

THE AFIB REPORT
Your Premier Information Resource for Lone Atrial Fibrillation
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VIRTUAL LAF CONFERENCE

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SUBJECT: ABLATIONS

I have made some posts on the BB recently about a topic that I think warrants some discussion on this Conference Board. I recently had a consultation with a surgeon who has just begun performing minimally invasive robotically assisted microwave ablations. From my meeting with him and my subsequent research I have culled the following facts:

1. Microwave ablations (MA) are performed outside the heart (as opposed to catheter based ablations which have dominated the BB). A surgeon uses a flexible probe and makes a contiguous ablation loop around all four pulmonary veins and across the left atrium.
2. Up until recently, MA have been performed secondary to coronary bypass and / or mitral valve repair surgeries where the patient was experiencing AF due to the compromised heart.
3. Over 3,000 MA have been performed worldwide using AFx's most recently approved probe (FDA approved in 2001) with no reported adverse events such as stenosis or stroke. 700 of these MA have been performed on beating hearts as opposed to patients who have been put on heart lung support during the more serious heart operations.
4. The success rates for MA in open heart surgeries runs around 75%.
5. I have come across certain hospitals that have started, in the past year or so, performing open heart MA on lone afibbers.
6. The technique used by the surgeon I consulted with employs robotic tools (surgeon controlled arms). A small incision is made in the rib area allowing room for the arms, catheter and camera. During the procedure the surgeon can see what he is doing (as opposed to catheter based ablations) and there is no radiation exposure.

This technique is very new, but I am surprised that there has been little discussion of MA since I have been on this board for the past five months. There have been countless discussion with respect to catheter based ablations. I realize that up until now, the only available method for an MA was through open heart surgery. I have heard of so many people on this board who suffer enough from AF that they have gone through catheter ablations, some of which have had terrible results. The risk of stenosis is clear using current state of the art procedures. I believe that eventually a catheter based procedure will be available that eliminates these risks. But if I were

suffering terribly from AF and had to watch everything I ate and drank, my exercise routine, stress levels, etc. , in other words, a condition that has totally consumed my life, I would consider an open heart procedure which did not involve the risk of stenosis. Obviously there are other risks, but it is something worth considering. This is why I do not understand why more people have not considered open heart MA rather than risk permanent damage from stenosis or stroke. I don't know the statistics, but I would bet that opening the chest of an otherwise healthy, reasonably young lone afibber, poses less of a risk of serious consequences than current catheter based ablations.

In any event, this new procedure, which eliminates the risk of open heart surgery, but may offer the full benefits of an open heart MA, is worth discussing. Some questions that I would have are:

1. If an MA is not successful, would this preclude having a future, safer catheter based ablation? A second MA is not possible as opposed to current catheter ablations where a second procedure is possible.
2. Does the minimally invasive procedure result in the same type of ablation as the open heart version? My surgeon says yes, but I would be curious if there are other opinions.
3. Does the substantial lesion that results pose a long term risk? He says no and other doctors I have consulted agree with him. Far worse surgeries have been performed for decades and I don't believe that scar tissue from these procedures have caused long term problems, but who knows?
4. Is the success rate likely to be better on otherwise healthy lone afibbers as opposed to the current database which consists of people with serious heart defects? The surgeon I consulted with believes very strongly that his success rate will be closer to 90-95% because of this distinction.

The facts I have presented are from one consultation and research I performed on the Internet. I would welcome any further facts, opinions, hypotheses, etc. from the participants of this board.

Kerry

Kerry,

A good post with good questions.... the majority of which I am unable to answer. What I can add, however, is that my own cardiologist (and EP) - Dr Linker at the James Cook University Hospital in northeast England - mentioned the procedure to which you refer when I last visited him in Dec 02. He had had just had a visit from a US party of EPs who had visited him specifically to discuss the robotically assisted microwave ablations (RAMAs if you like). Linker seemed genuinely impressed, and enthused about the procedure as a good prospect for the near-future here in the UK. (I did mention this as part of my 'visit to my cardio' posting to this board at the time.) As for more detail: e.g. how long will it take to get the equipment here in the UK etc., I don't know.... I didn't quiz him much at the time of my visit since I fortunately do not seem to be one of the many individuals here who get plagued by AF on a fortnightly or weekly basis. Having had 'only' 3 AF episodes in the last 3.6yrs, I am not interested in an ablation for myself at present. However, I DO like to keep up with all the chat on ablations since I am a something of a worrier (I know, a problem/predisposing factor in itself) and want to be as well informed as I can be in the event that I end up needing a surgical procedure for AF sometime in the future.

Mike F.

I will be keeping informed about this procedure as the surgeon performing it practices where I live and is closely associated with my EP. In fact, I wouldn't be surprised if the group of EP's you were

referring to included her. You can e-mail me at any time, kacker@nyc.rr.com, if you want to follow up. In addition, the surgeon is French and probably has many contacts in France, in the event they start doing it there. I hope I don't hear from you because that means you are doing well and won't need to consider the ablation. Until recently, I had been experiencing weekly events and the meds do not help, therefore my need to keep informed about state of the art and ready to schedule if I can't take it anymore.

Kerry

I wonder what Cleveland Clinic's opinion of this RAMA (great name Mike) is, and if they have any plans to do the procedure. Does anyone know?

Newman

I believe I saw a reference to the procedure on their website. A good friend of mine is a physician and as a favour to me, he made a number of calls to the right people in a number of institutions to get some input. He told me that they all agreed that this will be the surgical treatment of choice down the road. I don't think that we are talking too long either. My EP said she would want a patient who is doing OK either through lifestyle changes or meds to wait about six months to see his success rate and complications rate, if any.

My guess is that EP's doing ablations will find a way to dismiss new and potentially superior surgeries. In the end, it's all about the money and there are huge bucks at stake here. And the pie is growing every day.

Jon

Kerry:

Briefly looking into it , it appears to be a surgical technique and quite invasive.

With their probe, I believe they must get to the "endocardial layer" or the innermost lining of the heart and PV ostia. So they would need to open up the left atria with clamping and bypass after they make their incisions in the chest. The probe's "antenna" can be encircled around the PV's on the outside.

Apparently the procedure can be done quickly (ablation portion in 15 min.), which gives it a leg up on RF catheter ablations which take time to position and use the catheters. This is recommended for CAD (coronary artery disease) patients. It may be for chronic AFers at some time but its success rate of 70% needs to improve to beat out RF catheters.

Just my opinion-- and I'm interested in ablations in general as I'm a candidate. Also for general info they're doing cryo-ablations in NYC in trials on AFlutter.

Anton

Anton,

You are referring to microwave ablations done during open heart surgery. This is not what I am referring to. This is a new technique which is precisely minimally invasive. It is called robotically assisted minimally invasive microwave ablations. They do not open up any chamber of the heart. The camera and arms are inserted through a very small incision in the ribs. The microwave probe

is inserted through the chest cavity and the ablation lines are made on the outside of the heart.

The reason, I believe, that the success rate on microwave ablations in open heart surgery is lower than catheter is because up until now the ablations were only done on sick hearts i.e. coronary bypass or mitral valve repair. This is not the case with the procedure that I have brought up. I believe that this will be the procedure of the future and will have success rates equivalent to catheter based ablations as soon as more procedures are performed. The risks cannot be compared. No radiation and the procedure is not done right at the ostia. Rather the ablation lines are made in a circular loop around all four pulmonary veins and across the outside of the left atrium.

A couple of other doctors are performing the procedure or at least minimally invasive microwave, perhaps not with the robotic assistance. Dr. Adam Saltman in Worcester, Mass and Dr. Argenziano (I hope spelling is correct) at Columbia Presbyterian in New York as well as Dr. Didier Loulmet in New York City.

By all means check it out and let me know what you come up with.

Kerry

Kerry

You are correct that the left atrium is not opened up, but I didn't see how the inner ostium of the PV's could be ablated without going inside. I did read a report that I don't understand sufficiently but it appears as though inner entry is gained through other catheters. The pericardium (sac around heart) is opened up to gain outside access to PV's.

The report is by Saltman et al, "A Completely Endoscopic Approach to Microwave Ablation for Atrial Fibrillation" and you could find this .pdf document through Google. It describes the "minimally invasive" thoracoscopic approach. "A central venous catheter and a radial artery catheter were placed" which I take to mean going into a vein and artery to get inside the heart. Requiring 3 holes (two 5mm, one 10mm) in the LHS chest and another 3 holes in the RHS chest for camera and instrument access. On ventilator, the RHS lung is deflated to access the heart from that side, then repeat on the other side, LHS lung deflated. Two rubber tubes (also catheters) are maneuvered so they encircle the 4 PV's (boxlike; one outside loop around 4 veins) and the ablating catheter goes into these tubes. Unless the inner catheters act as receivers of the energy I don't know how the PV inner entrance (ostium) gets ablated successfully. I'd sure want to talk to the Doc on that one.

Compared to Maze, that's minimally invasive but also less successful. It still doesn't reach RF ablation "acute" success but long-term data=? Whew, that tired me out!

Anton

Kerry,

Thanks for the posts. As time goes by, new procedures, instruments and techniques replace previous procedures, instruments and techniques. Great and rapid advances have occurred in just a few short years. This may be the next major breakthrough. We may all be getting these RAMAs in a year or two instead of PVI ablations. If this procedure is as good as it sounds, all of the major ablation centers will be anxious to start using it so they won't be left behind.

Please keep us informed on anything else you learn.

Newman

Newman,

You've got it. It will be a race to the money. I am going to set up an appointment with the only other surgeon (right now) in New York who is performing this procedure. He is at Columbia Presbyterian.

I also have corresponded with a surgeon in Mass. who is performing minimally invasive microwave ablations but not using the robotic arms. He has performed six procedures. All are in sinus rhythm and no adverse events. He has problem with one patient but he said it had nothing to do with the microwave procedure. That patient is in NSR despite the complication.

I didn't discuss the particular technique he used to get to the heart, but I read about it and it sounds like the robotically assisted technique is much better.

I will let you know the results of my next consultation.

Kerry

I am wondering if anyone has any information concerning catheter size for ablation. My understanding is that the 8mm catheter has only been approved for flutter ablations here in the US since Sept 2002 by the FDA. Dr. Natale has been using the 8mm catheter for some time for afib ablations. Most other centers are using the 4mm catheter. In the Jan 2003 afib report, it states that the 8mm catheter is superior. I am not so sure that this is true. I understand that different catheter sizes are used for different circumstances depending on the thickness of the cardiac tissue in a particular patient. Is Dr. Natale & co really that far ahead of everyone else in the US? Or is it hype from the CCF? Why is it that Dr. Warren "Sonny" Jackson & team at the Univ Of Oklahoma only report a 70% success rate on the first try, use mainly the 4mm catheter, have been to Italy and France under supervision of the doctors there who pioneered the PVI techniques, & the CCF reports a much higher success rate? Is Dr. Natale really that much better? Does he really have "magic hands" or is this just more marketing by the CCF?

Dr. Wharton at MUSC who used to be head prof at Duke Univ doesn't believe the 8mm catheter is superior. He prefers the 4mm & says the possibility of stenosis is less risky than with the 8mm.

I would be interested in what others have to say-including Hans.

Jim W.

Jim W.

Regarding your hype and marketing comments on the Cleveland Clinic, you may be interested in the following:

U.S. News and World Report has released their 12th annual "America's Best Hospitals" guide. Cleveland Clinic was ranked the fourth "Best Hospital" in America overall. The Cleveland Clinic Heart Center has received top ranking in the guide for the past seven years. The hospital has ranked in the top five of hospitals since 1999. Cleveland Clinic was noted for exceptional performance in 15 of the 17 medical specialties.

I have read your negative comments on the Cleveland Clinic for months, which appear to be

based mostly on speculation. Well, I'm a betting man, and I'd bet that you will have your ablation at the Cleveland Clinic, and will insist on Dr. Natale. The best is obvious to me and I think it is to you also.

Whatever your decision, I wish you the best of luck.

Newman

I have heard it takes forever to see Natale. Is this true?

Kerry

Kerry - yes it is true. If you have any intention of getting in to see Dr. Natale, I would start immediately and expect at least 6 weeks to 2 months to get in.

I believe I started in March and got in about 6 weeks later - early April and when they gave me the appointment for ablation, it was early November.

Since he only does two a day and not every day, his schedule is very spread out. There are at least four other EP's there that do ablations.

Dr. Natale also travels to other hospitals and teaches how to do ablations.

Jackie

Hi Newman & Kerry,

Newman-

You may very well be right & thanks for wishing me luck. My comments about the CCF have probably been negative because I know they are a high volume institution (this is not speculation) & frankly I have never associated high volume with quality. I honestly can't say, and do not know that Dr. Natale is the best. I have talked with several EPs & I can tell you that they hold Dr. Natale in high regard, but do not necessarily believe he is the best.

I'm not sure what I think of the US News and World Report concerning their best hospitals guide.

Kerry-

Yes, it does take a long time to see Dr. Natale. The waiting list averages about a year. I made my appt with him in Jan or Feb & am scheduled for Oct 17th.

Kind regards,

Jim W.

Jim - you and I have kicked this quality thing around for some time. The obvious dilemma is how do we really know who is good. Recently, we have heard from some forum members who have had ablations with Dr. Natale and were "cured" and some reported no stenosis - others may still be waiting out the three months. I have talked personally with two people who have had ablations there in the past 2 years; one by Natale. Both are cured and delighted with the outcome.

I'm still on the fence about Dr. Wharton. I'm wondering if anyone on the forum has had an ablation with him and if so when and what were the results. Several members have said he is a

very caring person and exhibits a high degree of competence when discussing the afib problem.

While I'd prefer to have great rapport with the person who is puncturing my heart, what I really demand is outstanding expertise and skill with those hands. I want the best results possible without any whoops.

Question is -- how do we really know. Do the results speak for themselves? I would say yes - but we all know that errors can be minimized and often hidden...so the healthcare consumer may never really and truly know the truth.

How is the ranking done in the US News Report? Is it like clinical trials for new drugs - the studies are funded by the pharmaceutical manufacturer...no bias there.

If they are ranked #4 in the US for hospital facilities - I'd hate to go to a hospital down somewhere in the list. I've been in there for 8 years dealing with afib and testing procedures...I've been twice to their ER, once for outpatient surgery and once for a four-day med change.

Since I have a healthcare background, I am more observant than most patients. I'm not overly impressed with housekeeping, efficiency, quality of non-degreed staff and their billing department is very inefficient. On a positive note, the RN's and the nurses aids are generally very good...but not all of them. The doctors, I've seen with a few exceptions, are above average - in my long history of seeing doctors. I have very high standards for healthcare delivery and I am hypercritical of those who don't measure up. I have raised my eyebrows more than once about infection control procedures. Oh yes, and there is a definite shortage of RN's.... but I understand that is all over the country.

I was very impressed with Dr. Natale and his EP team during the consultation and after for additional questions.

If you determine any significant reason why the 8 mm is better or worse than the 4 mm catheter, please let me know...it could sway me.

Thanks for all your posts and information in sorting out this worry some thing we will be facing sooner or later.

Jackie

Newman - I don't know how much stock you can place on this comment, but when I had my ablation consult with Dr. Natale around the first of April, some of us were very interested in the potential trials with ultra-sound with which Dr. Wharton was going to be involved.

When I asked Dr. Natale about the future of ultrasound and his doing it, he said he had already tried it and was not interested in another trial....but - he did say that the up-coming procedure of the future would be ablation by laser. He suggested that was at least 2 years ahead in the future.

Jackie

Either way, Jackie, I believe that Natale only discusses procedures that are done by EP's. That is his world. If the shift is towards a surgical procedure, his business is threatened. And make no mistake, this is a big money business. The first microwave ablation that I referred to cost the patient a cool 100 Grand, all but 250 bucks paid for by his insurance company.

Kerry

Following are notes from my Ablation Consult with Dr. Natale and his EP Nurse, Charlene.

Ablation Consultation at CCF

Date: 4/2/03

Aptmt 8:30 a.m.

Taken In 9:40 for interview with Charlene, the EP Nurse. (1 hour)

10:45 left to wait for Dr. Natale

11:45 – still in surgery

1:00 put in room – He came right in

1:40 p.m. left CCF

Key – DN – his answers - C = Charlene since she did most of the interview beforehand. My questions in italics (which don't show on this forum) so it is the first question or statement.

Note: Dr. Natale is somewhat difficult to understand because of his accent, so it makes understanding what he is saying more difficult because first, you have to figure out what he said and then get that concept into your mind. He is an extremely personable man; soft spoken, very open; very receptive; very easy manner, casual... easy to like. Probably about 40 or less premature gray hair.

Where receive education and training on ablation?

Med school in Italy; Residency in Canada; Ablation techniques – lesser known facility in either Milwaukee or Minneapolis. At U of Kentucky – 4 years and CCF 4 years. DN

How many have you personally done?

600 – 200 last year - does 2 a day but not every day. DN

Discuss the stenosis problem with me. As I understand it – 75% stenosis is considered Severe and represents 1% of the patient population having ablation. 50% is considered moderate and is also 1% and slight, 25%...What are the symptoms? Treatment? Success of stent Treatment? How many/year?

Yes, this is correct. Many people have no symptoms either at 50 or 75% – it is measured by lung function as in those experiencing shortage of breath. Stents are used to treat. Some success. Can't recall any stents in the past year. DN

Define Success:

Success = no meds, no afib. - There is 80% success presently with ablation.

If second ablation is needed – success rate is 95%. C

How is it determined that I am a candidate?

Intolerance to antiarrhythmic drugs – not holding. And no heart defects.

The procedure- what to expect: C

--Post surgery – the heart is in a state of irritation for 2 – 3 months. Afib can occur.

--Pts. Placed on Lipitor – cholesterol lowering drug – they think it helps control the inflammatory process and may help inhibit stenosis.

--Pt. goes home with an event monitor to use when events happen – phone in results.

--In 3 months – a follow up with a spiral cardiac CAT scan is performed to determine if there is stenosis.

Conscious sedation is used...Phentonal (sp) and Versed... (Like for colonoscopy)

The reason why not general is because of risk of stroke during procedure and if this should happen, they are able to do remedial measures within the window of opportunity to reverse the consequences. Risk over age 60 is 2%

Pain – virtually none - some feel burning in chest.
Dr. Natale does the ablation; residents do the entry sites.etc.
Preparation and surgery is 4 – 5 hrs, but the actual ablation is only 1½ hour procedure.
There is 6 hours of bed rest afterward and then admitted to hospital overnight... home next day.
No heavy lifting for 48 hours.

The ablation is a ring of scar tissue around each of all four pulmonary veins. There is a risk of bleeding with the penetration of the septal wall.

Important to stay on coumadin until the procedure since if have to be cardioverted, and the INR is good – it's a quicker procedure.

There is a problem if the afib goes longer than 24 hours since – once ablated, can't be cardioverted for at least 2 weeks, so medication only is used to convert if possible.

Discussed bleeding tendency - She says they pay a lot of attention to the entry sites – which are 3 – 1 carotid and two groin areas. There is a heparin drip during the procedure but as it is completed, a coagulant is given and extra care is given to be sure there is no bleeding.. and they check several times for clotting levels and INR. There is pre-surgical routine - need to be off Flecainide one day before and off coumadin for 3 – 4 days prior. She said if I had a great concern, to discuss with my primary care doc and then see a hematologist.

Women vs. men – smaller vessels any more risk? No – the entry sites are small openings just like what would be for a regular IV and the size of the vessels isn't typically a problem. C

Need for autologous donating? No – isn't a common precaution...excessive bleeding isn't typically a factor. C

Question to Dr. Natale on the Ultrasound procedure.

There is talk of a new trial going on with Dr. Wharton in S.C. and two other area facilities. Internet people are suggesting it is a better procedure in that there is no stenosis risk?. Is this a true statement?

Do you know of Dr. Wharton?.

Yes, I know Dr. Wharton. We did the ultrasound here. There was a catheter tip in a balloon device. The problem was incomplete ablation – the balloon is structurally round and veins are irregular in shape and all different. The balloon did not contour or adjust to fit vein variation so places were missed and it wasn't evident that they were until afterward. I told these people I would not be interested in another trial because the balloon is essentially the same tip but just made by a different manufacturer who now wants to get approval.

The only equipment changes now will be to accommodate a wider skill range (allow more ablations by less skilled people- to allow more income) but result will be less precise.

In a year or two, laser will be the treatment of choice if it goes as they think it will.

Post op- he uses cholesterol lowering drug – Lipitor – for a 2 month regimen to reduce inflammation – thought to be a large factor in stenosis...those measured by CRP and found to be high – seem to correlate to the stenosis process. They are also going to try soon an additional drug – immune suppressing – to lessen chance of stenosis. It is a short course treatment and is not prednisone. (I didn't have the courage to ask him if he also prescribed CoQ10 to go along with the Lipitor.)

In the case of a second procedure – there is a 95% success rate – and is often needed in patients with thick myocardium... some have a much more dense muscle and seem to need a thicker layer of scar tissue laid down in the PV area of ablation.

How long can I go in afib now before going to the ER?

If you are comfortable, and not in any distress, you could wait 24 hours. I wouldn't wait longer than that. (That's better than 2 hours.)

I was given November 10 as the ablation date.

The End.

Jackie

Jackie,

Thank you very, very much for the synopsis of your consult with Dr. Natale. I am hungry for first hand information from those "on the front lines". There are dozens of ablations performed every week in this world, but it is seldom that we get reports like yours. If even ten percent of the people would report their consults and ablation summaries, it would be easy for all of us to keep up with the latest, and would make choosing an EP and a center and a procedure much simpler.

Please clarify a few of your comments:

(1) You said it is important to stay on coumadin until the procedure. You also said you need to be off coumadin for 3-4 days prior. This appears contradictory.

(2) You said intolerance to antiarrhythmic drugs-not holding. I don't understand "not holding".

(3) What is autologus doning?

(4) "How long can I go into afib now before going to the ER? You could wait 24 hours. I wouldn't wait longer than that". I don't understand. I often have episodes of afib for several days. I am on coumadin for stroke prevention and on Toprol XL for rate control. This works well and the risks of not going to the ER are nil. Why would one need to go to the ER if on the proper medication?

Thanks mucho again for your taking the time and effort to inform us. I will return the favor someday.

Regards,

Newman

1) The cardiologists all want me to stay on coumadin -- you know, the risk factor, the fact I've had a cardioversion - and just a CYA approach to the risk factor....standard of care protocol... so if I have a stroke, they have followed the rules and their liability for mal-practice should be limited.

But - they want you to be off coumadin 3 - 4 days prior to ablation because, I guess, you blood really is too thin for this type surgery. I can attest to the detrimental effects of coumadin because I have sustained two really nasty, huge hematomas - one from iatrogenic trauma while in the hospital and one, from exercise. Apparently, coumadin makes tissue very, very fragile.

2) Holding - meaning the antiarrhythmic drug keeps the patient in NSR. When it doesn't "hold" one in that state, it is called breakthrough events. It is the goal - in my case - and with increased dosage of flecainide, to keep me in NSR without breakthrough. Easier said than done. It is not "holding" me there.

3) autologous donating - self-donating of own blood. I have a history of bleeding a lot with surgery and have always donated a couple of pints of my own blood ...just in case so I don't have to accept the donor blood on hand. The answer was that little, if any blood, is lost during the procedure.

4) Waiting longer than 24 hours while in afib.... Since the cardioversion, my cardiologist, the ER people, and the EP are all very nervous about going longer than 24 hours in afib. I have been told emphatically that I must show up in 24 hours at the ER. I know there are many afibbers who simply wait out an event - I always did that as well, but when I had one session go 48 hours, I did go to the ER and I was in aflutter - didn't convert naturally, and after the wait in the hospital to get the INR within range as required for conversion. That was when they really began emphasizing coming in early. In fact, the rule for 6 weeks was to go to the ER if a breakthrough event lasted more than 2 hours. As you can imagine, this was very restrictive - how could I go anywhere or do anything when I needed to report to the hospital which was an hour away. Eventually, I relaxed that rule on my own - but did go within 24 hours - that event self-converted after 39 hours.... but I still was kept in the hospital several days. (maybe they needed the business?)

The urgency of the matter is not that your heart is in afib - but rather when you come out of afib - that's when the occurrence of clots is highest. I know Hans has waited out afib for - it seems - 10 days he said ... I think it all depends on one's comfort level with the risk involved. I was very comfortable riding out the flutter - but everyone at the ER was really upset and treated me like I had lost my mind. Actually, when I told them I had worked out on the treadmill in an effort to convert on my own, the jaws dropped open. (They should see this forum and the things we report we've tried.)

The odd thing (I feel) is I've ridden out this afib thing - as most of you all have - for 8 years.... with events becoming longer in duration and increasing in frequency.... yet - NOW - they are concerned? I'm at a loss to explain this new twist completely, myself...other than the risk factor and the medico-legal implications - which most probably is the driving force.

Of course, I'm not anxious to have a stroke. However, I've always taken all the natural supplements for blood thinning and my other doctor, the functional medicine MD, feels my protime is very protective and anti-clotting.

However, the cardiologists do not.

I hope this helps, Newman. I'll post any new news I receive and I fully intend to post a recap of the ablation procedure if and when it happens.

Jackie

Jackie,

Thanks for your reply to my questions. I have another. I am puzzled by: "The only equipment changes now will be to accommodate a wider skill range (allow more ablations by less skilled people - to allow more income) but result will be less precise". Is this an opinion by you or did Dr. Natale say this? Would you please elaborate?

(1) "The only equipment changes...". Did Dr. Natale say this and if so, does this mean that he is currently satisfied with his catheters and probes, etc. and will never change? Surely not. Or does it mean he won't change until something better comes along? Or did he not say this?

(2) "...will be to accommodate a wider skill range...". Did Dr. Natale say that the Cleveland Clinic will be changing some of their equipment because some of their EPs don't have the ability to use the state of the art equipment? Surely not.

(3) "...but result will be less precise...". Once again, this is surely not Dr. Natale speaking about the Cleveland Clinic lowering their standards.

(4) "...to allow more income...". This must be an opinion by someone. You?

So one short sentence raises many questions. I hope you can clarify it. It appears to state or at least imply some very negative things, and implies a lowering of quality in the future and maybe not adopting new procedures in the future. Am I interpreting this incorrectly?

Thanks in advance.

Newman

Jackie- - An excellent report on your CC visit; it describes most of the points they spoke about with me and then some. When Natale talked to me, he was still using a 4 mm cooled tip catheter but was hoping for a FDA approval of the 8mm that he favored after using it in a hospital in Europe.

Catheter notes--Jim W et al:

The 8 mm catheter generally ablates a larger segment of PV opening than does the 4 mm and decreases the ablation time. The penetration depth is also important but hinges on the temperature which can be increased or decreased during ablation. In CC the temperature is governed in part by the "bubbles" observed by their ICE (intra cardiac echo) catheter as seen on the echo screen. Small bubbles, good; large bubbles, too hot. (OK about 50 deg.C on a tip thermocouple) Yes, the bubbles are blood boiling and this could lead to one of the problems encountered with hot tip temperatures.

There is a 4mm catheter with a "cooled tip" that is very successful and is preferred by some PC's. The probe is cooled so that the ablation temperature can be increased and achieve better tissue penetration. Natale used to use a 4mm cooled tip cath prior to FDA approval of the 8mm. But the selection is not especially with the catheter but with the EP that will do the ablation. If a PC has had good success with a catheter, he won't want to try a new one without convincing evidence of it's superiority.

The mapping and echo catheters are important too. CC (among others) uses a "lasso" type cath to map the PV's and the ICE cath to help position and view the PV's and ablation "bubbles." CC uses another catheter in the right atrium to aid in mapping and will include ablation of the top vein on that side if needed. (sup.vena cava)

I'll quote a lab document that probably was lifted from Biosense-Webster so naturally it's biased: "Compared to standard 4 mm tip catheters, the larger 8 mm tip on both dual sensor catheters has a much larger surface area exposed to local blood flow during a procedure. This blood flow serves to cool the tip, enabling the delivery of higher energy levels - up to 70 watts with the Stockert 70 RF Generator. The presence of two temperature sensors in the 8 mm tip facilitates precise temperature control that can help to reduce the risks of incomplete, low temperature

ablations or excessively high temperatures at the tip that can cause char and coagulum formation."

Technically challenging!

Anton

Anton,

I'm sure you are right on about a doctor not wanting to try a different catheter if he is using one that is giving good results. What confuses me concerning Dr. Wharton is that he says the 8mm catheter can increase the likelihood of stenosis. Obviously the French, Italians, and Dr. Natale do not agree.

Jim W.

Jim--Re: Stenosis risk with 8mm-- in careless hands I guess that might be true. Only speculating but I think the 8mm takes more overall energy and the power needs to be monitored closely. The larger burn area means trouble if not positioned accurately. I'd trust Dr. Wharton's knowledge and his success rate.

Anton

Dr. Natale told Jackie that in a year or two laser ablations would probably be the treatment of choice. Fascinating.

Does anyone have any information on laser ablations?

Newman

Hi Jackie,

From your notes, "Yes, I know Dr. Wharton. We did the ultrasound here. There was a catheter tip in a balloon device. The problem was incomplete ablation – the balloon is structurally round and veins are irregular in shape and all different. The balloon did not contour or adjust to fit vein variation so places were missed and it wasn't evident that they were until afterward. I told these people I would not be interested in another trial because the balloon is essentially the same tip but just made by a different manufacturer who now wants to get approval."

I am still somewhat confused as to why Dr. Natale isn't interested in further trials while other top EPs in the US are. Dr. Wharton obviously still is. Also, here is an excerpt of an e-mail I very recently received from Dr. Warren "Sonny" Jackson at the Univ of Oklahoma, "There are several systems under development for ablation using ultrasound energy, laser, or cryotherapy for pulmonary vein isolation. The most promising of these uses high energy focused ultrasound delivered through a balloon, which is placed against the pulmonary vein. This system has been tested in animals with impressive results. We anticipate clinical testing will begin in 2-4 months."

As you can see, he doesn't seem to hold as much promise in laser as ultrasound-contrary to what Natale believes.

Oh Well,

Jim W.

Jim - Beats me.

As you and I have talked, and as in dentistry, you have favorite burrs for certain types of procedures.. and I had my favorite scalers and currettes. We are comfortable with these and find them reliable. Perhaps this analogy could be used with the catheter tips... Dr. Natale is blazing his own trail with what he likes and perhaps (ego) he prefers to lead than follow...

What I'm interested in is the perfect result without any harm to me. How can we know who will deliver this to us? We can become informed to the best of our ability and then turn it over to the experts and to God. It's out of our hands. Trust and faith.

Thanks for your thoughts - keep them coming.

Jackie

Jackie,

For what it's worth, here is the way I figure it - so far.

Dr. Natale graduated from med school in Italy at the top of his class. Came to the US and somewhere along the line became interested in Afib. (Maybe he realized how lucrative it would be-I don't know) Because of his connections in Europe he started working there yearly(for some time as I understand it)-studying and learning new ways of treating AF. Supposedly in Europe he has a 100% success rate because there he is allowed to use 100 watts with the 8mm catheter. Here his success rate is 80+% using 70 watts. He used the 8mm cath in Europe way before it was approved here in the US, and that is why he is probably more comfortable using it than most other EPs. Yes, this is speculation.

A couple of weeks ago I spoke with a person who has worked at Biosense Webster for years. She knew Drs. Natale & Wharton and spoke very highly of them, but wouldn't say much more. However, she phoned a patient and told him about me to ask if it would be OK to give me his phone # so I might ask him some questions. I called him & he ended up sending me an 8 minute video of him & Dr. Natale. Basically it seemed like an infomercial for Biosense Webster. Nevertheless, it was interesting. Dr. Natale seemed very humble.

Dr. Jackson & his team have been over to Italy (maybe France-not sure) and have had instructions in the cath labs there. This is not speculation. They are reporting a 70% success rate and say there isn't one catheter better than another at this point in time.

Dr. Wharton has been doing ablations for a long time, most probably longer than Dr. Natale. He knows of the 8mm catheter and is staying away from it most probably because he doesn't feel comfortable with it (this is speculation). Dr. Wharton success rate is high with the 4mm catheter because he takes an incredible amount of time doing the procedure. He calls himself a "tinkerer" and says sometimes if he feels there are more "rogue" impulses he will wait for them to occur-which prolongs the procedure. He said my total time on the table would be from 6 to 8 hours & if he needed to go to the bathroom he certainly wouldn't "hold it". I would be there when he got back. One impression my wife & I both got from talking with Dr. Wharton is that he wasn't in this for the money or ego. He is a very genuine individual.

So it all boils down to, I just want the best person to fix my afib! It seems the herd mentality is -

hands down - Dr. Natale. I never have liked going with the herd, but it may be that I am becoming one of the herd. Shucks.

Jim W.

Jim W. I appreciate your assessment and all the considerations involved.

I also appreciate your comments about the herd mentality. I agree - I don't want to be classified as one of the "herd."

Perhaps Dr. Natale and Dr. Wharton each are not willing to be in the herd of EP's who follow only one strict method or protocol for the tip, the procedure, etc. but rather make some refinements unique to their own thinking and their own skill...most likely by trial and error or for another term. success and the need for a second ablation.

From what you've told me about Dr. Wharton, I believe he is a fine EP and surgeon. I would definitely go to him if he were closer - and I may still do that. I like the idea he is taking it slow and thoroughly. I dislike the idea that "if it doesn't work the first time, no big deal, you come in for a second ablation - touch up procedure." I don't like anesthesia and the aftermath and a second procedure sounds like the trip from hell. Just my opinion.

For me, I have not yet decided if - when - and with whom.... but this forum is certainly helping me examine all the possibilities.

Keep your thoughts coming. They help. Thanks.

Jackie

Newman - Dr. Natale made the statement to me. And yes, you are interpreting it correctly. What I took it to mean was that new catheters would make it easier for people with less skill and less experience doing ablations - to do them anyway but the results would be less "precise" which I took to mean "accurate and results oriented"... maybe the success rate would be lower.

As we know, ablation is not offered in all medical facilities. We also know that cardiologists take "courses" or lessons on how to do them. If this works the way it did when gall bladder removal was first done by laparoscopy, the surgeons watched a video of the procedure and then went out to do it. This resulted in some bad outcomes - deaths and lawsuits... I remember discussions about it when I was taking paralegal classes about 10 years ago.

I believe the demand to do ablations locally is here and Dr. Natale is helping other locations get up to speed. After all, they lose money when patients go elsewhere.

Dr. Natale travels to various hospitals and teaches his technique. Not EP or cardiologist is going to have initially, or will develop, an infinite skill that is far superior. Hope this helps.

Jackie

Jackie,

Thanks for your reply to my questions. I have another. I am puzzled by: "The only equipment changes now will be to accommodate a wider skill range (allow more ablations by less skilled people - to allow more income) but result will be less precise". Is this an opinion by you or did Dr.

Natale say this? Would you please elaborate?

(1) "The only equipment changes...". Did Dr. Natale say this and if so, does this mean that he is currently satisfied with his catheters and probes, etc. and will never change? Surely not. Or does it mean he won't change until something better comes along? Or did he not say this?

(2) "...will be to accommodate a wider skill range...". Did Dr. Natale say that the Cleveland Clinic will be changing some of their equipment because some of their EPs don't have the ability to use the state of the art equipment? Surely not.

(3) "...but result will be less precise...". Once again, this is surely not Dr. Natale speaking about the Cleveland Clinic lowering their standards.

(4) "...to allow more income...". This must be an opinion by someone. You?

So one short sentence raises many questions. I hope you can clarify it. It appears to state or at least imply some very negative things, and implies a lowering of quality in the future and maybe not adopting new procedures in the future. Am I interpreting this incorrectly?

Thanks in advance.

Newman

Jackie,

How much time elapsed from the first contact you made with his office until the date of the actual ablation?

Kerry

Kerry - I haven't had an ablation - yet.

I made the appointment, I believe in early March 03- I think I had to wait about 6 weeks - so maybe the end of February; I had the consult in early April 03 and the date I was given for ablation was November 10, 03.

Jackie

Jim W.,

When it comes to ablations, if everything else is equal, I want the high volume guy. Natale has done 600 ablations. There is an EP out there somewhere who will do his first ablation tomorrow. Terrifying! I'm sure there are other excellent EPs who have done many ablations and have excellent records and success rates. It is just so damned hard to get information about them. I do feel that CC publishing their success rates is the right thing to do. I haven't heard anyone advertising higher rates. If I had an 80% success rate, I would certainly advertise it. They have earned the right to do so and be proud of it. Dr. Natale may not be the best. How would one determine who is the best? Success rates and the opinions of his peers is the best indicator. His success rates are excellent and all reports I have heard or seen about him are excellent. Is his choice of catheters the best choice? How can we know? I am scheduled for an ablation this autumn with Dr. Natale. He is my first choice based on the number of ablations performed, his success rate, his complication rate and comments by his peers, as well as many of his patients. I will let him choose his catheter. I have confidence that he has the knowledge and experience to

choose the right one. He may not be the best, but until someone can convince me with facts that someone else will give me better odds of a cure, he is my man.

Thanks for your research. I read the info you post avidly.

Concerning Dr. Wharton, how many ablations has he performed? What is his success rate? What is his definition of success? What is his complication rate? Does he speak clearly in answering these questions, or does he mumble like many of these guys do? Do you have answers to these questions about any other EPs? If so, please post them.

Newman

Hi Newman,

Dr. Wharton was head Professor at Duke Univ. During that time Dr. Natale was assistant professor under him. Dr. Natale then moved on to the Univ of Kentucky. Dr. Wharton has done well over 400 ablations and is giving me a 80% chance of success. He is a person who takes his time, is not interested in volume, and is very available. I haven't met Dr. Natale, but understand he is a very humble person who truly has a desire to cure people of afib.

At this point, I am in question that Dr. Wharton does use the 4mm catheter because from what I read from the French and Italians, the 8mm seems to be the main one they use because it is cooler and produces less charring of the tissues. But, hey, I'm just struggling here and trying to understand the difference. Dr. Wharton has his ideas, they have theirs. I'm not so sure I am the one to figure it out.

Jim W.

Jim W.,

Concerning Dr. Wharton and the important questions to be answered before choosing an EP for an ablation:

(1) Question: How many ablations has he performed? Answer: Well over 400. Excellent. No problem here.

(2) Question: What is his success rate? Answer: "He is giving me an 80% chance of success". This sounds like a prediction of the future instead of a record of the past. Is this a mumble?

(3) Question: What is his definition of success? Cleveland Clinic states unambiguously "No atrial fibrillation at three months and no meds". Answer: Unknown.

(4) Question: What is his complication rate? Answer: Unknown.

They are in the backstretch and Natale is about 15 lengths ahead! Maybe someone can give us some answers that will help Wharton close the gap.

Newman

Thought some of you may be interested in this.

I just received an e-mail from Dr. Wharton concerning the 4mm vs 8mm catheter. I asked him several questions and I'll quote here what he had to say:

"With regard to 4 mm vs 8 mm catheters, I do not feel that it makes much difference one way or another, although there is a lot of controversy around this due to the lack of prospectively acquired data. The thought behind large tip catheters is that the proximal portion of the electrode is cooled during RF application by ambient blood flow, which allows passage of higher powers of RF to generate larger lesions. In addition, it is supposed to cause less endothelial damage. While large tip catheters are useful for making larger or deeper lesions, for PV isolation you only need to make lesions 1 mm deep since the atria are so thin, and the PV even more so. While larger tips may be quicker due to making larger lesions, it is also true that it is harder to control where you make a lesion, thus you are burning more than is necessary. The more important issues are appropriate regulation of power (regardless of tip size) and ablation at the ostium of the PV, rather than within it."

Next, I asked if technology was really refined to the point where one could actually tell if you were 3-5mm away from the pul vein, and if so then was stenosis really not a problem as the French claim?

His answer:

3) "3-5 mm is 1/10th to 1/5th of an inch. Technology is NOT so refined that we have the capability of localizing catheters with that precision. In addition, during respiration, catheters slide in and out with excursions greater than 5 mm (a bigger problem by the way with the large tip). Furthermore, defining the ostium is problematic, since they are not like "drain pipes" with abrupt right angle junctions to the left atrium, but rather gradually taper into the atrium (especially the superior PV's). Various techniques are available to try to define the ostia, including venography, intracardiac echocardiography, and electroanatomic mapping to generate 3-D reconstruction of the vein. We use all three, the latter is extremely helpful, but more time consuming, but has the advantage that you can tell in real time where your catheter tip is relative to the ostium throughout your RF application without having to use fluoroscopy. Thus, we can monitor sliding, dislodgement, slipping into the PV, etc, much more closely. It, however, adds an additional hour to the procedure time, but I think it is worth it. Since mapping is more precise, it obviates the need for indiscriminate burning (ie, large tip catheters).

I would appreciate your comments and thoughts.

Many Thanks,

Jim W.

I exchanged e-mails with Dr. Saltman regarding microwave ablations. Keep in mind that he is not using the robot arms which I believe is better for the surgeon. I have included below the text of my questions and his responses. There were two mails. By all means, e-mail him at aesmdphd@hotmail.com:

FIRST RESPONSE FROM SALTMAN:

Well, you have a lot of questions, Kerry. And I'm sorry it took so long to respond, but here goes:

1. I know that open heart ablations are being performed using the Afx ablation system. Do you know how many ablations have been performed? Have these procedures been done on beating or non-beating hearts? If they have been done on beating hearts, should there be a difference in difficulty in using the probe on a beating vs. non-beating heart.

The AFx system has been used in over 3000 cases worldwide. About 2/3 have been arrested heart, but more and more are being done on beating heart. I strongly believe that beating heart

ablations are actually easier.

2. Have there been any adverse events (stenosis, stroke, etc.) associated with the open heart ablations?

No. Microwave is very safe.

3. How many minimally invasive procedures have been performed? Have there been any adverse events?

I have performed 6 minimally invasive cases and had to convert 1 to an open case for bleeding (which had nothing to do with the probe). Another surgeon has done a robotic case.

4. As a theoretical matter, should the minimally invasive technique make it more difficult for a surgeon to utilize the probe and achieve the same results as the open heart procedure? I guess what I am wondering is if a surgeon has a) experience in minimally invasive techniques and b) experience with the use of microwave probes in the open heart technique, how much room is there for improvement on the part of the surgeon? Can I feel confident that such a surgeon should have no problem helping me even though he has not performed many minimally invasive procedures?

Well, it is safe to say that all minimally invasive procedures are more difficult on the surgeon! But that's not the issue - it's much better for the patient. Experience has to be gained with all of these techniques and currently we (surgeons) are learning and developing new approaches all the time. What I can say specifically is that you will receive exactly the same ablation through the 'scope as you would through an open case - that is way I've designed and carried out the procedure. Nothing is sacrificed.

5. As a general matter, is a 47 year old, otherwise completely healthy male who has paroxysmal AF a good candidate for minimally invasive microwave ablation using the currently available techniques?

You would be an excellent candidate. The only real risk for you would be that of anesthesia.

6. Is there any good reason for me to wait for a period of months, or a year or so, to have this procedure done? In other words, is there likely to be an improvement in technology or technique over the next couple of years?

Things are always improving. I am actively working with several companies to improve the technology and I know it will get better. Will this be in 6 mos? 1 yr? I don't know. You have to decide how "miserable" you are and when you want to pursue things. There is an excellent cure for you available now with a high success rate (>80%) and low risk.

7. Do you know of any surgeons in the NYC area (where I live) who do microwave ablations, using minimally invasive technique?

Dr. Argenziano at Columbia is the one I was referring to : One case, with a robot. Nothing since, I think.

Good luck and let me know if you want to talk more.

SECOND RESPONSE FROM SALTMAN:

a. Since the majority of the 3000 cases done so far using the AFx probe were done on compromised hearts, do you think that the success rates will be higher for otherwise healthy

people. Or was the 80% success figure you gave referring to healthy cases?

This figure comes from all cases done on "all hearts". The vast majority were done in combination with coronary bypass or valve repair/replacement.

b. If the procedure is not successful, and sometime down the road a catheter based ablation is developed that does not pose the risks associated with such ablations today, would I be able to have this kind of procedure after having had a microwave ablation. Obviously a second microwave procedure would not be possible.

If the procedure is not successful by itself, many patients then respond to drugs whereas they did not before the ablation. Also, the "risks" of microwave ablation, particularly if done minimally-invasively, are extremely low. Lower, in fact, than any percutaneous procedure now available. And "second" microwave procedures certainly are possible - I have already done them.

c. On the six cases you performed using minimally invasive surgery, what was your success rate?

All patients are now in sinus rhythm, although all experienced some temporary post-operative AF and one required a cardioversion as an outpatient.

d. Is the procedure an all nothing thing, that is, is success a total cure or does success also include improvement without total elimination of Afib?

Typically people are cured. No more AF.

2. You mentioned that you believe that beating heart ablations are easier. I am curious about that. I would think (in my layman view of course) that a heart that is "still" would pose less difficulty for the surgeon in terms of placement of the probe, etc. Could you explain?

Well, it is easier to see the landmarks and perform the ablation from the outside of the heart. Motion is not a significant problem.

3. Are you concerned at all about the possible long term effects of the scar tissue created as a result of the procedure?

No. Other operations, such as the classic cut & sew maze, resulted in far more scar and patients appear to have done well over many years.

Kerry

Jim,

Great information.

Does anyone know if Dr. Natale uses venography, intracardiac echocardiography, and electroanatomic mapping to generate 3-D reconstruction of the vein?

Newman

Newman,

Dr. Natale uses the same Carto mapping system made by Biosense Webster. ICE & venography are also used at CCF. Also the fluoroscopic time of exposure is about the same length of time for

both EPs even though Dr. Wharton's procedure is longer.

Jim W.

Sounds like this guy has his act together. Does he have real data available on "success rates" and stenosis rate.

Kerry

Kerry,

I too made first contact with Cleveland Clinic in March and they scheduled me for an ablation in mid October. There was a seven-month wait in March, 2003.

Don't despair. Before our very eyes we have at least two people with ablation dates at Cleveland Clinic who may change to Dr. Wharton. There may be many more who cancel. If your afib is bad enough, maybe CC would slip you into a cancellation slot.

Newman

- 2.) no mumble
- 3.) Same as CCF
- 4.) ditto

Jim W.

Jim W.,

If you are correct on (2) and (3) and (4), then we may be down to only catheter size and magic hands. As for me, I trust Dr. Natale to choose the catheter size. There is some evidence that he does have magic hands. Therefore, I put Natale a length or two ahead. You may have them neck and neck.

Thanks for your research. It is nice for us to be able to make a choice between two thoroughbreds.

Newman

P.S. No one has talked about Dr. H. and Dr. Jais at the French Bordeaux Group for a long time. I believe they may also be at the front of the pack. All of my research puts them in the same league with Natale and Wharton.

Hi Newman,

I am curious as to the "evidence" that Dr. Natale has "magic hands". I have heard this before, and so far consider it hearsay. Maybe it would take "magic" to know you were exactly 3-5mm away from the PV as I don't believe the technology is that exact yet. Anyway, I would love to hear.

Thanks,

Jim W.

To those interested,

I think this article may provide some "clues" as to choosing an EP to do the ablation. It makes me wonder that I may not be a very good candidate since my AF is persistent.

I would be interested in hearing comments, etc.

Thanks,

Jim W.

N.A. Mark Estes, III, MD, New England Medical Center, Boston, MA
Pierre Jais, MD, Hospital du Haut-Leveque, Bordeaux, Pessac, France

May 15, 2003

Ablation of Atrial Fibrillation: Patient Selection and Technique Catheter Ablation

Speakers at this mini-course emphasized that patient selection for ablation hinges on three key factors.

These are (1) the presence of paroxysmal rather than chronic or persistent atrial fibrillation, (2) failed previous clinical trials of pharmaceutical interventions and (3) left atrium volume below 5.0 cubic centimeters.

The meeting also heard from experienced practitioners that, according to long-term outcome data, linear ablation of atrial fibrillation might offer a survival advantage over medical therapy.

Experts elucidated in detail several of the many available ablative techniques, such as pulmonary vein isolation and linear ablations. They reported that long-term success rates of 70-90% had been achieved, with complication rates of only 3-5%. The chief complication, pulmonary vein stenosis, could be reduced by ablating in the left atrium rather than in the pulmonary veins.

In a presentation on patient selection and post-ablation management and outcomes, Carlo Pappone, MD, PhD, H.S. Raffaele, Milano, Italy, emphasised that "very aggressive" curative and symptom-palliating approaches were needed in patients with long or frequent episodes of atrial fibrillation or who had significant symptoms. "The ablation strategy is the most important way to do this", he declared. "Our ablative strategy is to create circular RF lines of conduction block around all four pulmonary veins, using a non-fluoroscopic electrogeometric 3D mapping system". To avoid vein narrowings, ablation was performed more than 5.0 millimeters outside the pulmonary vein ostium.

However, it was now clear that the dream of a cure had not been achieved. Nor was it possible to regard pulmonary vein disconnection as equivalent to cure. Dr. Pappone's unit's approach had been to use atrial debulking to modify the substrate in the left atrium by performing a single circumferential line involving all four pulmonary veins in order to isolate the posterior wall. His unit had also shown that the successful treatment of chronically affected atrial fibrillation patients, the most important group, was probably due to both pulmonary vein trigger isolation and left anatomical remodeling of the area encompassing the pulmonary vein ostia.

Dr. Pappone outlined a non-randomised study which evaluated mortality, morbidity and quality of life in 1,171 consecutive myocardial infarction patients after circumferential pulmonary ablation (n=589) or medical therapy (n=582). There were significantly fewer recurrences of atrial fibrillation in the ablation group; recurrences of paroxysmal and chronic atrial fibrillation were concentrated in the first six months after ablation and the recurrence rate was especially low after 10 months. "The idea that the effect of ablation is only brief is untrue — the long term effect is better than the short term". Modification of the substrate was crucial in this, Dr. Pappone added. All subsets benefited more from ablation than from medical therapy. In those receiving ablation, reduction of left atrium size was four times greater than with drug treatments, and patient survival was in line with the life expectancy of the general Italian population. Patients' quality of life after ablation was clearly better at six months, and was still markedly better at 12 months, than with medical therapy. "This is the first demonstration that ablation therapy is more effective in prolonging survival than medical therapy", Dr. Pappone told his audience. His unit's results questioned previous conclusions about the lack of benefit of sinus rhythm control by drugs in atrial fibrillation patients, he concluded.

In a presentation on the anatomy, musculature and pathophysiology relevant to atrial fibrillation, Samuel J. Asirvatham, MD, Mayo Clinic, Rochester, Minnesota, elucidated aspects of atrial morphology, which was "exceedingly complex". In the left atrium, the frequency of pouches, abnormal venous structures and other anatomic variations were implicated in atrial flutter and other arrhythmias. In terms of atrial fibrillation, it was important to keep in mind such factors as whether there were any preferential circuits in the left atrial musculature, what discrete connections in terms of electrical conduction from the left to right atrium there might be and what other atrial connections were present. Dr. Asirvatham used a video to demonstrate that knowing the location of the ostium was critical for most ablation procedures. He noted that close study of structures using various pulmonary vein imaging modalities (such as venous phase pulmonary arteriography, retrograde pulmonary venous angiography, trans-esophageal or intra-cardiac echocardiography, computerized tomography, magnetic resonance imaging and others), had brought important anatomic relationships to light.

Discussing the ablation of pulmonary vein foci, Dr. Michel Haissaguerre, MD, Université de Bordeaux, Hôpital Cardiologique du Haut Leveque, Bordeaux-Pessac, France, said that in pulmonary vein isolation, the clinician's experience was crucial — "only after 75-150 patients will you feel comfortable in ablating the vein. And you need to do at least two patients a week (except during holidays) to maintain your skills. With experience, you will achieve ablation within one hour, with minimal risks".

Pulmonary vein stenosis after catheter ablation, how to screen for it and when to treat it were considered by Dr. Javier E. Sanchez, MD, University of Alabama, Birmingham, Alabama. He pointed out that it was only thanks to various forms of electrophysiologic investigation that it had become possible to make quick and correct diagnoses of pulmonary vein stenosis.

The clinical course of the condition was characterised by progression in both symptomatic and asymptomatic patients. In asymptomatic cases, progression usually remained a non-clinical problem even after diagnosis. All symptomatic patients should be offered therapy such as angioplasty or stenting to provide relief.

There was some controversy, Dr. Sanchez observed, about whether to treat patients who were hemodynamically compromised as evidenced by scan, even though they were asymptomatic. The presumption in favour of treatment was that there would be progression of the stenosis, leading to irreversible lung damage: there might thus be a case for seeking to salvage the segment. But the principle of good therapy was that it should affect the natural history and that was not yet assured for pulmonary vein stenosis. For that reason, his unit placed the emphasis on prevention, and had set up a registry accordingly.

Course attenders also heard an overview from Chun Hwang, MD, Utah Valley Medical Center,

Provo, Utah, about non-pulmonary vein foci and the anatomic correlation of the three or four most common types. These, he said, were mostly in the left atrium and the pulmonary vein junction area.

Summary:

Speakers at this session emphasized that patient selection for ablation is based on three factors:

- Presence of paroxysmal rather than chronic or persistent atrial fibrillation (AF)
- Failed previous clinical trials of pharmaceutical intervention
- Left atrium size of less than 5.0 cms.

Many techniques are available, including pulmonary vein isolation and linear ablations.

Long term success rates are 70-90% with complication rates of 3-5%. The most notable of these complications being pulmonary vein stenosis. This complication can be reduced by ablating in the left atrium and not in the pulmonary veins.

Long-term outcome data indicated that linear ablation might confer a survival advantage over medical therapy for atrial fibrillation.

I am a 70-year-old female and my paroxysmal vagal lone atrial fibrillation (LAF) lasted 10 years. It improved during the last two years, from 3-5 (even 7) to 1-2 episodes per month. They usually lasted 1-8 hours (up to a few days). In earlier years all attempts to ease the frequency and duration using drugs, diets, supplements, etc, failed. Oral magnesium worked for a while, but then it caused diarrhea and I had to stop taking it.

A couple of years ago I learned about magnesium in liquid form which is absorbed sublingually, and it was apparently very effective. For all that time I lived with AF without too much trouble.

Then, in November 2002 two things happened. First, I switched to another magnesium formulation from the same company, to be absorbed through the skin in the bathtub, either through the whole body or only the feet. I am not sure if this latter product worked. Second, I had a very bad experience with dental work which caused a lot of anxiety.

An AF episode followed which lasted 2.5 days before I went to an emergency room for conversion. This was my third time in 10 years. They did not want to convert my heart because they thought I might already have developed a blood clot. I left the hospital with the fear that if my heart converted on its own, I might get a stroke. So, instead of converting spontaneously as usual, my AF became persistent.

My life changed completely, from very active I became sedentary and spent nights feeling the beats of my struggling heart. The only way I could get some sleep was by sitting up in bed. Ablation was my only hope. I called the Cleveland clinic, which had a 7-month waiting list. I also called Prof. Haissaguerre's clinic in Bordeaux (France), where the waiting list was only 3 months.

From my reading of bulletin boards on the web and speaking with cardiologists I was not always encouraged to go ahead with an ablation. Most people recommended waiting another 2 years. This was unacceptable to me. Even if it had a 50% chance of success, I was willing to get the procedure done. I thought that if ablation failed I could always get MAZE.

In this state of mind I flew to Paris, took the bullet train to Bordeaux and spent two days in a hotel near the hospital. There I read the book "The Healer Within" by Roger Jahnke. This book was a real help during those lonely days full of uncertainty in the hotel room.

On March 24th I bravely walked down the road from the hotel to the hospital with my suitcase rolling behind --a one mile walk. Shortly after being admitted, Dr. Haissaguerre kindly came to meet me in my room. We exchanged few words but what I remember most is having to hide my deep admiration for him. Later that day, the ablation was performed by Dr. Jais. The procedure was not simple. It lasted four hours instead of the expected two and a half. One good thing was that he did not have to puncture the wall between the atria. A second good thing was that the sources of fib were close to the surface, so they were easy to ablate. The problem was that there were many of them. I had to receive eleven electrical shocks, and I really felt the last ones.

When I first felt my heart had returned to normal rhythm I was exhilarated. I did not know how to express my gratitude to Dr. Jais. Two days later, I developed AV tachycardia (right atrium) and had to have a second ablation. This was a tricky procedure because of the risk of damaging the AV node which would require implantation of a pace maker. Dr. Haissaguerre performed the surgery, which was quick and successful. He also verified that the sources of fibrillation had previously been successfully ablated.

Then I left for Paris to celebrate my recovery. One week later, walking down the Seine river I had another attack of tachycardia and I had to return to Bordeaux/Pessac. This time the problem was in the left atrium. Dr. Jais successfully performed this third ablation and also checked everywhere for possible sources of AF, and found none. Apparently, both sources of tachycardia had been present for many years. I had not been aware of them because tachycardia usually rapidly turns into AF.

During my seven days in the hospital Dr. Jais visited me daily. During his visits he gave me his full attention, listening, explaining procedures, drawing sketches. He did not show the least urgency to leave, although the nurse told me in the operation room that they were very busy performing three to four ablations a day. The last time I saw him that day, he was going to perform an ablation on a pregnant woman. I had full confidence in him and in Dr. Haissaguerre. It was a pleasure and a privilege to meet them both.

It has been two months since I had surgery and I still do not know if I will stay permanently free of AF (I am not taking any medication). Regardless of outcome, I know I made the right decision.

Now I still experience occasional PACs which are sometimes uncomfortable, especially at night. I hope this will improve, as the heart fully heals. However, I much prefer having these than AF.

In conclusion I am pleased that I made the decision to have this surgery. If I had to, I would certainly do it again.

MC

Jim W.,

You are correct. Many advances come from Europe. The reason is that our F.D.A. is very slow to approve new drugs, instruments and procedures, but in Europe they seem to be able to do a lot of experimentation at will. Once Europe discovers an advance, however, the top doctors in the U.S.A. quickly go to Europe to learn about the advance, and then our F.D.A. can usually be convinced to approve trials rapidly. So the top centers in the U.S.A. are normally not far behind the Europeans.

Newman

A couple of thoughts or questions concerning the NASPE 24th Annual meeting brief I posted below:

1.) What Dr. Haissaguerre says about experience and achieving ablation within 1 hour describes Dr. Natale's approach, and I don't believe I have heard of anyone else here in the US doing an ablation in that short amount of time.

2.) I'm not sure what to make of Dr. Pappone's statement (below). Does the left anatomical remodeling of the ostia occur during routine PVI, therefore still only requiring an hour for the ablation? Is the 8mm catheter responsible for the remodeling due to the larger burn? And therefore a greater chance of success? Would such remodeling occur with a 4mm catheter?

"Dr. Pappone's unit's approach had been to use atrial debulking to modify the substrate in the left atrium by performing a single circumferential line involving all four pulmonary veins in order to isolate the posterior wall. His unit had also shown that the successful treatment of chronically affected atrial fibrillation patients, the most important group, was probably due to both pulmonary vein trigger isolation and left anatomical remodeling of the area encompassing the pulmonary vein ostia."

"Discussing the ablation of pulmonary vein foci, Dr. Michel Haissaguerre, MD, Université de Bordeaux, Hôpital Cardiologique du Haut Leveque, Bordeaux-Pessac, France, said that in pulmonary vein isolation, the clinician's experience was crucial — "only after 75-150 patients will you feel comfortable in ablating the vein. And you need to do at least two patients a week (except during holidays) to maintain your skills. With experience, you will achieve ablation within one hour, with minimal risks".

Jim W.

Newman,

As you probably know I have been trying to decide which Dr. to do my ablation. I have put my thought processes down somewhat here in the conference room. It seems Dr. Natale is most probably the one I am going to have do it. I was wanting Dr. Wharton because he is so much closer, but my gut feeling is turning towards Natale.

Thanks for your comments.

Jim W.

First, my feeling is that both Dr. Natale AND Dr. Wharton are in the very top tier of EP's who do RF ablations. I think there are different categories of skill with respect to EP's who do ablations: superb, excellent, good, average, below average. I think both Drs. Natale and Wharton are in the superb category.

Secondly, I don't think the professional consensus is clear whether the 8 mm or 4mm catheter tip is superior. I think this whole issue is bathed in controversy, and among EP's who do the procedure I strongly believe there is lively debate over which tip is clearly better.

Thirdly, I don't think the critical issue is the catheter tip size, but the skill and experience of the EP who does the ablation. Key questions, in my humble opinion, are as follows: how many has he done? where did he receive his training? what is his success rate? what is his complication rate and what types of complications does he have? what do other EP's and cardiologists think of

him? does he do the entire procedure, or do those who assist him prepare for the actual ablation, and he then comes in to do the ablation? what do his former patients who have had ablations performed by him think of him, his availability, the entire hospital experience where he practices?

Fourthly, if different EP's are achieving about the same success rate and have about the same complication rate--though using different catheter tip sizes--then I think this shows that what is not so important is the catheter tip size and what is important is how skilled is he and how comfortable is he with the tip he prefers.

Fifthly, in support of the above, I sought a second opinion from a very respected EP in Columbia, SC about my upcoming ablation, and he also felt that catheter tip size is not the critical issue, but the skill and experience of the EP with the tip he is comfortable with is the big issue.

If all things are about equal between two EP's I am considering for an ablation, I personally would go to the one closest to me, especially if that facility had a state-of-the-art catheterization lab, the EP was very available to all my questions and his personal care and attention to me were better than at a high volume place. Also, if problems developed post-procedure, I would sure as hell hate to have to get on a plane with an agitated heart and have to fly off to some distant location.

Just something to think about...

Stan B.

Oh, and one more thing, I would never just show up for my scheduled ablation without first having had an extensive initial consultation with the EP more than just a few days before he did the procedure, regardless of what I had heard or read about the guy doing the ablation. Maybe it's just me, but I would want to form my own impression of the EP in a face-to-face meeting and get a feel for how they ran their ship where I chose to have my heart procedure. But, maybe, if the EP had a really terrific reputation, it wouldn't matter. But still, I don't know about the wisdom of that...

Just something else to think about from a fellow afib sufferer...

Stan B.

Stan,

I also agree with you here.

Last week I spoke with a good friend of mine who is an anesthesiologist in Kentucky. I was telling him of my concerns, and one of them is what you have spoken of here. He responded by saying, "Marcus Whelby (of TV fame) is dead!" And frankly, that is the way it is today.

But, yes Dr. Wharton IS definitely more available! The question is, "Will that make the ablation more successful?"

Take care,

Jim W.

Hi Stan,

I really appreciate your thoughts and opinions. They mean a lot, and I agree with what you say. However I do think about the following:

You say,

"Thirdly, I don't think the critical issue is the catheter tip size, but the skill and experience of the EP who does the ablation. Key questions, in my humble opinion, are as follows: how many has he done? where did he receive his training? what is his success rate? what is his complication rate and what types of complications does he have? what do other EP's and cardiologists think of him? does he do the entire procedure, or do those who assist him prepare for the actual ablation, and he then comes in to do the ablation? what do his former patients who have had ablations performed by him think of him, his availability, the entire hospital experience where he practices?"

I think,

Natale-over 600 ablations

Wharton-over 400 ablations

Natale received his training from a Univ in Italy, has been back repeatedly for study, and doing ablations with the Italians and French where the PVI technique originated in the first place.

Last year his (Natale) complication rate was less than 1%! He is reporting an 80+% success rate - saying chronic and persistent afibbers are included in this group.

Dr. Wharton (I know this may be nitpicking), on the other hand is reporting 75-80% success rate and his rate of stenosis is 2-3%. Wharton's procedure takes about 2 hours longer & after reading the NASPE 2003 meeting brief where they say, "It takes at least 175 procedures to become competent, and after doing two procedures/day-except holidays-one can achieve ablation within 1 hour (which is what Natale does). I know the French and Italians use the 8mm which speeds up the process-so this could be a mute point; however can one achieve remodeling as easy with the 4mm cath? My sense of this is, NO. But, hey I guessing here, just a hunch, and sometimes that is all one has to go on.

Then, the other thing I think about: Teamwork IS important & personally it doesn't matter who does the "prep" work-as long as they are proficient. Which place would you think would have the most experience with teamwork? Obviously the answer is the CCF because they have been doing this a long time. The facility at MUSC is very new, and even if some of Dr. Wharton's team has come with him (which I personally doubt) their teamwork may not be as smooth as CCF(speculation). Actually, my cardiologist pointed this out.

Availability is important, but I am going for the cure and can't think about it. Obviously, my hopes are that I will be cured and availability will not be an issue. Gotta stay positive here.

Concerning other EPs and what they have to say about the 4 vs 8mm cath: I doubt many really know, and the only answer could be what they say, "whatever the doctor is most comfortable with". This is just not good enough for me. Has that EP used the 8mm or 4mm catheter (for that matter)? I wonder how many EPs have even held an 8mm catheter in their hand?

Why have the French & Italians abandoned the 4mm and are now getting better results? As Dr. Wharton says, " the jury is still out". I think several years ago (when I was going to have a focal ablation) the jury was out on the PVI technique.

Stan, having said all of this, it still wouldn't take much for me to go to Dr. Wharton (I am somewhat torn). I appreciate so much all your comments and concern. Thank you for caring.

Kind regards,

Jim W.

Newman, Jim W and Stan –

I've been busy thinking about all the great information posted here recently. It is a lot to consider.

Stan – I have to agree with you that skill is critical and at least for me, it is the #1 priority. Perhaps because I did dental hygiene for 25 years, working with surgically sharp instruments has made me very critical of any person going to lay hands on me for any reason. Not that doing dental hygiene compares in any way to an ablation procedure, but knowledge, dedication, enthusiasm and manual skill are paramount. I'm sure you all have been on the receiving end of a heavy-handed hygienist...so have I - Ouch. So with respect to ablation, I want a highly skilled person who is very dedicated.

I also agree that the size of the catheter tip may not matter all that much as long as the person using it is comfortable with it and the knows he can rely on the results. Another factor which is a personal preference for me is the length of time for the procedure and being exposed to the radiation and anesthesia. I'm not comfortable with long anesthesia. Yet, I love the idea that Dr. Wharton takes so much time to look for rogue cells even after the ablation to ensure success rate. The thought of a second ablation does not bring any degree to comfort to having the first one!

Given that we seem to agree that both EP's are seemingly comparable in skill and history of ablations, my thinking is that I will go to the CCF simply because I live here. That said, however, I like knowing have another option – travel to S.C.

Perhaps it is because we have explored this topic quite thoroughly and we have shared some important points of consideration, I find that I am much more relaxed in my attitude about having this procedure. (One which I never wanted to have.) Or perhaps it is the new-found peace I am experiencing from more and deeper meditation and the faith that a higher power is there to guide those skilled hands to a perfect outcome. At any rate, my events, while still with me once or twice a week, have become far less intense and far less in duration.

I have asked to be placed on a cancellation list in case I could be moved up sooner than November. There is no guarantee this would happen, but I did make the request which was accepted.

I will be posting a question for forum consideration about post-ablation medication. I will appreciate your input/feedback. Stand by.

Thanks for all the great points explored here and Jim W for providing that great referenced data for consideration.

Best regards,

Jackie

Hi Jim, I greatly appreciated your responses to my postings in the Conference Room. I have some feedback.

Dr. Wharton's availability would sway me more a little toward him, provided that both he and Dr. Natale were in the same top tier of EP's who did RF ablations.

I think it is a non-issue that Natale has done over 600 ablations and Wharton over 400. I think, as you yourself posted a while back in the Conference Room, anything over 175 or so is fine.

Thirdly, I have some questions about the statistics you quote for Natale. Are these statistics reported to you personally by him or what you were told by CCF? If he didn't tell you, how do you know that marketing strategy is not behind those slightly inflated numbers? Also, maybe how Wharton measures success and complications differs slightly from CCF, and thus the discrepancy.

Fourthly, have you ever read a statement from the published, official proceedings of any national EP professional meeting or a national cardiologist meeting stating clearly and unequivocally that the 8 mm catheter is better than the 4 mm one for RF ablations? I doubt you have ever read this. I know I haven't. Jim, in all sincerity I firmly believe that the 4 mm tip, in the right hands, can achieve the same results as the 8 mm tip. I think the success and complication rates of the other top-tier EP's who use the 4 mm tip is very comparable with Natale's results. Which tip the EP uses would not be the critical factor for me in deciding where to go.

Do you know for a fact that the 4mm tip has been abandoned by the French and Italians, and that they ALL use in Europe nothing but the 8 mm tip? I wonder about that...

I completely agree with what you said about the importance of teamwork. Dr. Wharton is a perfectionist and very dedicated to his craft, and I can't imagine that his team is anything but very, very good.

Just points to ponder.

Stan

Hello again Stan,

Boy, I love your responses. Maybe I'll go to Dr. Wharton after all.

I agree, availability is important.

The statistics were reported to me by the CCF & I agree they may be inflated as my EP here in Asheville believes. As a matter of fact he (my EP) says he usually quotes low statistics so when he succeeds the patient feels much better about him & the procedure outcome.

I honestly believe both doctors define success the same. Complications, I'm not so sure. The CCF is very confident (at least it seems) about their results. Dr. Wharton's are 2-3% reported by him.

I have never read a statement from a cardiology meeting here in the US regarding the 8mm catheter. You have to remember that the 8mm cath. has only been approved here in the US for flutter ablations (since Nov 2002), so why would someone here in the US say the 8mm cath. is better? Hardly no one has been using the 8mm for afib(speculation). I believe Dr. Natale is most likely the ONLY one using the 8mm with skill and control.

No, I don't know that the Italians & French have abandoned the 4mm. In fact I'm sure they still use it along with the 8mm. Different conditions require different instruments. It is the same in dentistry, and all fields of medicine. So it is nice to have all instruments available-especially when you feel competent using an assortment of instruments you are familiar with.(The right instrument extracting a tooth can be a jewel.)

Another point: I have read of only one other person on this board who actually had an ablation with Dr. Wharton, and it wasn't successful; however she is happy with Dr. Wharton, and is going back for a "touch up." On the other hand, there have been several people on this board who are(so far cured) of afib by Dr. Natale. I haven't read anything negative about Dr. Natale (and

believe me-I am looking). A long time employee of Biosense Webster referred me to a patient who was cured by Dr. Natale of chronic AF. He does live in Cleveland. It is a remarkable story.

More to ponder,

Jim W.

Hello again,

Geez, I just will not let this thing rest!

Today I spoke with Dr. Peng-Sheng Chen at Cedars-Sinai Medical Center in Los Angeles to ask who he would recommend here on the East Coast to do a PVI ablation. He gave me the following names: Dr. Packer @ the Mayo Clinic, Dr. Elenbogen @ MCV, Dr. Kay in Birmingham, Ala, & Dr. Wharton @ MUSC. He did not recommend the CCF over any of these doctors.

Then I asked him about the 4mm vs 8mm catheter. Was the 8mm superior even though it had a larger (and possibly deeper) burn when it was being used for PVI ablations on tissues that were relatively thinner than what the catheter is supposed to be used on according to the FDA.? Dr. Chen said that was a very difficult question because in the field of ablations at this time the technology is rapidly changing and there is NO one catheter that is superior! Ablations are NOT an exact science and can be risky. He said he would NOT make a decision (as many of you have also said) as to where to have an ablation done because of difference in preference for catheters. He went on to say whichever the particular doctor felt most comfortable with (Sorry to be boring).

I'm in NSR now, and in times like these I honestly think about "chucking" the whole idea of having an ablation. I don't like it that technology still has a way to go & putting myself at risk. I know stenosis rates are low, but.....

Also, being on coumadin has taken the fear of stroke away-especially after being in Afib over 48 hrs. The 240mg of diltiazem (when I take it) keeps my rate below 85. I feel good most of the time. Anybody else feel this way? Sorry, guess this should be on the BB.

Jim W.

Jim, good for you for taking the step to get some objective information from an informed professional source. EVERYTHING in this Conference Room and on the Bulletin Board has been very subjective. Everyone has had something at stake in supporting a particular EP or a particular piece of technology. No one has been, or has quoted anyone, who has been very unbiased and very objective. You took the right step to remedy this situation by seeking out a neutral, objective, informed, professional opinion from someone who has no personal interest in supporting a particular EP or a particular catheter tip. I think you need to put what Dr. Chen told you into the context of what you have been told from others and what you have read, and draw your own conclusions. I'll bet when you do this you won't feel that the CCF (and Dr. Natale) represent the only answer for a top-quality RF ablation.

Tell me more about Dr. Chen. Is he an EP? Did he seem knowledgeable? Were you impressed with him? Did he mind talking to you?

Now you need to compare the COST of an ablation at CCF with MUSC. If it is more expensive at CCF (and maybe even if it isn't), then I think you might have your answer, judging from what Dr. Chen told you.

Keep me posted!

I am delighted you are in NSR! I know exactly what you mean about wondering about the wisdom of having an ablation when you are in NSR and also knowing if you're not, it's not too bad, not a medical threat, and that you can handle it. My 100 mg of flec. is continuing to hold me in NSR with no breakthroughs at all. I wonder what in the hell I am thinking about in terms of having my ablation on Sept. 8! If we wait, then the technology and skill and experience of the EPS will all be better. But then maybe the new techniques won't prove to be that good, and RF will continue to be the "gold standard," as Dr. Wharton likes to call it. And maybe by then our general health won't be as good as it is now, and maybe our afib will be worse, and thus they won't be able to do as successful an ablation as if they did it in the near future. I, too, Jim, am going back and forth about whether to go through with it. My gut feeling, though, is to do it on the 8th of September. I realize that an ablation is nothing to be taken lightly, that it is risky and a serious procedure, but I still am leaning toward doing it. How about you?

Stan

Jim and Stan,

My opinions:

(1) Drs. Natale and Wharton are both excellent for ablations and among the best in the world. Take your pick.

(2) As time goes by, ablations will get safer and the success rate will get better.

(3) When I have a seven-day stretch in sinus rhythm, I tell myself I need to wait on an ablation (currently scheduled in October, 2003). Then I go into afib three or four times in the next few days and I decide I need to go ahead with the ablation. My mind plays games with me.

(4) I would love to get off of the three drugs I am taking. I am sure they are doing some kind of harm to my body, even if I can't see it.

(5) If I wait, maybe something else will happen to my body that will cause me to no longer be a candidate for an ablation.

(6) Even on coumadin, the risk of stroke is somewhat higher than the general population of the same age.

(7) I am 63.5 years old with excellent medical insurance that will pay for most of the ablation and let me pick my own doctor and won't hassle me. In 1.5 years I will be on Medicare and the government will be making the decisions, at least on some issues. The government screws up everything it touches, so I am very inclined to have the ablation before age 65.

To ablate or not to ablate. That is the question. We must each put all of the pluses in one hand and all of the minuses in the other, a true balancing act. Whichever hand drops will be our present course of action.

It is a very personal decision. It is not black and white. It is gray.

Best of luck and stay in touch.

Newman

Thanks Stan & Newman for your responses,

No surprise to me, I went back into AF yesterday evening & didn't sleep that well last night (happens often when I am in AF).

So it's times like this when I look forward to an ablation.

Newman, when in Oct is your ablation scheduled? If I go to the CCF mine is scheduled Oct. 17th. My insurance will pay 60-80%, most probably only 60% as I will be out of network.

Stan, The cost of an ablation at the CCF is 35-40K. I haven't heard back from MUSC so far, but will let you know when I hear.

You guys take the most of care.

Jim W.

Jim W.

Good information. How did you know about Dr. Chen - was he recommended to you?

I know what you and Newman mean about getting complacent when in NSR - especially if it goes for a good run without afib. I do the same thing.

Start thinking about delay. Perhaps it is a good thing these ablations are off in the future. It gives us time to weigh all the factors....and as we all agree - they boil down to personal choices.

Yesterday, at a routine MD visit - my blood pressure was 104/70 and my pulse was 61. This is with a double dose of flecainide because I woke up with arrhythmia...which corrected in about an hour. While the drugs work most of the time, walking around with a Bp and HR like that is very tiring....my enthusiasm for life is waning.

I am looking forward to not having to take drugs any longer. I just can't believe they do us any good other than keep us in sinus rhythm - mostly.

Anyone thought on how long it will take to detoxify our liver once off drugs? I bet it will be a long time before it becomes happy.

Thanks for sharing your information and your thoughts.

Sorry you are out of NSR - hopefully, back to normal soon.

Jackie

Jim W.,

I'm YOUR guinea pig. My ablation with Dr. Natale is 14 October, three days before yours.

I plan to be at the stadium in Columbus, Ohio four days after my ablation watching the Iowa Hawkeyes beat the Ohio State Buckeyes.

Regards,

Newman

Hi people,

I just thought I would post this article to possibly stir up a discussion again. I talked with two different representatives at Biosense Webster and they both told me they weren't allowed to say anything about this concerning atrial fibrillation because it wasn't approved for afib ablation, yet the CCF & I assume others are using this tool for afib ablations. We all know it has been used in Europe for some time.

Have a good day everyone-

Biosense Webster, Inc., Announces U.S. Release of the First Dual Sensor 8mm Tip Ablation Catheters For Treating Atrial Flutter
Diamond Bar, CA (November 13, 2002) – Biosense Webster, Inc., a Johnson & Johnson company, today announced U.S. release of the first Dual Sensor 8mm Tip Ablation Catheters specifically designed for the treatment of atrial flutter. The NaviStar™ DS and Celsius™ DS Catheters received marketing clearance by the U.S. Food and Drug Administration on September 30, 2002.

Roy Tanaka, U.S. president of Biosense Webster, Inc., said, "U.S. introduction of the first Dual Sensor 8mm Tip Catheters reinforces our commitment to remain at the forefront of advanced catheter technology. Our company has achieved an industry milestone by providing clinicians with the first approved product for atrial flutter ablation."

Industry sources estimate that less than 20 percent of patients with atrial flutter are referred for ablation therapy. Yet, while available pharmaceutical treatments are only palliative, a successful ablation can be curative and eliminate the arrhythmia. Although atrial flutter ablations are challenging with standard catheters, the new Dual Sensor 8mm Tip Catheters are designed to simplify the ablation procedure for all electrophysiologists.

NaviStar™ DS and Celsius™ DS Catheters are designed to benefit electrophysiologists by providing greater temperature control while delivering a long deep lesion across the isthmus to achieve anatomical blocks with fewer ablations.

Compared to standard 4 mm tip catheters, the larger 8 mm tip on both dual sensor catheters has a much larger surface area exposed to local blood flow during a procedure. This blood flow serves to cool the tip, enabling the delivery of higher energy levels – up to 70 watts with the Stockert 70 RF Generator. The presence of two temperature sensors in the 8 mm tip facilitates precise temperature control that can help to reduce the risks of incomplete, low temperature ablations or excessively high temperatures at the tip that can cause char and coagulum formation.

Dr. David Wilber of Loyola University Medical Center, lead investigator for the NaviStar™ DS Clinical Trial, said, "The 8 mm NaviStar™ Catheter provides effective cooling, confirmed both by clinical and experimental data. The dual sensor technology is an important safety feature, allowing the physician to optimize energy delivery and lesion size, while avoiding charring, coagulum and steam pops," he said. "These characteristics facilitate the production of permanent, bidirectional isthmus conduction block, making atrial flutter ablations easier than in the past with the 4mm tip. Clinical efficacy for patients ablated with only the NaviStar™ DS catheter (N=166) was high in both acute success and six-month freedom from recurrence at 98.8 percent and 94.4 percent, respectively. Including patients ablated with non-protocol catheters (N=182), acute success and six month freedom from recurrence were 90.1 percent and 93.8 percent, respectively."

Both the NaviStar™ DS and the Celsius™ DS Catheters are designed to increase the confidence

of electrophysiologists as they tackle the challenges of creating successful atrial flutter ablations.

Mr. Tanaka noted, "We continue to explore and develop catheter technologies that will broaden the electrophysiologist's ability to treat more complex arrhythmias with increased confidence and effectiveness."

About Biosense Webster, Inc.

Biosense Webster, Inc., pioneered EP diagnostic catheters more than 30 years ago and continues to lead the industry as an innovative provider of advanced diagnostic, therapeutic and mapping tools. The market share leader in navigation systems, Biosense Webster, Inc.'s, technology includes more than 400 systems installed worldwide in leading hospitals and teaching institutions. With proprietary products such as the Carto™ XP Navigation and Ablation System and the Lasso™ Circular Mapping Catheter, the company is changing the way electrophysiologists diagnose and treat arrhythmias.

Biosense Webster, Inc., is a member of the Johnson & Johnson worldwide Family of Companies marketing health care products in more than 175 countries. Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products.

Jim W.

Hello again,

As you know I reported that the CCF has said the cost of a PVI ablation was 35-40K.

Today I talked with Dr. Wharton's nurse and finally got an answer (if you want to call it that). She might of been having a bad day-I don't know.

She said, "We can't really tell you."

I said, "Can't you just give me a ballpark figure?"

She said, "Well, we don't know how long the procedure is going to take, and what medicines may be involved."

I said, "Oh."

Then she said, "Between 25 to 50K."

I said, "That's a pretty big park."

She said, "That's the best we can do."

I said to myself, "Screw you", and hung up.

Is it me, or is there something wrong with this picture?

Jim W.

Jim, thanks for following through on the cost of a RF ablation at MUSC, although I feel bad that you had such a frustrating conversation with Dr. Wharton's nurse. I can understand where it is difficult to give an exact price because of the reasons she noted: length of procedure and medicines involved. However, she should have been able to have done better than to have said between 25 and 50 K. There must be an average price they could quote. I am wondering if you talked to the right person. Would a nurse, as you talked to, be knowledgeable about the COST of a procedure? Maybe you should talk again to Shirley, Dr. Wharton's secretary, and tell her about your unfortunate conversation with the nurse and ask Shirley who might give you better information. Perhaps someone in the business office or in the insurance division would be in a better position to help you than a nurse OR maybe you could e-mail Dr. Wharton himself for some cost information.

Also, when I read Biosense Webster extolling the virtues of their own product I've got to wonder how objective they are being, and, also, I couldn't help but juxtapose what they said with what Dr. Chen said (who, I would think, would be in a position to be more objective than Biosense Webster). Also, I keep reading that the 8 mm tip is officially been approved only for atrial flutter, a fact which leaves me wondering why it was approved for flutter and not for fibrillation. Do you know what those reasons are? I would want to hear WHY it was not approved for fibrillation, but for flutter, BEFORE I decided which catheter I wanted cauterizing my heart tissue.

Jim, what weight do you give what Dr. Chen told you? If he is involved in AF research and seems very knowledgeable, it would seem to me that, as a layman, I am not in a creditable position to refute what he says. I think I have read his name several times in various articles, and I assume he is a respected authority with regard to atrial fibrillation and its treatments.

Again, my friend, just points to ponder...

(I would urge you to try again to find out the approximate price of a RF ablation at MUSC. You are very good, outstanding, at ferreting out information.)

Stan

Hi Stan,

The nurse I talked to WAS Shirley. I agree, I should have been referred to the insurance personnel or someone else, but I wasn't. I talked to someone there in the insurance dept some time ago and never heard back.

Stan, I am not refuting what Dr. Chen says. He told me he & Dr. Wharton received their training at Duke at the same time. He did not speak negatively about any doctor. He was very general and simply told me the doctors here on the East coast that are doing PVIs. Another thing- when I asked him about catheter size, etc he mentioned that the CCF was also using a larger catheter tip than the 8mm-whatever that means.

My computer is down at home. I'll e-mail you when it's fixed.

Take care,

Jim

Hi Jim: I hope you can pursue things at MUSC and find out a better estimate of the cost of an ablation there. By the way, I am sure that Shirley is Dr. Wharton's secretary, not his nurse. I wouldn't think she would know much about the cost of an ablation. Surely she could refer you to a more knowledgeable source. Maybe you could call and ask for the business office or insurance dept. You said that you had contacted the insurance dept. earlier, and had not heard back from them. Call back. Get a person's name so you can direct concerns to them personally. Or could you wait on the phone while they got the information for you?

Stan

Hi Jim - What a frustration! No, it isn't you.

I would think that the financial arrangement department has either a standard fee or some better parameters for the cost of an ablation with a little more refinement than the range you were given.

Further, I would also want to know from my (your) insurance company what they will cover for the ablation procedure...what is their UCR number or range..... Because if your insurance company will not accept the full charge but will only deal with the UCR for the area - the question then becomes: are you (we) obligated to pay the additional difference from our pockets - ouch - that could be substantial!

I have been meaning to delve into this, and am prompted by your frustration to begin dealing with it now - of course by November, the fees most likely will have increased - who knows?

I was given a contact number at the CCF for financial details. I'll try that and let you know what my response was here.

You may or may not know that the cost of medications provided - in hospital- is totally obscene. It's been written up in papers etc. that the markup is like a thousand % or more... totally ridiculous. Perhaps they refrain from quoting a price until they see what type of insurance the patient has and how much they can gouge. I'm talking generalities, here, nothing specific with the CCF or Dr. Wharton's facility.

Jackie

Anyone having to pay for an ablation out of their own pocket should seriously consider going to Bordeaux. Drs Haissaguerre and Jais are, if not the best in the world, certainly right near the top. The cost for the pulmonary vein ablation there is about \$15,000 US all included (except the air fare).

Hans

I talked to MUSC today about the cost of a PVI ablation with Dr. Wharton. The business office manager whom I spoke to was very knowledgeable and had specific information for me. She said the total price for the "average" PVI ablation (i.e., without significant complications)--and without an EP study done during the procedure-- is about \$26,670. \$23,000 of that is the hospital fee, the remaining \$3,670 is the doctor's fee and the anesthesia fee. An EP study done during the procedure adds another \$2,245 to the total cost. So, with an EP study, the total cost would be \$28,915; without the EP study, \$26,670. Both prices are significantly better than what Jim quoted for Cleveland Clinic: 35-40K.

Considering the fact that professional consensus is there is not much difference, if any, between Drs. Wharton and Natale, I would think that cost would be a serious reason to strongly consider MUSC and Dr. Wharton as the possible for your ablation.

Points to ponder...

Stan

Hans - This would be good if the all the money were out of pocket, but in some insurance cases here, at least, if one goes out of network, the coverage changes dramatically. Plus, I don't think that Medicare covers any treatments outside the US - if this would be a consideration.

Certainly if it were all out of pocket, then \$15K versus 40 or 50K is a no-brainer!

Jackie

Hi Jim - My first attempt to determine cost was a flop. The phone number I was given by the EP nurse in Natale's lab, connected me with a person who was pleasant, but told me she had nothing to do with what I was wanting to know.

She then transferred me to the "financial person in the EP area" (why I didn't get that number the first time, I have no clue, but in any event, he was not answering his phone so I left a voicemail message, but I didn't get a call back on Friday. I'll try again Monday.

The first person told me that she doubted if I could get an estimated cost because - just as you found, it was dependent on time, meds, etc.

She also said that any quote that would be given would be inflated dramatically so was actually not a practical estimate. Cute.

I will continue to pursue this because I'm curious as to just how much of this is going to be out of pocket.

Guess it's not like a root canal. The fee is X for 1 canal and Y for 2 or 3 canals.

I still think they should have some idea rather than a range with 25K differential and I'm surely going to exhaust all possibilities to find out.

Let you know. Thanks to Stan for his info from Dr. Wharton.

Jackie

From the Atrial Fibrillation Foundation:

Who is a Candidate for Pulmonary Vein Isolation?

The procedure is most rewarding for patients whose recurring symptomatic episodes of AF have not been suppressed by antiarrhythmic drugs or who do not wish to take long-term antiarrhythmic drugs or long-term anticoagulation. To an individual patient, the relative merits of a catheter ablation approach is proportional to the impact of atrial fibrillation and the prospect of long-term drug therapy on his or her quality of life. The success of the procedure is lower in patients with long-standing continuous (chronic) AF compared to patients with intermittent (paroxysmal) atrial fibrillation. It is believed that catheter ablation is more likely to be successful in patients with normal or near-normal heart function at present.

A multicenter study in Europe and the US is comparing clinical outcome (freedom from AF recurrence and risks) for antiarrhythmic drug therapy versus pulmonary vein isolation in patients with paroxysmal AF. Until the results of such studies become available, the comparative effectiveness, limitations, and relative risks of antiarrhythmic drug therapy versus catheter ablation as first line therapy will remain unproven. Thus, at present, most patients undergoing an invasive procedure such as pulmonary vein isolation, have first failed at least one antiarrhythmic drug before an invasive procedure is undertaken.

It seems to me that Newman is right. To ablate or not to ablate is a grey area & the decision is an individual choice.

Good Luck to all-

Jim W.

This is the first time I've posted to this site. When you mentioned my Doctor, I thought I should let you know that I had a Left Pulmonary Vein Ablation by Dr. David Wilber last December. He was recommended by my husband's nephew, who had LP Ablation, give or take, 5 years ago. He is just fine. He had to have it under an emergency, because no one could stop his high heart rate and they took by ambulance to his hospital.

After my EP's had tried all the meds and I couldn't tolerate any of them and I was in and out of AF very often I asked him about Dr. Wilber. He said very good, and went on to explain what an excellent Dr. he is, and really pushed for me to get it done. He made all the arrangements for me.

It's 6 mos. and no AF, no meds and I feel great. I still have some strange things going on with my heart, but I will discuss this by EP in Wi. I may have to live with them or they may go away.

I know they are doing Left Pulmonary Vein Ablations in Milwaukee, but I choose the expert who has done many - Dr. David Wilber of Loyola University Medical Center in Illinois.

I'm 70, and in good health and very active and now I can continue to be very active thanks to the ablation.

Gwen

Gwen - Welcome and thanks for posting your history. It is always encouraging to learn of successful treatments and people glad to have made the big decision. It is important that people share.

May you continue to feel better every day and remain your active self.

That's a goal for us all.

Regards,
Jackie

Dear MC,

Thanks for your story.

I live in Europe and wonder if you could provide the number and name of hospital please?

Thank you kindly,

Thomas E.

Dear T.E.

I am sorry to respond so late to your question. I did not know where my message was posted until Hans informed me about.

The hospital information:

Hopital Cardiologique Haut-Leveque
Avenue de Magellan
33604 Bordeaux Pessac

Tel. 05 56 55 64 01 Fax: 05 57 65 68 59

Mirjana

Dear T.E.

I do not know if the telephone number I sent you in my first message will work. I copied it from one of the papers I have. My French-speaking friend did all the telephone calls for me with the hospital in Bordeaux. I just got from him the correct telephone number. Here it is: 05 57 65 64 71. This is if you call from France. From Europe it is: 33 5 57 65 64 71.

I hope it will work.
Best wishes,

Mirjana

Hi Jackie,

I was quoted the 35-40K by a Mike Siedlecki who is in charge of financial arrangements, insurance, etc @ CCF. The phone # is 1-800-223-2273, ext 49434. I have another call in to him to make "sure" about his numbers, thanks to Stan.

Jim

Hi Jackie,

Mike just called this morning, and we went over the costs again. He said the 35-40K included doctors fee, hospital stay, medicines, anesthesia, radiology-the whole bit. However, this price could be higher if other tests are ordered. He said he has seen bills of 45K down to 33K, but he average is 35-40K. Let us know if you learn anything different.

Good Luck,

Jim W.

Hello again,

This is for those who are looking for a place on the West Coast, and also I thought this also might be interesting for some others. At the end of the web page it states a "variation of the PVI" is being done, and there are only a "handful" of EPs doing this procedure in the US. So, of course, I called them to ask about it. Turns out Dr. Natale goes there to do ablations.

MGH Offers New Hope For Patients Suffering Common Irregular Heart Rhythm

Individuals suffering from atrial fibrillation, the most common type of irregular heart rhythm, can now be treated at Marin General Hospital with a new technique that holds real hope as a cure for this debilitating condition.

Unlike any other facility on the West Coast, Marin General has attracted a team that has used this

technique successfully on a high volume of patients.

Cardiologist Dr. Richard Gray, medical director of the new Joint Cardiac Program of Marin General and San Francisco's California Pacific Medical Center, said, "Although many treatments for atrial fibrillation are offered, they are often ineffective and not long lasting.

"Now, for the first time we have something that holds real hope for a cure. We have a procedure that will return people to a regular rhythm. The technique is a major advance in the treatment of irregular heartbeat. A high percentage of patients with irregular heartbeats can benefit from this."

Patients are treated for this condition in Marin General's new \$3.4 million Electrophysiology Laboratory, one of only 12 labs in California. The technique is quicker than most others and with dramatically fewer complications and can only be done in an EP Lab equipped with the most advanced medical technology.

Salwa Beheiry, RN, director of Marin General's Electrophysiology Program, said, "Five million Americans are affected by atrial fibrillation. It is most common among older people. The older you get the more likely you are to have it. A large percentage of the population can benefit from the technique that we offer."

Atrial fibrillation is a chaotic, irregularity of the heartbeat from the upper two chambers of the heart and can lead to clots and strokes.

People suffering from AF may feel dizzy, lightheaded or weak. They may complain of fluttering in the chest, shortness of breath or, sometimes, chest pains. While the condition is not necessarily life threatening, it has a major impact on the quality of a person's life.

For years, the standard treatment for atrial fibrillation was medication, Gray explained.

"But the difficulty is that once you have AF for more than a year, it's hard to return to regular heartbeat even with medication," he said. "At some point the medication stops working."

Usually the next step in the treatment process is cardioversion - a low voltage shock to the chest wall to restore the heart's normal rhythm - but even this has to be repeated and eventually stops working.

Atrial fibrillation treatment sometimes also includes the implantation of pacemakers after ablation (localized disruption of electrical pathways in the heart).

In the past few years, a small group of electrophysiologists began using a procedure known as localized Pulmonary Vein Isolation (PVI) a form of ablation.

The technique used at Marin General - a variation of PVI - is available at only a hand full of hospitals in the U.S. and is done by fewer than a half dozen electrophysiologists.

Jim W.

Jim, what I am about to write is not meant to be contrary, but sincerely to stimulate dialogue and further thought. Please keep in mind that the information from Marin General is a form of advertisement and they are tooting their own horn. It is not objective, in my opinion. Secondly, who are these other EPs who go to Marin General to do ablations? Did they supply you with names? I would like to know who they are. Thirdly, how is the ablation done at Marin General different from a standard PVI? I think this is an important point. Also, why--exactly--is it better than the PVI ablations done by other leading EPs? Are there any reservations in the EP world about the technique they practice there? Is there another side to the coin? Have you researched

this? Is it possible that the leading EPs do what they do at Marin General, but at their own institutions, and do not travel to California to do them?

I hope you are doing well, and that this is food for thought.

Take care, my friend

Stan

Hello Everyone-

I'm not so sure this is appropriate to post here, but I am doing it because it does pertain to ablation (my ablation) and my feelings about it. I am grateful for having this forum to kick around ideas concerning AF and possible cures, whether it's diet, meditation, supplements, lifestyle change, or ABLATION. After 14 years, for me, it has come down to ablation. I have used this conference room and BB for some time now-as a way to make a decision as to where I would go to have my ablation. I realize this is probably not what this conference room is about, but it has in some ways helped me.

As many of you know I have been trying to make a decision between Drs. Wharton & Natale. My cardiologist told me from the beginning to go with my gut feelings, because I would be in good hands in either place. I definitely know what my gut is saying. Dr. Wharton is much closer to me, cheaper, is available, honest, caring, and most probably very meticulous with his ablations. He spends a great amount of time looking for "rogue" impulses after the PVI ablation in hopes of eliminating all aberrant circuits. He is probably one of the best EPs in the US. Knowing all of this, I am still choosing Dr. Natale, and I haven't even met him!

I first heard of Dr. Natale from reading Han's book, "AF towards a cure". Then I learned more about him from some on the afib BB & on the maze BB. Then I talked with someone from Biosense Webster who referred me to a man who was "cured" from chronic AF two years ago. Dr. Natale performed the ablation. A short video (probably made by Biosense Webster) was made post ablation about how this man's life had changed due to the success of the ablation. Dr. Natale was interviewed in this video.

When I first mentioned to my cardiologist (over a year ago) that I was thinking of seeing Dr. Natale, he referred to him as a cowboy, and very aggressive-but also that he was good. Something tells me my heart needs a "renegade cowboy" to do what has to be done to stop this AF! I have been reading about the French and Italian's success with PVIs for some time now. They developed the procedure, and are developing and using an assortment of catheters and other equipment that most doctors here in the US haven't even seen! Dr. Natale graduated from med school in Italy and goes to Europe to perform ablations every year using this equipment. I want someone who is experienced with using all types of equipment. Even though Dr. Natale is younger than Dr. Wharton, he has been a board certified EP one year longer than Dr. Wharton. Before going to the CCF, Dr. Natale started learning about ablations in Canada, Wisconsin, Michigan, Duke Univ (with Dr. Wharton), Kentucky, and then to CCF. He performs ablations on the West coast at Marin General Hospital where I believe(by the way) the PVIs are the same as at the CCF. MGH describes their PVIs differently because (gut speculation) of difference of technique(here in US)and experience in using an array of equipment-the 8mm catheter being an example.

If my AF was paroxysmal I would definitely see Dr. Wharton; however in my case, I feel I need all the armamentarium I can have available to me.

When I go to the CCF on the 16th of Oct for my workup and appt with Dr. Natale, I will ask him directly about the 8mm cath and my percent chance of success since I am persistent. If I get

answers contrary to what I have been told and read-or feel anything negative about my experience with him, I will cancel my ablation for the following day, go to MUSC, and start the process all over again. If I have to wait another 3-6months, so be it. It is my heart.

Good Luck and Thanks to Everyone,

Jim W.