THE AFIB REPORT

Your Premier Information Resource for Lone Atrial Fibrillation!

NUMBER 86 **FEBRUARY 2009** **9th YEAR**

Welcome to a brand new year and our 9th year of publication. In this issue we complete the evaluation of the responses received in the 2008 ablation/maze survey. A total of 87 afibbers reported on their experiences with procedures other than the standard radiofrequency ablation procedure. Twelve respondents reported on cryoablation procedures, 15 on AV node + pacemaker implantation, and 26 on the full maze procedure and 41 on the mini-maze. These numbers are clearly very small compared to the number of respondents (611) who reported on their RF ablation experience in Part 2 of the survey.

Thus, the conclusions drawn about the efficacy and safety of cryoablation, AV node ablation, maze and mini-maze procedures are clearly less reliable than the conclusions drawn about RF ablations. Cryoablation does not appear to have any advantage over RF ablation as far as success rate is concerned. AV node ablation + pacemaker implantation provides significant symptomatic relief, but does not eliminate afib, requires warfarin treatment for life, and is still the procedure of last resort.

The full maze procedure performed by a top-ranked cardiac surgeon provides the best chance of being cured of afib with one single procedure (complete success rate of 88%). However, full maze procedures performed by less skilled surgeons tend to be considerably less successful. This, combined with the potential for significant adverse events (especially associated with the use of the heart/lung machine), would lead one to the conclusion that it may be "overkill" for a paroxysmal afibbers, with no underlying heart disease, to select the full maze over a conventional RF ablation or mini-maze procedure.

A mini-maze procedure performed by a top-ranked cardiac surgeon provides the second-best chance of being cured of afib with one single procedure. It is also likely that even a mini-maze performed by a less than top-ranked surgeon will have a substantially better outcome than a single standard RF ablation performed by a less than top-ranked EP. However, the risk of adverse effects accompanying the mini-maze procedure is somewhat higher than for RF ablations.

In any case, the main, inescapable conclusion from this survey is that the all-important variable determining success or failure is the skill and expertise of the EP or surgeon performing the procedure. The type of procedure would appear to be significantly less important.

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

Wishing you good health with lots of NSR,

Hans

2008 Ablation/Maze Survey

PART 3 – PROCEDURES OTHER THAN RF ABLATION

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 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.

The procedures covered in this part of the survey are cryoablation, AV node ablation + pacemaker installation, the maze procedure, and the so-called "mini-maze" procedure (thoracoscopic epicardial pulmonary vein isolation). The main difference between the full maze and the mini-maze procedure is the method of access to the heart. The maze involves a 6-12 inch long cut through the breastbone, while the mini-maze provides access through two or more 2-inch incisions between the ribs. Another important difference is that the maze procedure requires the use of a heart/lung machine, while the mini-maze does not.

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

Afib burden – The number of episodes over a 3-month period multiplied by their average duration.

Evaluation of Background Data

Eighty-seven afibbers had undergone one or more surgical procedures (maze, mini-maze, AV node + pacemaker installation) or cryoablations. The distribution of these procedures is detailed in Table 23 below.

TABLE 23

	No. of Procedures				
Procedures	1st	2nd	3rd	Further	Total
Cryoablation	8	4	0	0	12
Maze procedure	20	3	1	2	26
Mini-maze procedure	29	4	6	2	41
AV node ablation + pacemaker	9	3	1	2	15
Total	66	14	8	6	94
RF ablation*	21	18	10	5	54
Total procedures	87	32	18	11	148

* RF ablations performed before or after cryoablation, maze, mini-maze, or AV node ablation + pacemaker implantation procedure.

Sixty-six respondents had undergone a surgical procedure or cryoablation as the initial attempt to cure their afib. Another 21 had theirs following an initial RF ablation – right atrial flutter (2), PVI or focal ablation (19).

General Background of Respondents

The general background data for the 87 respondents whose treatments for the purpose of curing atrial fibrillation included one or more cryoablation, maze, mini-maze or AV node ablations is given in Table 24.

TABLE 24

Demographics	Male	Female	Total/Average
Gender distribution, %	80	20	100
Average (median) age*, yrs.	62	61	62
Underlying heart disease, %	22	29	23
LAF confirmed by diagnosis, %	100	100	100
Afib Type			
Adrenergic, %	1	6	2
Mixed, %	37	50	39
Vagal, %	18	6	15
Uncertain, %	12	6	11
Total paroxysmal, %	68	69	68
Persistent, %	7	19	10
Permanent, %	25	13	23
Total	100	100	100

* At time of completing questionnaire

The only statistically significant difference between this group and the group undergoing RF ablations is the considerably higher incidence of underlying heart disease (23% vs 8%).

The majority of the cryoablation/maze group had paroxysmal afib (68%). Mixed (random) AF was the most common type of paroxysmal afib, followed by vagal and adrenergic. There were no statistically significant differences in afib type between this group and the RF ablation group.

Cryoablation

The cryoablation procedure is similar to the standard RF ablation procedure except that the ablation catheter is cooled by liquid nitrogen or argon rather than electrically heated. The advantage of cryoablation is that it reduces procedure stroke risk and does not create pulmonary vein stenosis even if the ablation is done inside the pulmonary veins.

Eight paroxysmal afibbers with no underlying heart disease (7 male, 1 female) had undergone cryoablation as their first procedure. Three of these procedures were fully successful (no afib, no drugs) giving a first procedure complete success rate of 38%.

Three of the unsuccessful ablatees went on to have other procedures – 2 had another cryoablation of which one was a success, while the third had an unsuccessful PVI procedure. The 2 remaining unsuccessful ablatees went on to have RF ablations, one of which was successful. Two respondents underwent a cryoablation following a failed PVI. One was partially successful (afib controlled with antiarrhythmics).

The outcome (at least 6 months after procedure) was known for 12 cryoablation procedures. Four (33%) were fully successful and one (9%) was partly successful. The average single procedure

complete success rate for cryoablation is thus 33%, not significantly different from the average single procedure complete success rate for PVI procedures at 34%. There is insufficient data to say what the final success rate would be after repeated cryoablations.

AV Node Ablation + Pacemaker Implantation

Palpitations, elevated heart rate, and other major symptoms of an atrial fibrillation episode are associated with rapid and irregular contractions of the left ventricle rather than with the actual "quivering" of the left atrium. So, although the root cause of AF is found in the left atrium, its symptomatic effects can, to a large extent, be eliminated by isolating the AV node (the ventricular beat controller) from impulses originating in the left atrium and feeding the ventricles their "marching orders" from an implanted pacemaker. AV node ablation + pacemaker installation is a relatively simple procedure and is therefore mostly successful. It does also provide substantial symptom relief allowing afibbers to live a fairly normal life. Nevertheless, the procedure is considered a last resort for the following reasons:

- It does nothing to stop the fibrillation in the atrium and may, in fact, hasten the progression to permanent AF.
- It does not reduce stroke risk as do successful PVIs and maze procedures. Thus, the patient must continue on warfarin for life.
- It makes the patient dependent on the pacemaker. If it or the leads malfunction, or the battery runs out the patient may die.
- It does little to prevent the fatigue and reduced exercise capacity felt by some afibbers during an episode.

Fourteen respondents (36% female) underwent AV node ablation + pacemaker implantation procedures. One had a second procedure to replace a pacemaker lead after 6 years. Of the 14 patients, 29% had underlying heart disease; the median age of the patients was 65 years.

Nine patients underwent the AV node ablation as their first procedure in an attempt to alleviate their afib symptoms (44% had underlying heart disease and 60% had permanent afib). Six patients had no further follow-up, while of the remaining three, one had a pacemaker replacement (6 years after the initial one), one had a PVI (partially successful), and one had a maze procedure (partially successful) with no further follow-up.

Two respondents underwent their AV node ablation following a failed PVI and a failed maze procedure respectively. One respondent had his procedure after 2 failed focal ablations, and one had his as a fifth procedure after 3 PVIs and a mini-maze. Finally, one respondent had his AV node procedure after 3 failed right atrial flutter ablations and 3 failed PVIs.

It is somewhat difficult to evaluate the success of an AV node ablation + pacemaker implantation since it, at best, provides symptomatic relief only. Eighty percent of respondents felt (subjectively) that their procedure had been a success, while the remaining 20% felt that it had been partially successful.

Based on this small sample of 14 respondents, it is clear that AV node ablation + pacemaker installation is usually a successful procedure and provides significant symptomatic relief even though it does not eliminate AF. Nevertheless, it is still the procedure of last resort.

Maze Procedure

Twenty-six respondents reported having undergone a full maze procedure – 20 as their initial procedure, 5 after failed PVIs or focal ablations, and 1 after an AV node ablation + pacemaker implantation. The maze group differed significantly from the group of 552 afibbers who underwent catheter ablation. While the percentage of patients in the RF ablation group who had underlying heart disease was only 6%, it was 35% in the maze group. Also, while the percentage of patients having permanent afib was only 15% in the ablation group, it was 33% in the maze group. Both differences were statistically highly significant.

Five of the 26 procedures were cryo-maze. In other words, the maze lesions were applied with a nitrogen-cooled or argon-cooled catheter rather than with RF energy or the cut-and-sew approach. Only 2 of these procedures were successful. One of the unsuccessful patients went on to undergo a pulmonary vein isolation procedure with Dr. Natale, which was a complete success.

Twenty-three patients had gone 6 months or more following their maze procedure and knew the outcome. It is problematical, perhaps even unwise, to pronounce on success rates with only 23 procedures in the sample. Nevertheless, as with catheterization procedures, there would appear to be a definite trend for procedures performed by top-ranked cardiac surgeons to be more successful than those performed by less prominent ones.

TABLE 25

	# of	Success Rate,%		
Surgeon	Procedures	Complete	Partial	Failure
Top-ranked	8	88	0	13
Other	15	33	7	60
Total	23	52	4	43

It is, of course, open to argument who is and who is not “top-ranked”, but I do believe that the surgeons in the above group (Drs. Niv Ad, Ralph Damiano, Dale Geiss, Marc Gillinov and Patrick McCarthy) would all fall in this category.

The complete success rate for top-ranked surgeons is thus 88%, very close to the oft-quoted 90% success rate for maze procedures[1,2]. However, the complete success rate for other than top-ranked surgeons is only 33%, very close to the 34% found for other than top-ranked EPs performing RF ablation procedures.

Our results, albeit based on a very small sample, lead to the conclusion that, just as in the case of conventional PVIs, the choice of surgeon or EP is the all-important variable with the type of procedure playing a lesser role in the final outcome.

As reported in the 2006 Ablation/Maze Survey, 7 out of 12 (58%) of patients undergoing the maze procedure experienced one or more adverse events, some of them quite serious. Two suffered a transient ischemic attack (TIA, mini-stroke), one reported excessive fluid retention, and one pericarditis. This rate of serious adverse events is higher than experienced in any other procedure.

A comparison of objective and subjective success rates show that the respondents’ subjective impression of outcome is identical to the actual (objective evaluation) when it comes to complete success (no afib, no antiarrhythmics). However, it would seem that respondents were more likely to feel that even a failed procedure (still experiencing afib episodes) was at least partially successful.

	Objective	Subjective
Complete success	52%	52%
Partial success	4%	26%
Failure	43%	22%
Total	**99%**	**100%**

As far as post-procedure problems (trigger avoidance, ectopics, tachycardia, flutter) are concerned, it is clear (Table 26) that a successful maze procedure is far less likely to be accompanied by post-procedure problems than is an unsuccessful one. Although a similar trend was observed for catheter ablations, it is far more pronounced for the full maze procedure.

TABLE 26

Variable *	Complete Success	Failure
Still need to avoid triggers	15%	100%
Still have ectopics	33%	100%
Still have tachycardia	17%	100%
Still have flutter	0%	33%

* As observed at least 6 months following the procedure

The full maze procedure performed by a top-ranked cardiac surgeon provides the best chance of being cured of afib with one single procedure. However, full maze procedures performed by less skilled surgeons tend to be considerably less successful. This, combined with the potential for significant adverse effects (especially associated with the use of the heart/lung machine), would lead one to the conclusion that it may be "overkill" for a paroxysmal afibber, with no underlying heart disease, to select the full maze over a conventional radiofrequency PVI or mini-maze procedure.

This conclusion is supported by the following quote from an article reporting the results of 130 Cox-maze IV procedures, "It is a weakness of this study that we did not examine pulmonary vein isolation in patients who had lone AF. Further data are needed to evaluate the efficacy of this procedure in this group. However, our historical results with the cut-and-sew procedure (Cox-Maze III) had higher success rates in patients who had AF associated with concomitant cardiac pathology as opposed to those who had lone AF".[1]

Of course, the full maze procedure is obviously preferred if other heart surgery is needed.

Mini-Maze Procedure

Forty-one respondents (17% female) reported undergoing a mini-maze procedure, 29 as their initial procedure and 12 after one or more failed radiofrequency (RF) PVIs. The 12 patients had undergone a total of 22 PVIs before their mini-maze. Only 3 of the failed PVIs were performed at top-ranked institutions. A total of 8 patients underwent PVIs (7) or AV node ablation + pacemaker implantation (1) following a failed mini-maze. There were no repeat mini-mazes. The incidence of underlying heart disease was significantly higher in the mini-maze group than in the RF ablation group (20% vs. 6%).

The majority of procedures (84%) used RF energy in creating the ablation lesions, 13% used microwave energy, and the remaining 3% (1 procedure) used high-intensity focused ultrasound (HIFU). The HIFU procedure was unsuccessful as were 3 of the microwave procedures.

The final outcome at least 6 months following the procedure was known for 31 procedures. Of these, 13 were carried out by 4 top-ranked cardiac surgeons.

- Dr. Randall Wolf — University of Cincinnati Hospital — 8 procedures
- Dr. Michael Mack — Medical City, Dallas, TX — 3 procedures
- Dr. James Cox* — Ohio State University Hospital — 1 procedure
- Dr. Adam Saltman** — University of Massachusetts — 1 procedure

* Now medical director at ATS Medical Inc, Minneapolis, MN
** Now at Maimonides Medical Center, Brooklyn, NY

RF-powered catheters or clamps were used for lesion creation in all procedures. The outcomes are presented in Table 27.

TABLE 27

	# of	Success Rate,%		
Surgeon	Procedures	Complete	Partial	Failure
Top-ranked	13	62	8	31
Other	18	50	6	44
Total	31	55	6	39

The average complete success rate for top-ranked cardiothoracic surgeons is 62%. This is very close to the initial procedure complete success rate of 61% experienced at the Cleveland Clinic, but significantly better than the average 50% single procedure complete success rate obtained at the 15 top-ranked RF ablation institutions. Considering both top-ranked and other institutions, the 55% average complete success rate for the mini-maze is clearly superior to the average single procedure success rate of 34% for RF ablation.

The standard RF ablation can, of course, be repeated, whereas I have not seen any example of full maze and mini-maze patients being given the option of undergoing a second procedure if the initial one fails. The complete success rate after an average of 1.5 RF ablation procedures is 65% for the 15 top-ranked centers and is now 82% at the 3 top-ranked centers – Cleveland Clinic, OH, Hopital Cardiologique du Haut Leveque, Bordeaux, and California Pacific Medical Center, San Francisco. The overall mini-maze success rate of 50% with other than top-ranked surgeons is, however, superior to the "other institutions" RF ablation complete success rate of 32% after repeat ablations.

A mini-maze procedure performed by a top-ranked cardiac surgeon provides the second-best chance (after the full maze procedure) of being cured of afib with one single procedure, although the Cleveland Clinic single procedure success rate of 61% is very close. It is also likely that even a mini-maze performed by a less than top-ranked surgeon will have a substantially better outcome than a standard RF ablation performed by a less than top-ranked EP.

The incidence of adverse events (as per the 2006 survey) tended to be slightly higher than for RF ablations and involved pneumonia (9%), tamponade (4%), serious hemorrhage (4%), and subcutaneous nerve pain (4%). As far as post-procedure problems (trigger avoidance, ectopics, tachycardia and flutter) are concerned, it is clear (see Table 28) that a successful mini-maze procedure is far less likely to be accompanied by post-procedure problems than is an unsuccessful one. A similar trend has also been observed for the maze procedure and RF ablations.

TABLE 28

Variable *	Complete Success	Failure
Still need to avoid triggers	6%	63%
Still have ectopics	25%	100%
Still have tachycardia	10%	40%
Still have flutter	10%	75%

* As observed at least 6 months following the procedure

Published Studies on Effectiveness

Several studies have been published regarding the efficacy of the mini-maze procedure with complete success rates (no afib, no antiarrhythmics) varying between 58% and 91%.

- A group of cardiothoracic surgeons (including Dr. Randall Wolf) reported on the success of 27 mini-mazes performed in 2003-2004. The complete success rate (no afib, no antiarrhythmics) after 3 months was 65%, which compares well with the 62% observed in this survey for top-ranked surgeons. The average hospital stay was 3.3 days and the average procedure time was about 3 hours[3].

- A group led by Drs. James Edgerton and Michael Mack of the Medical City, Dallas Hospital presented at the 2008 Annual Meeting of the American Association for Thoracic Surgery the results of a study involving 150 patients. The majority (55%) of the patients treated had paroxysmal afib, 20% had persistent afib, and the remaining 25% had the permanent variety. The patients were followed for 6 months at which time 58% were in normal sinus rhythm without the use of antiarrhythmics (complete success). The complete success rate for paroxysmal afibbers was 70% versus only 40% for persistent and permanent ones. Procedural adverse events were significantly worse than for standard RF ablations with 2 patients (1.3%) dying on the operating table, 4 patients (2.7%) developing a new heart block, and 2 patients (1.3%) suffering phrenic nerve palsy[4].

- Cardiothoracic surgeons at the Ohio State University treated 32 patients with persistent or permanent afib with laparoscopic full maze procedures and observed a complete success rate of 88%[5].

- A group of American and Japanese cardiothoracic surgeons treated 20 patients (80% paroxysmal, 20% persistent) with the mini-maze procedure and observed a complete success rate of 85% after 6 months. No major adverse events were reported[6].

- An American team based in Florida treated 100 lone afibbers (64% paroxysmal, 11% persistent, 25% permanent) with a mini-maze procedure using microwave energy for lesion creation[7]. The complete success rate after 6 months was only 31% and adverse effects were serious (3 patients died following the procedure, 2 patients experienced a TIA (mini-stroke), and 2 had a stroke). These results confirm the survey findings of a 25% success rate with microwave energy (based on a sample of only 4 patients).

- A team at the Nebraska Heart Hospital treated 22 paroxysmal afibbers with a mini-maze procedure and observed a complete success rate of 91% after an average follow-up of 18 months[8].

Summary

A total of 94 procedures, other than the conventional RF ablation (PVI), were performed in attempts to eliminate AF. The following observations were made:

- The outcome (at least 6 months after procedure) was known for 12 cryoablation procedures. Four (33%) were fully successful and one (9%) was partly successful. The average single procedure complete success rate of cryoablation is thus 33%, not significantly different from the average single procedure complete success rate of PVI procedures at 34%. There is insufficient data to say what the final success rate would be after repeated cryoablations.

- It is not possible, based on a small sample, to evaluate the success rate of an AV node + pacemaker implantation since it, at best, provides symptomatic relief only. Eighty percent of respondents felt (subjectively) that their procedure had been a success, while the remaining 20% felt that it has been partially successful. Thus, based on a small sample of 14 respondents it would appear that AV node ablation + pacemaker installation is usually a successful procedure and provides significant symptomatic relief even though it does not eliminate the fibrillation of the atria. Nevertheless, it is still the procedure of last resort.

- The full maze procedure performed by a top-ranked cardiac surgeon provides the best chance of being cured of afib with one single procedure (complete success rate of 88%). However, full maze procedures performed by less skilled surgeons tend to be considerably less successful. This, combined with the potential for significant adverse events (especially associated with the use of the heart/lung machine), would lead one to the conclusion that it may be "overkill" for a paroxysmal afibbers, with no underlying heart disease, to select the full maze over a conventional RF ablation or mini-maze procedure.

- A mini-maze procedure performed by a top-ranked cardiac surgeon provides the second-best chance of being cured of afib with one single procedure. It is also likely that even a mini-maze performed by a less than top-ranked surgeon will have a substantially better outcome than a single standard RF ablation performed by a less than top-ranked EP. However, the risk of adverse effects accompanying the mini-maze procedure is somewhat higher than for RF ablations.

This concludes the evaluation of the 2008 Ablation/Maze Survey. Again, my sincere thanks to all those who participated. A special thanks goes to Mellanie True Hills for providing the references regarding the effectiveness of the mini-maze procedure.

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