type followed by vagal, permanent and adrenergic.

Afib Frequency

Three hundred and twenty-three respondents had provided information about their episode frequency. The distribution was as follows:

TABLE 4

Afib Frequency*	Male, %	Female, %	Total, %
Permanent	19	10	17
Daily	21	26	22
Twice weekly	24	25	24
Weekly	13	10	12
Twice a month	9	13	10
Monthly	6	6	6
Every 2 months	0	1	1
Every 3 months	3	7	4
Every 6 months	2	1	2
Once a year	1	0	0
Less than once a year	2	1	2

* prior to first procedure

The majority of respondents (75%) experienced episodes at least once a week and 39% were in afib every day (including permanent afibbers). Only 9% 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 9.5 hours with a wide range of from a few minutes to 120 hours. There was no statistically significant difference in episode frequency and duration between paroxysmal afibbers taking antiarrhythmics or blockers and those taking no medications on a continuous basis.

Use of Antiarrhythmics and Blockers

The majority of respondents (86%) were taking one or more drugs on a continuous basis to reduce their episode frequency and duration, or ameliorate the effects of their permanent AF. The popularity of the various drugs among the 335 afibbers who had provided information about AF type and drug use is presented below.

TABLE 5

Drug	Adrenergic %	Mixed %	Vagal %	Permanent %	Unknown %	Total %
Beta-blockers	5	13	9	17	14	**13**
Calcium channel blockers	5	4	4	17	5	**7**
Amiodarone	0	9	7	15	20	**11**
Digoxin	0	1	0	2	2	**1**
Disopyramide	5	2	4	2	0	**2**
Dofetilide	0	6	0	4	11	**5**
Flecainide	16	17	23	13	20	**18**
Propafenone	5	15	13	4	11	**11**
Sotalol	32	13	10	9	2	**11**
Combination A	5	2	4	0	0	**2**
Combination B	0	1	0	2	4	**1**
Other (incl. combinations)	11	5	1	6	2	**4**
No drugs	16	12	24	11	11	**14**
TOTAL, %	100	100	100	100	100	100
No. in group	19	136	70	54	56	335

Combination A – antiarrhythmic + beta-blocker
Combination B – antiarrhythmic + calcium channel blocker

Flecainide (Tambocor) was the most prescribed antiarrhythmic and was used on a continuous basis by 18% of respondents. Beta-blockers were the second most popular drugs followed by propafenone, sotalol and amiodarone. About 35% of permanent afibbers were, as would be expected, solely on beta-blockers or calcium channel blockers. However, a rather astounding 49% were on antiarrhythmics, which would not be expected to benefit permanent afibbers. It is encouraging to see the low usage of digoxin (Lanoxin) which should never be used by lone afibbers.

Over 40% of vagal afibbers (paroxysmal or persistent) were on drugs with beta-blocking properties (beta-blockers, propafenone, amiodarone and sotalol) on a continuous basis. These drugs are generally contraindicated for vagally-mediated AF. Flecainide was the most prescribed drug for vagal afibbers followed by propafenone, sotalol, beta-blockers, and amiodarone. Sotalol was the most popular drug for adrenergic afibbers, while flecainide was the most prescribed drug for mixed afibbers. Fourteen percent of all respondents used no drugs to manage their afib.

As would be expected in a group of afibbers awaiting ablation or maze procedure, the drugs were clearly not effective in preventing episodes or in lessening the overall burden of the afib. The following table shows the average values for afib frequency, duration and burden (frequency x duration) for a group of 223 paroxysmal afibbers during the 3-month period preceding their first procedure.

TABLE 6
Episodes 3 months prior to procedure

Drug	# in Group	# of Episodes Mean	# of Episodes Median	Duration of Episodes, hrs. Mean	Duration of Episodes, hrs. Median	Burden, hrs. Mean	Burden, hrs. Median
Beta-blockers	30	35	25	13	9	282	190
Calcium channel block.	12	31	19	16	15	580	156
Amiodarone	20	36	19	16	12	361	180
Dofetilide	11	56	90	20	16	774	540
Flecainide	50	33	25	16	7	364	149
Propafenone	32	31	25	15	8	289	176
Sotalol	29	27	25	18	10	390	150
No drugs	39	35	25	17	10	529	300

NOTES – Episodes per 3 months estimated as follows:
Daily = 90 episodes per 3 months
Twice-weekly = 25 episodes per 3 months
Weekly = 13 episodes per 3 months
Twice-monthly = 6 episodes per 3 months
Monthly = 3 episodes per 3 months
One every 2 months = 1.5 episodes per 3 months
One every 3 months = 1 episode per 3 months
One every 6 months = 0.5 episode per 3 months
One every year = 0.25 episode per 3 months
Burden = # of episodes over 3 months x duration in hours

There was no statistically significant difference in episode burden between using no drugs or using a blocker or antiarrhythmic. Dofetilide (Tikosyn) was significantly less effective in easing overall afib burden than were beta-blockers, amiodarone, flecainide, propafenone and sotalol. In view of the potential serious side effects of dofetilide, its use should probably be restricted.

Thirty-six of 253 paroxysmal afibbers (14%) were using the on-demand (pill-in-the-pocket) approach in an attempt to shorten their episodes. Median episode duration with flecainide was 9 hours (range of 1 – 80 hours), 14 hours with propafenone (range of 2 – 90 hours), and 17 hours with other approaches. This compares to a median episode duration of 9 hours (range of 0.1 – 96 hours) when not using the on-demand approach. Thus, in this group of afibbers, 80% of whom were using antiarrhythmics or blockers on a continuous basis, the use of the on-demand approach did not seem to confer any benefit. It is possible that the main beneficiaries of this approach will be afibbers who are not taking antiarrhythmics on a regular basis.

Initial Procedure Results

Demographics

A total of 277 afibbers underwent a RF ablation for atrial fibrillation as their first procedure. The majority of the 275 respondents who knew their type of afib had the paroxysmal form (78%), 6% had persistent afib, while the remaining 16% were in permanent afib. Among the 179 paroxysmal afibbers who were aware of the initiating circumstances for their episodes, 61% characterized themselves as mixed, 31% were vagal, and 8% were adrenergic.

The median age of respondents at the time they completed the questionnaire was 57 years with a range of 26 to 86 years. The median age at diagnosis was 47 years for men and 50 years for women with a range of 5 to 79

years. The median age at the latest procedure was 55 years for men and 56 years for women with a range of 26 to 85 years. The average (median) number of years between diagnosis and last procedure was 6 years for men and 7 years for women with a range of 0 to 48 years.

Twenty-four percent of respondents were female. Seven percent of respondents had been diagnosed with heart disease, 6% with mitral valve prolapse (MVP), and 11% with minor mitral valve regurgitation.

Respondents with reported heart disease were diagnosed with afib significantly later in life than those without heart disease (54 versus 46 years of age) and underwent their ablation later (60 versus 55 years of age).

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, 247 afibbers who knew their afib type (paroxysmal, persistent, permanent) and the outcome of their first ablation were included. Results are presented in the table below.

TABLE 7
Results of Initial RF Procedure

	# in Group	Complete Success,%	Partial Success,%	Failure,%
Ablation Results				
Adrenergic	12	42	0	58
Mixed	104	43	5	52
Vagal	49	39	4	57
Not sure	30	23	17	60
Total paroxysmal	195	39	6	55
Persistent	15	27	20	53
Permanent	37	38	0	62
Grand total	247	**38**	**6**	**56**
Adverse event rate	247	**29**	**53**	**51**
Other Possible Variables				
Underlying heart disease	20	35	0	65
Mitral valve prolapse	14	29	14	57
Minor MV regurgitation	30	53	3	43
Outcome for males	189	41	3	56
Outcome for females	58	28	17	55
Demographics		years	years	years
Present age, median	247	58	54	57
Age at diagnosis, median	247	49	45	47
Years of AF	247	6	6	7

The overall rate of complete success (no afib, no antiarrhythmics) was 38%. The rate of partial success (afib controlled with antiarrhythmics) was 6%, and the overall failure rate was a disappointing 56%. There was no significant difference in failure rate for the 3 types of AF (adrenergic, mixed and vagal). The failure rate for permanent afibbers tended to be slightly higher than for paroxysmal afibbers, as did the failure rate for afibbers with underlying heart disease and mitral valve prolapse. However, none of these differences reached statistical significance.

The difference in outcome for male and female afibbers was not statistically significant, nor did present age, age at diagnosis, or years of AF correlate with success/failure. The difference in the percentage of procedures accompanied by adverse events was, however, significantly different (p=0.004) between successful procedures (29%) and failures (48%) indicating that a failed procedure is more likely to be accompanied by adverse events than is a successful one.

The success rate (38%) observed in this survey is clearly disappointing, as is the high rate of adverse events. However, as previous surveys have shown, both the success and complication rates are highly dependent on the skill and experience of the EP performing the procedure.

Fifteen afibbers underwent their first RF ablation at the age of 70 years or older. The rate of complete success was 46%, partial success was 7%, and the failure rate was 47%. Thus, based on this very small sample, RF ablations in elderly afibbers are not less successful than those in younger ones.

Success Rate vs. AF Severity
It is conceivable that the success rate might be affected by the severity of the AF (frequency and duration of episodes).

TABLE 8
Success Rate vs. Afib Severity

Parameters	# in Group	Complete Success,%	Partial Success,%	Failure,%
Episode frequency				
Permanent	37	38	0	62
Daily	49	27	4	69
Weekly or twice-weekly	93	42	4	54
Monthly or twice-monthly	37	41	11	49
Less than once a month	22	50	18	32
Episode duration				
Less than 10 hrs	86	40	6	55
10 - 24 hrs	66	38	8	55
Longer than 24 hrs	31	45	3	52
Permanent	37	38	0	62

Episode duration, somewhat surprisingly, did not play a statistically significant role in determining the outcome of the first ablation. Episode frequency, however, showed a statistically significant linear correlation with outcome. Afibbers with daily episodes experienced more than twice the failure rate of afibbers who experienced episodes less than once a month. This would indicate that increasing frequency would be a warning that an ablation would be a good idea.

Second and Third Procedure Results

Only afibbers who had undergone their second and third ablations at least 6 months prior to completing the survey were included in this tabulation in order to avoid making premature conclusions as to success. Results are presented in the table below.

TABLE 9
Outcome of 2nd and 3rd Ablations

Procedure outcome	# in Group	Complete Success,%	Partial Success,%	Failure,%
1st procedure	247	38	6	56
2nd procedure	89	37	10	53
3rd procedure	17	41	6	53
Total/Average	**353**	**38**	**7**	**55**

The outcome of the second and third procedures is not significantly different from those 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 the 358 RF ablation procedures for which the outcome is known (including 5 fourth, fifth and sixth procedures).

Procedure Outcome

Popularity of Procedures

It is clear that focal ablation has declined markedly in popularity over the years in the group surveyed. The popularity of the various procedures aimed at isolating the pulmonary veins have, on the other hand, increased. The two most popular procedures over the period 1998-2006 were the Natale method (PV antrum isolation) and the generic pulmonary vein ablation (PVA), which likely includes elements of the Haissaguerre, Natale and Pappone methods. These methods are followed by the Haissaguerre (segmental PVI) and Pappone (circumferential PVI) methods at 18% and 15% respectively.

Considering just the last two years (2005 and 2006), the Natale and Haissaguerre methods vie for top spot at 26% each with the Pappone method following at 18%. Of course, this distribution may be quite different if another population group was surveyed.

TABLE 10
Popularity of procedures, %

Procedure	1998-2002	2003-2004	2005-2006	1998-2006
Focal ablation	30	7	5	9
PV ablation (PVA)	39	27	13	22
Segmental PVI	7	14	26	18
Circumferential PVI	5	16	18	15
Antrum PVI	5	23	26	22
Unspecified	16	13	12	13
Total, %	100	100	100	100

Outcome of Procedures

TABLE 11
Outcome of procedures, %

	1998-2004			2005-2006			1998-2006		
Procedure	Complete Success	Partial Success	Failure	Complete Success	Partial Success	Failure	Complete Success	Partial Success	Failure
Focal ablation	21	8	71	50	0	50	28	6	66
PV ablation (PVA)	24	5	71	38	5	57	28	5	68
Segmental PVI	29	0	71	43	2	55	38	2	61
Circumferential PVI	33	19	48	29	14	57	31	16	53
Antrum PVI	61	13	26	73	2	24	67	8	25
Unspecified	15	4	81	32	16	53	22	9	70
Average, %	31	8	61	47	6	47	**38**	**7**	**55**

The average complete success rate for 358 individual RF ablation procedures performed during the period 1998-2006 was 38% - identical to the rate observed for the 247 afibbers who underwent their initial RF procedure. The partial success rate was 7% and the failure rate 55%.

Complete success rates have improved markedly from the average 31% observed for the 1998-2004 period to 47% for the 2005-2006 period. Failure rates also declined from 61% to 47%.

By far the most successful procedure was the pulmonary vein antrum isolation procedure (Natale method) as primarily practiced at the Cleveland Clinic and the Marin General Hospital. Complete success rate for the period 1998-2006 was 67% and the failure rate was 25%. The complete success rate increased from 61% in 1998-2004 to 73% in 2005-2006.

The second most successful procedure was the segmental PVI (Haissaguerre method) as practiced in Bordeaux and several other clinics. Average complete success rate for the period 1998-2006 was 38% and an average failure rate of 61%. The circumferential PVI (Pappone method) had an average complete success rate of 31% and an average failure rate of 53% over the period 1998-2006. There was no improvement in success rate from the 1998-2004 period to the 2005-2006 period. However, the failure rate increased from 48% to 57%, perhaps indicating an influx of relatively inexperienced operators.

In interpreting these results it should be kept in mind that 63% of the pulmonary vein antrum isolation procedures were performed by Dr. Andrea Natale, a recognized world leader in RF ablation.

Adverse Events

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 12
Incidence of adverse events

	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 13
Distribution of adverse events, %

	1998-2004			2005-2006			1998-2006			
	Complete Succ	Partial Succ	Failure	Complete Succ	Partial Succ	Failure	Complete Succ	Partial Succ	Failure	Total Adv. Events
No adverse event, %	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 ev.	5	0	3	7	10	1	6	4	3	**4**
Life-threatening ev.	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. This approach prevented post-procedural right atrial flutter in 93% of cases.

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.

Stenosis Check

A check for pulmonary vein stenosis was carried out post-procedure in 41% of cases. Twenty-two percent were not sure if they had been checked, while the remaining 37% had not been checked. The percentage of reported stenosis checks declined from 44% in the period 1998-2004 to 37% in the period 2005-2006.

Post-Procedure Inflammation

The majority (90%) of afibbers were not aware of their level of the inflammation marker, C-reactive protein, immediately after their procedures. Only 4 patients (1%) reported levels above 5.0 mg/L (0.5 mg/dL), which is usually associated with inflammation. Fifteen ablatees (4%) reported CRP levels in the normal range (1.1 – 5.0 mg/L, and ten (3%) reported levels below 1.0 mg/L (0.1 mg/dL).

Forty-seven percent took anti-inflammatory drugs or supplements after their procedure, while 53% did not. The most popular anti-inflammatories were the following:

Fish oil	used after 20% of all procedures
Aspirin	used after 18% of all procedures
Statin drugs	used after 16% of all procedures
Prednisone	used after 3% of all procedures
Herbal anti-inflammatories*	used after 4% of all procedures

* beta-sitosterol, *Zyflamend* and boswellia

NOTE: Some afibbers used more than one anti-inflammatory

There was no indication that taking anti-inflammatories after the procedure improved the outcome.

Potassium and Vitamins

The majority (85%) of afibbers did not know their level of serum potassium after the procedure. Among the 15% who did know their level, 14% were in the normal range (3.6-5.0 mmol/L) and only 1% had a level below 3.5 mmol/L post-procedure. For these people, potassium supplementation is likely to be especially important.

Overall, 26% of ablatees supplemented with potassium after their procedure, while 51% supplemented with vitamins, antioxidants or minerals. There was no indication that doing so improved the outcome.

Ectopic Activity after Procedure(s)

TABLE 14
Ectopics after procedure

	# in Group	Complete Success, %	Partial Success, %	Failure, %
Increased ectopic activity				
None	96	44	38	24
Less than 1 month	36	4	14	19
One month	15	7	0	4
Two months	30	10	19	10
Three months	31	16	0	8
More than 3 months	83	20	29	35
Total	291	100	100	100

Complete success was associated with a 46% incidence of continuing increased ectopic activity (PACs and PVCs) after the first, often unstable month. Failure, on the other hand, was associated with a 53% incidence of continued increased activity. This difference was not statistically significant. However, experiencing increased ectopic activity beyond the first 3 months was associated with a higher incidence of failure (35%) than of complete success (20%). This different was statistically significant (p=0.04).

Afib Episodes after Procedure(s)

TABLE 15
Episodes after procedure

	# in Group	Complete Success, %	Partial Success, %	Failure, %
Continuing afib episodes				
None	112	64	45	12
Less than 1 month	59	17	14	21
One month	16	9	5	2
Two months	19	6	14	5
Three months	12	3	0	5
More than 3 months	96	0	23	56
Total	314	100	100	100

Complete success was associated with a 9% incidence of continuing afib episodes after the first, often unstable month. Failure, on the other hand, was associated with a 66% 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 no successfully ablated afibber 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].

Warfarin Usage Post-Procedure

The percentage of ablatees who were taking warfarin after their procedure is presented in the table below. A surprising 10% were not on warfarin at all post-procedure. The practice of not using warfarin was not limited to one or two institutions, but was fairly widespread. Most (58%) of successfully ablated afibbers were on warfarin for 2 or 3 months, while most partially successful and unsuccessful ablatees (80% and 67% respectively) remained on the drug for 3 months or longer.

TABLE 16
Warfarin usage after procedure

	# in Group	Complete Success, %	Partial Success, %	Failure, %
Warfarin usage				
None	33	7	8	12
Less than 1 month	18	2	4	7
One month	28	10	4	7
Two months	40	21	4	6
Three months	85	37	13	17
More than 3 months	141	23	67	50
Total	345	100	100	100

Post-Procedural Medication Use

TABLE 17
Antiarrhythmic/blocker use after procedure

	# in Group	Complete Success, %	Partial Success, %	Failure, %	Total, %
Antiarrhythmics/blockers					
None	91	35	16	24	28
Less than 1 month	12	2	0	5	4
One month	22	11	0	4	7
Two months	43	27	0	5	13
Three months	34	12	5	10	10
More than 3 months	128	13	79	52	39
Total	330	100	100	100	100

NOTE: This table refers to the use of antiarrhythmics/blockers immediately following the procedure(s).
Some respondents went on to discontinue drugs completely and were deemed successful if they were free of afib at the 6-month evaluation point. Others who did experience episodes were later placed on antiarrhythmics and, if the medication prevented episodes, were classified as partially successful.

A total of 28% of all ablatees were not prescribed any medication to be taken during the first few months after the procedure. Only 13% of successfully ablated afibbers continued on drugs after the first 3 months (usually beta-blockers), but 79% of partially successful and 52% of failed ablatees continued beyond 3 months.

The following table shows the type of antiarrhythmics/blockers used **IMMEDIATELY AFTER** the procedure(s).

TABLE 18
Antiarrhythmic/blocker use after procedure

	# in Group	Complete Success, %	Partial Success, %	Failure, %
Antiarrhythmics/blockers				
None	91	31	12	18
Flecainide (Tambocor)	88	24	27	20
Propafenone (Rythmol)	34	6	23	8
Disopyramide (Norpace)	8	1	0	3
Amiodarone (Cordarone)	24	2	0	9
Dofetilide (Tikosyn)	12	1	8	4
Sotalol (Betapace)	45	11	8	11
Beta-blocker	76	19	19	18
Calcium channel blocker	32	6	4	10
Total	410	100	100	100

Please note that several respondents took more than one medication. Thus, the total number in the group (410) is larger than the number of respondents (358).

The most popular post-procedure medication was flecainide, followed by beta-blockers and sotalol. A combination of flecainide and beta-blockers was also quite popular.

Recovery Time

The time it took to recover fully from a procedure is presented in the table below.

TABLE 19
Recovery time

	# 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

This evaluation of final outcome of RF ablations includes 237 afibbers whose last reported procedure was a RF ablation of the left atrium for the purpose of curing atrial fibrillation. All respondents included here reported their afib status at least six months after their last procedure. The average observation period after the last ablation was 16 months with a range of six months to four years.

One hundred and thirty-four of the 237 afibbers were no longer experiencing episodes and were no longer on antiarrhythmics (complete success). Twenty-six were also afib-free, but only with the help of antiarrhythmics (partial success). The remaining 77 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	57%	65%
Partial success	11%	16%
Failure	32%	19%
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.

Continued Stroke Prevention

As shown in the table below 49% of afibbers continued a stroke prevention program after completion of their procedures.

TABLE 20
Continuing stroke prevention

	# in Group	None,%	Warfarin,%	Aspirin,%	Natural Remedies,%
Stroke prevention					
Complete success	134	69	4	10	17
Partial success	26	31	35	15	19
Failure	77	27	38	10	25
Total	237	51	19	11	20

Not too surprisingly, most (96%) of afibbers whose final procedure had been completely successful did not continue with warfarin. Seventeen percent did, however, continue with a natural stroke prevention program, and 10% continued with a daily aspirin. Seventy-one percent of afibbers whose final procedure had failed continued with a stroke prevention program with most (38%) using warfarin, but a significant 25% used a natural remedy. The most commonly used natural supplements used for stroke prevention were fish oil, nattokinase, vitamin E, and garlic.

Trigger Avoidance

While 78% of successful ablatees no longer needed to avoid previous triggers, only 19% 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 21
Trigger avoidance

	# in Group	Complete Success,%	Partial Success,%	Failure,%	Average,%
Trigger avoidance					
No longer necessary	131	78	46	19	55
Still necessary	37	5	12	35	16
Much less sensitive	37	8	19	28	16
Uncertain	32	9	23	18	13
Total	**237**	**100**	**100**	**100**	**100**

Post-Procedure Afib Episodes

Forty-nine paroxysmal respondents whose ablation had not been successful had kept track of their episode frequency prior to and after their procedure(s). The median number of episodes prior to the first procedure was 25 (over a 3-month period) compared to 5 after the last procedure. This is clearly a very noticeable improvement and is statistically extremely significant ($p < 0.0001$). Seventy-three percent of the 49 respondents saw a substantial decline in their episode frequency; six percent saw no change while 21% experienced an increase. Two persistent and 2 permanent afibbers converted to paroxysmal after their procedure. The median duration of episodes decreased from 8 hours to 4 hours and this change was again statistically significant ($p= 0.002$). Most (63%) saw a decrease in their episode duration, 16% experienced no significant change and 25% saw their episode duration increase. The total afib burden (episode frequency times duration) over a 3-month period

decreased from a median of 178 hours to 21 hours, again a highly significant decrease ($p < 0.0001$). Overall 65% of respondents saw a 50% or better decrease in their afib burden, but the remaining 35% saw an, often substantial, increase in the time they spent in afib.

Use of Pill-in-the-Pocket Approach

Twenty-five percent of afibbers still experiencing episodes used the on-demand approach in an attempt to shorten their duration.

Changes in Heart Rate

Changes in resting heart rate after RF ablation were quite common.

TABLE 22
Post-procedure heart rate change
Persistent and paroxysmal afibbers

	# in Group	Complete Success,%	Partial Success,%	Failure,%	Average,%
Heart rate change					
Increase	119	69	46	39	56
No change	58	25	33	28	27
Decrease	36	6	21	33	17
Total	**213**	**100**	**100**	**100**	**100**

The most frequent post-procedural change was an increase in heart rate (experienced by 56%). This increase was most common among afibbers who had undergone successful procedure(s) (69%) and least common among those whose procedures had failed to cure the afib (39%). This difference was statistically significant ($p=0.04$). A decrease in heart rate was rare among successfully ablated afibbers (6%), but more common (33%) among those whose procedure had failed. The median increase in average resting heart rate was 10 bpm for paroxysmal afibbers (1-30 bpm) who had undergone a successful ablation.

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 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.

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 57%. 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 68%. Further considering that about 65% 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.

Summary

- The overall objectively-rated complete success rate (no afib, no drugs) for 237 afibbers after an average of 1.5 RF ablations was 57%; partial success was achieved in 11% of cases, and 32% 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 66% feeling that the end result was total success, 15% claiming partial success, and 19% judging their procedures as a failure.

- The average objectively rated complete success rate for a single RF ablation procedure was 38%, that of partial success 7%, and that of failure 55%.

- 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.

- 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.

- 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 (75%) of respondents experienced AF episodes at least weekly prior to their ablation.

- 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. Underlying heart disease, mitral valve prolapse, and permanent afib showed a statistically non-significant trend towards a higher failure rate.

- The most successful procedure for the period 2005-2006 was the pulmonary vein antrum isolation procedure (Natale method) with a combined single procedure complete and partial success rate of 75%. The segmental PVI (Haissaguerre method) was the second-most successful procedure with a combined single procedure success rate of 45%.

- There was no indication that anti-inflammatories, potassium or vitamin supplementation affected the outcome of the procedure and no evidence that potassium supplementation reduced the incidence of increased post-procedure ectopic activity or episodes of AF.

- Increased ectopic activity continuing beyond 3 months post-ablation was associated with an increased incidence of failure.

- A significant majority (64%) of afibbers who had a completely successful ablation experienced no AF episodes at all after the procedure. Only 12% of those "doomed to failure" experienced no episodes at all after their procedure. No completely successful ablatees experienced episodes for more than 3 months after the procedure, while 56% of unsuccessful ablatees did so. Thus, if increased ectopic activity and 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.

- 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.

- Most (96%) of afibbers who had a completely successful ablation did not continue with warfarin, but 17% of them continued to use natural stroke prevention remedies such as fish oil, nattokinase, vitamin E and garlic. Ten percent took a daily aspirin for stroke prevention. In contrast, 38% of ablatees with a failed procedure continued on warfarin.

- While 78% of successful ablatees no longer needed to avoid previous triggers, only 19% 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.

- Even an unsuccessful ablation resulted in a significant reduction in episode frequency in 73% of cases and in 63% of cases was associated with a significant decrease in episode duration. Overall, 65% of unsuccessfully ablated patients experienced a 50% or better decrease in their afib burden while the remaining 35% saw an, often substantial, increase in the time they spent in afib.

- A post-ablation increase in heart rate was a common occurrence. This phenomenon was more prevalent among successful ablatees (69%) than among those whose ablation had failed (39%). This may indicate that a more aggressive approach (increased destruction of vagal nerve endings) is associated with a better outcome.

Performance Rating

Previous ablation/maze surveys have all arrived at the same 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 chance of undergoing a successful and safe ablation at a particular institution, I have developed a Performance Rating scheme. This rating takes into account the success rates and adverse event rates reported by afibbers treated at specific institutions and by specific EPs. The factors entering into the Performance Rating are as follows:

Success Score

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

Adverse Events Score

- No adverse events — score = 0
- Hematoma — score = -2
- Minor reversible events — score = -2
- Right atrial flutter — score = -5
- Left atrial flutter — score = -5

- Supraventricular tachycardia score = -5
- Moderate PV stenosis score = -5
- Pericarditis score = -5
- TIA score = -5
- Phrenic nerve damage score = -10
- Severe PV stenosis score = -10
- Tamponade score = -10
- Atrial/esophageal fistula score = -10
- Other life-threatening events score = -10
- Minor stroke score = -10
- Events causing permanent disability score = -20

The Outcome Factor adds the scores (for degree of success and adverse events) for each RF ablation and the Performance Rating then averages these outcome factors for each individual institution. For example, if a procedure is fully successful with no adverse events, than the outcome factor is +10. If a procedure is a failure and accompanied by the creation of left atrial flutter, then the outcome factor is –5. The primary performance rating does not take into account that a large number of adverse events are resolved within a few months after the procedure. To acknowledge this, an adjusted performance rating is also shown in which the effect of resolved adverse events have been ignored.

Please note that in this evaluation of 358 single RF ablation procedures a procedure is not considered a failure unless followed by another RF 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. Based on the Adjusted Performance Rating (combination of success and safety) the various institutions stack up as follows:

TABLE 23
Procedure performance rating
(6 or more procedures)

Rank	# of Procedures	Institution
1	10	University of Michigan
2	58	Cleveland Clinic, OH
3	26	Marin General Hospital, CA
4	7	University of Pennsylvania
5	37	Hopital Cardiologique du Haut Leveque, Bordeaux
6	11	Medical University of South Carolina (MUSC)
7	7	New York University (NYU) Medical Center
8	7	Freeman Hospital, Newcastle, UK
9	10	Royal Jubilee Hospital, Victoria, Canada
10	6	Good Samaritan Hospital, Los Angeles
11	10	University of California at San Diego
12	9	St. Paul's Hospital, Vancouver, Canada
13	6	Centinella Hospital (Pacific Rim Electrophysiology), Inglewood, CA
14	6	Hollywood Hospital, Perth, Australia
15	9	St. Barts and London Bridge, London, UK
16	6	Massachusetts General, Boston
17	7	Brigham & Women's Hospital, Boston

The first 10 institutions in the above table account for 50% of all ablation procedures performed; their performance is evaluated in detail below (ranked by complete success rate).

TABLE 24
Procedure success
Top-ranked institutions

Rank	Institution	# of Procedures	Performance Rating Adjusted*	Performance Rating Primary	Success Rate, % Complete	Success Rate, % Partial	Success Rate, % Failure	Adverse Event Rate,%
1	Cleveland Clinic	58	6.7	5.2	69	5	26	40
2	Marin General	26	5.6	5.0	62	12	26	35
3	Bordeaux	37	4.3	2.7	49	0	51	41
4	MUSC	11	4.1	1.9	45	9	46	55
5	U of Pennsylvania	7	5.0	3.7	43	14	43	43
6	Freeman Hospital, UK	7	3.6	2.6	43	0	57	43
7	U of Michigan	10	7.4	7.2	40	10	50	50
8	Royal Jubilee, Canada	10	3.0	1.6	40	0	60	30
9	Good Samaritan, LA	6	2.9	2.3	33	0	67	17
10	NYU	7	3.6	2.7	29	14	57	29
	Average/Total	**179**			**54**	**6**	**40**	**39**

***resolved adverse events not included**

Please note that the adverse event rate includes all adverse events reported by patients. Over 70% of these events resolved on their own.

The electrophysiologists performing the procedures in the above 10 institutions are as follows:

Institution	Electrophysiologists
Cleveland	Drs. Andrea Natale, Walid Saliba, Robert Schweikert, Patrick Tchou
Marin General	Drs. Andrea Natale, Steven Hao
University of Pennsylvania	Drs. David Callans, Frank Marchlinski
Bordeaux	Drs. Michel Haissaguerre, Pierre Jais
MUSC	Dr. Marcus Wharton
Freeman, UK	Dr. Stephen Furniss
U Mich	Drs. Fred Morady, Frank Pelosi, Hakan Oral
Royal Jubilee	Drs. Richard Leather, Larry Sterns
Good Samaritan	Drs. Anil Bhandari, Neala Hunter
NYU	Dr. Larry Chinitz

The average procedural success and adverse event rates for the remaining 179 procedures are given below. The procedures have been grouped by the institution at which they were performed.

Group 1 contains 11 institutions not included in the top 10 for which reports of 4 to 6 procedures were available.
Group 2 contains 6 institutions for which reports of 3 ablation procedures were available
Group 3 contains 66 institutions for which reports of less than 3 procedures were available.

TABLE 25
Procedure success
Other institutions

	# in	Performance Rating		Success Rate, %			Adverse
Institution	Group	Adjusted	Primary	Complete	Partial	Failure	Event Rate,%
Group 1	71	2.1	1.1	20	6	74	45
Group 2	18	1.7	0.2	22	6	72	28
Group 3	90	1.8	0.4	23	12	64	44
Total	**179**	**1.8**	**0.4**	**22**	**9**	**69**	**43**

The above statistics are indeed sobering. Undergoing a single RF ablation procedure other than at the 10 top-ranked institutions is associated with an **average** complete success rate of 22%, a partial success rate of 9%, and a failure rate of 69%. This is accompanied by an **average** adverse event rate of 43%.

Despite the overall bleak picture, there are some good performers in Groups 1 and 2, bearing in mind that the number of procedures upon which this conclusion is based is extremely limited.

TABLE 26
Good performers – Groups 1 and 2

	Number of	Success Rate, %			Adverse
Institution	Procedures.	Complete	Partial	Failure	Event Rate,%
Group 1					
Aurora Heart Inst.	4	25	50	25	25
Loyola Medical	5	40	0	60	40
Johns Hopkins	5	40	20	40	75
Group 2					
Mayo Clinic	3	67	0	33	33
Univ. of Alabama	3	33	33	33	33

Aurora Heart Institute, Milwaukee, MN	EP: Dr. Jasbir Sra
Loyola Medical Center, Maywood, IL	EP: Dr. David Wilber
Johns Hopkins Hospital, Baltimore, MD	EP: Drs. Hugh Calkins and Ronald Berger
Mayo Clinic, Rochester, MN	EP: Dr. Douglas Packer
University of Alabama, Birmingham, AL	EP: Dr. Neal Kay

Combined Procedure Success Rate

Combining the top ten with Groups 1, 2, and 3 yields the following total procedural success rates.

TABLE 27
Combined procedural success
All institutions

Institutions	Individual Patients	Final Success Rate,% Complete	Partial	Failure	Adverse Event Rate,%
Top 10	179	54	6	40	39
Group 1	71	20	6	75	45
Group 2	18	22	6	72	28
Group 3	90	23	12	64	44
Total	**358**	**38**	**7**	**55**	**41**

Final Success Rate

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. This part of the evaluation includes 237 afibbers whose last reported procedure was a RF ablation of the left atrium for the purpose of curing AF. All respondents included here reported their final afib status at least 6 months after their last procedure. Overall final results for the 10 top-ranked institutions are presented below.

TABLE 28
Final performance rating
Top-ranked institutions

Institution	Individual Patients	# of Procs.	Repeat Rate, %	Final Success Rate, % Complete Success	Partial Success	Failure
Bordeaux, France	22	37	37	82	0	18
Cleveland Clinic, OH	49	58	18	78	6	16
Marin General, CA	21	26	18	76	14	10
MUSC	7	11	22	71	14	14
Good Samaritan, LA	3	6	20	67	0	33
NYU	3	7	40	67	33	0
U of Pennsylvania	5	7	40	60	20	20
U of Michigan	7	10	25	57	14	29
Royal Jubilee, Canada	8	10	11	50	0	50
Freeman, Newcastle, UK	6	7	17	50	0	50
Total	**131**	**179**	**23**	**72**	**8**	**20**

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

5 patients came to the Cleveland Clinic from other institutions for their follow-up.
4 patients came to the Bordeaux Clinic from other institutions for their follow-up.
2 patients came to Marin County from another institution for their follow-up.
1 patient came to U of Michigan from another institution for their follow-up.

The best chance of ensuring a successful outcome is by undergoing the procedure(s) at one of the top 3 institutions – Hopital Cardiologique du Haut Leveque in Bordeaux, France, the Cleveland Clinic in Ohio, and Marin General Hospital in California. The complete success rates there are 82%, 78% and 76% respectively (difference not statistically significant). The complete + partial success rates are 82%, 90% and 84% respectively – impressive indeed.

The excellent ultimate success rate in Bordeaux is, unfortunately, associated with a high repeat rate (37%). This drawback is somewhat ameliorated by the Bordeaux practice of performing most required "touch-ups" within a week or two following the initial procedure. The lowest repeat rate (11%) is associated with the Royal Jubilee Hospital in Victoria, Canada, no doubt reflecting the inordinately long waiting times within the Canadian healthcare system.

The average complete success rate in other institutions (Groups 1, 2 and 3) was 37% or about half that achieved, on average, at the 10 top-ranked institutions. The failure rate was 48% as compared to 20% at the top 10.

TABLE 29
Final procedural success
Other institutions

	Individual	Repeat	Final Success Rate, %		
Institutions	Patients	Rate, %	Complete	Partial	Failure
Group 1	40	34	35	10	55
Group 2	9	20	44	11	44
Group 3	57	20	37	19	44
Total	**106**	**25**	**37**	**15**	**48**

Combining the results for the 237 patients and 358 procedures yields an average complete success rate of 57%, a failure rate of 32%, and an average repeat rate of 24%.

TABLE 30
Final procedural success
All institutions

	Individual	Repeat	Final Success Rate, %		
Institutions	Patients	Rate, %	Complete	Partial	Failure
Top 10	131	23	72	8	20
Group 1	40	34	35	10	55
Group 2	9	20	44	11	44
Group 3	57	20	37	19	44
Total	**237**	**24**	**57**	**11**	**32**

Comparison With Other Surveys

At least 5 surveys of PVI procedure success rates have now been published. One, the Cappato Study, published in 2005 involved 8745 patients treated at 90 different institutions around the world.[2] The outcome experience at the Cleveland Clinic, Ohio was presented for 323 patients who underwent a PVI for drug-resistant AF.[3] The University of Michigan experience (755 patients) was presented in a 2006 paper by *Oral, et al*[4], while Johns Hopkins Hospital outlined their PVI outcomes for 200 PVI procedures in a 2006 study authored by *Cheema, et al*.[5] 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.[6]

A comparison of the results of these surveys and my own current survey is presented in the tables below. Table 31 summarizes the results of initial procedures, while Table 32 summarizes final outcome, that is, outcome after repeat ablations as required.

TABLE 31
Outcome after initial procedure

Survey	Institutions	No. of Procedures	Initial Success Rate, % Complete	Partial	Failure	Observation period, mos.
TOP-RANKED INSTITUTIONS						
Bhargava[3]	Cleveland Clinic, OH	323	71	0	29	6
Afibbers.org	Cleveland Clinic, OH	58	69	5	26	6
Afibbers.org	10 top-ranked	179	54	6	40	6
OTHER INSTITUTIONS						
Nilsson[6]	Copenhagen Univ.	100	17	0	83	3
Afibbers.org	Other	179	22	9	69	6

There are, unfortunately, only 2 studies, other than the afibbers.org survey, which 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 54% for the 10 top-ranked institutions and 22% for other institutions.

TABLE 32
Outcome after final procedure

Survey	Institutions	No. of Patients	Initial Success Rate, % Complete	Partial	Failure	Repeat Rate, %	Observation period, mos.
TOP-RANKED INSTITUTIONS							
Bhargava[3]	Cleveland Clinic, OH	323	83	0	17	12	12
Afibbers.org	Cleveland Clinic, OH	49	78	6	16	18	6
Cappato[2]	Top-ranked (world)	3244	64	16	20	27	12
Oral[4]	Univ. Michigan	755	73	?	?	?	12
Afibbers.org	10 top-ranked	179	72	8	20	23	6
OTHER INSTITUTIONS							
Cappato[2]	Other (world)	5501	45	29	26	27	12
Cheema[5]	Johns Hopkins	200	41	11	48	32	12
Nilsson[6]	Copenhagen Univ.	100	44	?	?	74	12
Afibbers.org	Other	106	37	15	48	25	6

The final outcome results are somewhat better documented with complete success rates varying from 83% to 41% with the afibbers.org survey finding an average rate of 72% for the 10 top-ranked institutions and 37% for the other institutions. It is comforting to note that the success rates published by the Cleveland Clinic [3] are very close to those found in our own survey for this institution.

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 2006 LAF Ablation/Maze Survey agree well with those found in published studies. The LAF survey is based on a total of 358 procedures performed on 237 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 institutions. The rating of the top 3 institutions, Cleveland Clinic, Ohio, Hopital Cardiologique du Haut Leveque, Bordeaux, and Marin General Hospital, California are probably reasonably indicative since they are based on almost 100 patients and 120 procedures. A ranking based on just 4 to 6 procedures per institution is clearly not very significant and it is quite possible that a large sample would produce different results.

However, based on conversations with hundreds of afibbers, perusal of hundreds of articles relating to RF ablation, and my own instinctual feeling, I have no hesitation in recommending the 10 top-ranked institutions presented in this survey. There may well be other institutions and individual EPs that deserve top ranking, but I have no evidence that this is indeed the case.

To summarize, the inescapable conclusion of this survey is that RF ablation for atrial fibrillation is still an emerging technology and that a half decent chance of success can only be expected in top-rated institutions. To go anywhere else, at this point in time, will no doubt lead to disappointment and perhaps serious adverse effects. That said, it is also clear that most, probably as many as 90%, 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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