



Welcome to this belated Dec'15 / Jan'16 issue of The AFIB Report. We're still in the midst of our website redesign and likely will be until mid-autumn time frame, based on best current estimates. We have several choices for the look of the site now that will be finalized end of July, after which the pace will all pick up substantially from there. Not surprisingly, this project is a big one, and I'm looking forward to finally opening the doors to the new website for all our readers and forum members.

In this issue, we start with a review of an important international multicenter study that gives direct evidence to the efficacy of addressing the posterior left atrial wall (LAPW) as a key step in an extended PVAI ablation protocol for all classes of afibbers, from paroxysmal to long standing persistent cases.

I was impressed, but not surprised, by such solid proof now showing that these extended ablation techniques, properly executed and used in the right patient groups, reliably confer what so many on our forum have anecdotally experienced as excellent long-term freedom from arrhythmia. What is unique, is that this study design included confirming both durable LAPW isolation and PVAI as well. For the first time directly validating that documented durable LAPW isolation leads to significantly improved persistent AFIB ablation outcomes (and for most paroxysmal cases too).

Next up, is an in-depth follow-up report on rotor-mapping technology that we first examined in our last issue with a thorough look at the state of FIRM-mapping and ablation technology, and where it stood as of last Feb. 2016. In that initial report, we reviewed a preliminary Group 1 arm of the complete and larger OASIS-Randomized Control Trial (RCT) that was due for May '16 release at the HRS conference.

In light of the dismal results from that first arm of OASIS looking at 29 non-paroxysmal cases undergoing FIRM-Only ablation with no companion PVAI, I had noted that perhaps results from the complete OASIS-RCT, as the first and so far only formal RCT yet done on FIRM, might yet show a ray of light for the almost 5-year-old and still controversial and embattled technology.

As such, we now wrap-up our marathon investigation into the 'state of FIRM' circa July 2016, to see if any greater confidence was inspired by a thorough review of the completed OASIS-RCT presented at this year's large Heart Rhythm Society Scientific Sessions in May at San Francisco.

Our third contribution in this issue is a succinct overview of the nutraceutical supplement and amino-acid L-Theanine and its impact on Brain health by Jackie Burgess RDH

Finally, we wrap up this belated first issue of 2016 with an inspiring personal story from a physically fit 68-year-old Canadian man, *Richard D.*, from Calgary. Richard contacted me in mid-May seeking advice for a possible ablation. He's a very avid golfer, and after having a coronary bypass graft surgery (CABG) a bit over 2 years ago, developed persistent AF which is not uncommon after CABG. Over the past 1.5 years Richard's AFIB became long-standing persistent, and his local EP informed him he was no longer a candidate for ablation or even ECV!

Needless to say, there is much more to Richard's story. And he asked if he could share his experience with our readers, feeling certain many may relate and appreciate what he had gone through. I think you all will enjoy reading about Richard's fast transformation back to the links!

I much appreciate, too, all of your patience during this lengthy website revamp and the inevitable issue delays.

Be well all and enjoy unbroken NSR!  
**Shannon**

## Proven Isolation of pulmonary vein antrum with or without left atrial posterior wall isolation in persistent AFIB (Liberation Trial)

AUSTIN, SAN FRANCISCO, NEW YORK CITY, BEIJING CHINA, FOGIA, MILAN & ROME ITALY. One of the challenges in pushing the field of AFIB ablation forward, beyond reliance on an anatomical-only PVI/PVAI<sup>1</sup>-alone ablation strategy as the protocol for all classes of AFIB, including even non-paroxysmal AFIB cases, have been a pair of equivocal results with LAPW isolation, for example, in one study that added **left atrial posterior wall isolation** (LAPW) to standard PVI that found no benefit.

A number of top volume centers have routinely touted, and consistently demonstrated in their own studies a superior outcome from addressing extra-PV ... also called 'Non-PV' ... trigger sources beyond the pulmonary vein isolation alone, and found in other areas of the left and right atriums, including the LAPW. However, even as other high volume centers have replicated those results confirming the efficacy of combining a PVI/PVAI with LAPW isolation, in contrast to the Tamborero<sup>2</sup> study noted below that could confirm no real value in LAPW isolation in persistent AFIB patients.

Of note: this Tamborero report used a linear-line approach for LAPW isolation, which is highly prone to reconnections as noted by 70% of study patients having recurrence of AT showing reconnections across the LA roof-line and across the body of the LAPW. In short, their finding of poor efficacy of LAPW isolation did not include proof of having actually achieved durable LAPW isolation to begin with.

PVI/PVAI ablation is the cornerstone of all AFIB ablation methods proven to restore durable NSR in the majority of paroxysmal cases, when isolation of the PVs is durable and free from reconnections. However, in persistent and LSPAF (long standing persistent AFIB) cases, PVI/PVAI has been shown to not be enough to grant a robust endpoint of reliable long-term freedom from all arrhythmia and off all AAR drugs for a significant majority of these more difficult class of afibbers.

The logic and premise behind isolation of the LAPW arises from the fact that the LAPW is embryological identical to, and originates from, the very same cells as the primordial pulmonary veins. It is, therefore, no surprise that the LAPW is also found to be highly arrhythmogenic as well.

Thus, it doesn't take a rocket scientist to surmise and postulate that further ablation or isolation of this same type of tissue within the LAPW, as is found around the PVs, should further improve outcomes in AFIB ablation by eliminating this additional likely source of AFIB drivers. Indeed, the LAPW is largely an extension of the PV antrum area as it is, and like PV antral tissue, neither are involved in the contractile function of the left atrium.

Leading EP's and centers have demonstrated to themselves the unequivocal value of more extended step-wise ablation protocols, including adding at least LAPW isolation to a PVAI from their repeated industry-leading AFIB ablation study outcomes. St. David's Medical Center enlisted experienced centers from New York, China and Italy to finally prove, one way or the other, whether or not LAPW isolation is truly a necessary adjunct for better ablation outcomes, especially in persistent and LSPAF cases.

### Liberation Trial

The study design for this 'LIBERATION' Trial theorized that the equivocal results from adding LAPW isolation to a PVI, had to be due to these operators not achieving consistently durable isolation of either the LAPW, the PVs, or both, during their ablation process of those equivocal studies.

In order to prove beyond a shadow of a doubt that adding a durable LAPW isolation to an equally durable PVI/PVAI ablation would result in better more lasting freedom from all atrial tachycardia's in persistent cases, St. David's proposed a bold and unusual protocol for which it received approval from the hospital's ethics committee.

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<sup>1</sup> PVI/PVAI = Pulmonary Vein Isolation or Pulmonary Vein Antrum Isolation

<sup>2</sup> Tamborero D, et al, Left atrial posterior wall isolation does not improve outcome of circumferential vein ablation for atrial fibrillation: a prospective randomized study. *Circ Arrhythm Electrophysiol* 2009;2:35-40

This approach called for upfront patient approval as well, of course, to perform up to 3 procedures per patient in order to conclusively prove not only complete PV and LAPW isolation, but also to only register a given patient in the long-term follow-up study phase, once the proven isolation of both their PVs and LAPW was achieved.

The endgame here was to determine the impact of proven PVAI and LAPW isolation versus just a proven PVAI-alone on the outcome of persistent AFIB ablation (Superior Vena Cava (SVC) isolation was added, as required, in each ablation as well).

## **Study Methods**

Fifty-two consecutive ablation naïve patients with persistent AFIB (defined as continuous AFIB sustained for >7days) were enrolled in the study after giving consent before undergoing their primary AFIB ablation.

All 52 consecutive persistent patients underwent their index ablations between Oct 2010 and July 2012 and were grouped according to ablation date. The first 20 patients comprised Group 1 and the last 32 patients made up Group 2.

### **Group 1**

During the first procedure in Group 1 (n=20) had only PVAI alone performed by ipsilateral circumferential ablation method. Procedure end-point was PV-LA entrance block with a circular Lasso mapping catheter. If AFIB was sustained or converted into an organized atrial tachyarrhythmia (AT), then cardioversion was applied but no further ablations were performed in this Group 1. These patients were given AAD (Anti-Arrhythmic drugs) during the blanking period.

Three months after the first ablation, all patients regardless of atrial arrhythmia recurrence, or not, underwent a second procedure. In this procedure, after transseptal access a Lasso catheter was introduced into the LA (left atrium) in order to check the connection between the LA and PVs. If all four PVs remained silent and isolated, no further ablation was performed and these patients were immediately enrolled in long-term follow-up.

If there was any reconnection between the LA and one or more PVs, additional LA and venous access was obtained and re-isolation of the PV antrum was performed. Cardioversion was performed when NSR could not be restored during this repeat PVAI ablation. Three months later (a total of 6 months after the index ablation), patients who had PV antrum re-isolation during the second procedure now underwent a third procedure identical in process and protocol to the second procedure. All these patients were then followed for outcome with, or without, a 3 month blanking period depending on whether or not they had a redo procedure in the third ablation.

### **Group 2**

When patients in Group 2 underwent their first procedure, PVAI was extended (ePVAI) all the way to the CS (coronary sinus) and to the left side of the interatrial septum, along with extensive ablation on the LAPW to achieve isolation of the entire LAPW (ePVAI + LAPW). The SVC was similarly empirically isolated as in Group 1.

The endpoint of this first procedure in Group 2 was isolation of all PVs and isolation of the LAPW, the latter being defined as entrance block and complete electrical silence on the LAPW confirmed by absence of near-field atrial activity on the lasso circular mapping catheter placed on the LAPW. Next, AAD drugs were resumed for the 3 month blanking period.

Irrespective of any recurrent atrial arrhythmias, all patients had a second procedure three months after their index ablation. In this second ablation, PV to LA connection and LAPW conduction were examined. In cases, in which the patients had no reconstructions, then no ablation was applied during this second procedure and these patients began follow-up for longer term outcome.

In patients during this second procedure with reconstructions detected around the PV antrum or LAPW, then re-isolation ablation of the PV antrum and/or LAPW was performed and a third procedure was scheduled for three months after the second ablation (i.e. 6 months after the index ablation) in order to verify beyond any doubt that both the PVs and LAPW remained fully isolated before follow-up monitoring and tabulation of outcomes for this group began.

Similarly, re-isolation of the PVs with, or without, LAPW isolation was performed only in subjects who were found to have conduction recurrence during the third and final procedure included in this study.

## Results

Of the total 52 study patients, none in either Group 1 or Group 2 had undergone a prior ablation. Duration from diagnosis of AFIB to first ablation in this study for these persistent afibbers was the same at around 8.0 months, though self-reported duration of persistent AFIB ranged from 10.5 to 12 months respectively in Groups 2 and 1. (Editor: the sooner you get ablation after diagnosis of persistent AFIB the better ... preferably within 6 months or as soon as feasible from persistent AFIB diagnosis to ablation).

In the first procedure, all patients in both Groups 1 and 2 achieved the predefined endpoint, that is isolation of PVs in Group 1 and isolation of all PV's plus LAPW isolation in Group 2. Isolation of the Superior Vena Cava (SVC) was confirmed in both groups as well.

Three months later, during the second procedure, remapping of the left atrium confirmed that all PVs remained isolated for 12 in Group 1 (60%), and PVs plus LAPW remained isolated in 20 (63%) group 2 patients. All of these patients then entered follow-up for outcome at this time.

Re-isolation of PV antrum for group 1 reconnectors, and re-isolation of group 2 PVs and/or LAPW reconnectors (as needed) in Group 2 was performed.

In the third procedure done 3 months after the second procedure, PV isolation was confirmed in all 8 Group 1 patients, and both PV plus LAPW isolation was confirmed in all 12 patients of group 2. Making for 100% freedom from atrial arrhythmia when all 52 patients entered long-term follow-up.

## Follow-up

After confirming durable PV and/or PV plus LAPW isolation at end of this unique three stage ablation protocol for Groups 1 and 2, respectively, the long term 1 year, 2 year and 3 year follow-up for each group were as follows:

### Group 1 - Confirmed PV-iso + SVC-iso only = 20 patients

Free of all AT/AFIB and off all AAR drugs at: Free of all AT/AFIB with or without AAR drug:

Year 1 = 4 (20%)

Year 1 = 6 (30%)

Year 2 = 3 (15%)

Year 2 = 4 (20%)

Year 3 = 2 (10%)

Year 3 = 2 (15%)

Median recurrence time 8.5 months in Group 1

### Group 2 - Confirmed PV-iso + LAPW-iso + SVC-iso only = 32 patients

Free of all AT/AFIB and off all AAR drugs at: Free of all AT/AFIB with or without AAR drug:

Year 1 = 21 (65%)

Year 1 = 24 (75%)

Year 2 = 16 (50%)

Year 2 = 18 (56%)

Year 3 = 13 (40%)

Year 3 = 14 (44%)

Median recurrence time 28 months in group 2

## Conclusion – Editors comments:

*I found this study very important as the very first in-depth investigation confirming significant benefit of durable of both Pulmonary Vein isolation and LAPW isolation. Prior to this report, in none of the studies in which LAPW was attempted was there documented durable isolation of either structures before follow up was started. In light of these results, it's clear now that the few studies that did not find value in adding LAPW to a PVI/PVAI procedure surely lacked robust isolation of the LAPW and/or PV's.*

*This confirmation of the key role confirmed LAPW isolation brings in this class of cases, joins a similar rigorous investigation in another recent study by this same top volume ablation center conclusively showing that when adding real-time detected 'Non-PV trigger' ablation to this largely anatomic PVAI + LAPW + SVC isolation ablation for persistent AFIB, even significantly better long-term outcomes result. We will review this Non-PV trigger ablation study in a future issue of the newsletter in light of how many of our readers either have had, or are planning to have, such an advanced ablation method.*

We see here, that resorting to even a confirmed durable PVAI alone for these more challenging persistent cases is not an effective strategy. Keep in mind too, that the majority of the 52 persistent AFIB patients evaluated in this study were difficult compared to even earlier stage persistent cases, as indicated by the very small number who recorded an acute endpoint of AFIB termination during ablation.

In addition, the ablation technique employed by all operators in this study was restricted to the very common 'dot by dot' circumferential PV isolation method to compare apples to apples with other studies, and did not use the advanced gliding catheter technique created by Dr Natale, and used by some other St. David operators, that achieves significant reductions in both PV and LAPW reconnection rates.

Finally, keep in mind that the modest long term success rates in this tough persistent class of patients also reflects a limited ablation strategy used, specifically to prove the value of the LAPW-iso phase. A state-of-the-art extended PVAI + LAPW + Non-PV trigger protocol including coronary sinus (CS) and left atrial appendage (LAA) isolation, if needed, typically used on such patients at the main study center, shows a much higher long-term overall success rate than listed in this study.<sup>3</sup>

**Bai, R. et al. Proven isolation of the pulmonary vein antrum with or without left atrial posterior wall isolation in patients with persistent atrial fibrillation. *Heart Rhythm* 2016;13:132-140 <http://dx.doi.org/10.1016/j.hrthm.2015.08.019>**

## **Impact of Rotor Ablation in Non-Paroxysmal AF Patients: Results from a Randomized Control Trial (OASIS)**

AUSTIN, LEXINGTON KY, BAD NEUSTADT-GERMANY. In our last issue 140 of *The AFIB Report*, we took an in-depth look at the state of FIRM-guided mapping and ablation (Focal Impulse and Rotor Modulation), as our collective knowledge and experience of this controversial almost five-year-old ablation technology stood as of Feb 2016. I had promised then to complete this review of FIRM for our readers once this first randomized controlled trial ... OASIS-RCT ... yet published on FIRM was released in the coming months.

To make good on that promise, I attended the Heart Rhythm Society 2016 Scientific Session in San Francisco in May where this long-awaited OASIS trial was first presented to the press and public as a Late-Breaking Clinical Trial by trial leader, Dr. Andrea Natale.

For many of our frequent online forum readers, we first extensively reviewed the ins and outs of the OASIS-RCT starting with a May 13<sup>th</sup> forum thread on the topic about a week after the trial was first presented at HRS. A lengthy follow up thread on OASIS and FIRM from June 11<sup>th</sup>, based on the interest shown and questions asked online over the last two months about this important trial, covered most of the following discussion, and then some.

Since a majority of our newsletter subscribers don't often visit the forum, the following report primarily is aimed at them, and any who missed our forum discussions on the same to complete our investigation into FIRM for everyone based on publicly released studies and information up through mid-May 2016.

In that first review of FIRM mapping and ablation late last winter, we learned that even though the initial handful of published studies about FIRM + PVI ablations from 2012 through end of 2014 were largely positive, they all included at least some degree of FIRM developer, or FIRM company advisor participation in each of those studies. In addition, prior to OASIS-RCT, not one of these FIRM-studies, whether showing positive or more negative outcomes that has been published to-date in any peer-reviewed journal has examined FIRM-Only ablation without a companion PVI/PVAI to get a better sense of the inherent core impact FIRM might have in contributing to long-term freedom from atrial-

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<sup>3</sup> Di Biase L, Burkhardt JD, Mohanty P, et al. Effect of empirical left atrial appendage isolation on long-term procedure outcome in patients with long-standing persistent atrial fibrillation undergoing catheter ablation: Results of the BELIEF randomized trial. *European Society of Cardiology 2015 Congress. August 30, 2015; London, UK. Abstract 2188.*

tachyarrhythmia's (AT). Nor has any FIRM study so far, until OASIS, used the gold standard for reliable evidence with a randomized controlled design.

As such, while the early studies look promising at first glance, none stand as convincing evidence beyond any reasonable doubt that FIRM-mapping and ablation adds anything significant above and beyond a well done execution of the companion PVI/PVAI procedure. The more diligent one is at carefully reading through all FIRM-related studies so far, and truly factoring in the details being conveyed to better make apples to apples comparisons, the more this reality above becomes clear.

As if to underscore this key issue, since the beginning of 2015 when more recent independent studies on FIRM published since then started to trickle in from the US and Europe, a solid majority of these latest investigations have shown opposite poor outcomes for both FIRM + PVI, and now also dismal results from the first two complete FIRM-Only studies yet published; OASIS-RCT's Group 1 arm of 29 total 100% non-paroxysmal cases, plus a Norwegian FIRM-Only ablation study of 27 all paroxysmal cases, and both protocols without PVI ablation and very poor results that span 4 separate centers.

The contrast in outcomes is especially stark compared to the reported findings from the initial run of universally favorable FIRM + PVI studies. In addition, the handful of more recent FIRM + PVI studies reporting poor outcomes, were mostly done by independent centers and operators not affiliated with FIRM or its original developing company, Topera Inc., with a few individual operator exceptions.

It's understandable and even expected to a degree, when initial studies about a new technology are conducted with some measure of assistance or guidance by the developer, advisors and/or supporters of the concept, to then tend to show more impressive sounding stats compared to often more modest outcomes published by more independent studies as a promising new technology matures.

What one doesn't wish to see is for the majority of more recent and current reports to tell a very different story than any of the earlier mostly developer-assisted reports. Alas, this has been the case here with 4 out of the latest 5 studies published on FIRM through May 2016 that I have read. Independent study outcomes may not look quite as robust, but we at least expect them be on the same page as the initial concept study outcomes for us to gain real confidence in any new technology.

Nevertheless, in spite of the wave of negative reports coming in, with the exception of OASIS, they all used non-randomized design as well. As such, I expressed hope in the last newsletter that perhaps the complete OASIS-RCT might shed more light on the possible true value of FIRM.

And yet, it was clear that due to the importance of such rigorous RCT data emanating from one of the largest AFIB ablation research centers in the world, a lot was riding on the full OASIS-RCT outcome for FIRM and giant multinational, Abbott Medical Inc., as the new owner of the technology. Abbott having bought Topera Inc. a year and a half ago, well before any RCT had been done to confirm a more reliable verdict on the controversial system, one way or the other.

The OASIS presentation was, no doubt, among the most important and eagerly anticipated events at HRS and was attended by more EPs, cardiologists and related medical professionals than any other EP-related presentation I witnessed at the conference this year.

FIRM and its supporters have been under increasing pressure and skepticism over the last two years due to the rising tide and backlash from the publication of these latest mostly negative studies. In addition, skepticism has only been fueled by the concurrent lack of any well-structured RCT having been published by any center, be that a FIRM-supporting team or not, after more than 4+ years of system development. And all the while, FIRM has been vigorously promoted as a new paradigm-shift sure to change the face of ablation technology.

The FIRM contingent at HRS could not have been pleased when hearing the largely deflating outcome from this very straight forward and unambiguous OASIS-RCT.

### **Oasis RCT Structure**

In Issue 140 we reviewed the first preliminary 'Group 1' arm from a total of 3 groups comprising the complete OASIS-RCT. This first glimpse of OASIS, published last December, included 29 patients

made up of only persistent and LSPAF (non-paroxysmal) patients undergoing a FIRM-Only mapping and ablation with no combined PVAI ablation.

The results reported from Group 1, as now updated in the completed OASIS-RCT data released at HRS, showed FIRM-Only ablation in this non-paroxysmal group to simply be ineffective with only 14% (4 of 29) experiencing freedom from all arrhythmia and off all AAR drugs at  $12 \pm 7$  months. Results so bleak that it forced premature termination of this arm of the RCT so as not to inhibit these patients from being eligible for a more effective treatment soon, including at least a PVAI.

To make matters even less inspiring, all 4 of the patients making up the 14% 'successes' from the FIRM-Only Group 1 cohort had recently been taking the very long-acting anti-arrhythmic drug amiodarone, which is renowned for suppressing AFIB for up to 6 months, even after stopping the drug.

In spite of the lack of efficacy in using FIRM-Only ablation in this challenging cohort of patients from preliminary Group 1 outcomes reported in the last issue, many of us had hoped the larger full OASIS-RCT findings might yet better support using FIRM, at least as an adjunct to PVI/PVAI, and as implied by the published positive views of the earlier FIRM + PVI studies.

Even though all of these early reports examined FIRM + PVI ablation in non-randomized fashion and with variable degrees of vague and/or liberal outcome and end-point language employed from one positive study to the next.

Each of these FIRM + PVI positive reports also included a rough overall 50% patient average having had a mean of 1.2 prior PVI ablations, thereby making those FIRM + PVI ablations a literal follow-up procedure. And thus, further clouding the picture of just how much benefit one might honestly assign, if any, to the FIRM-mapping and ablation portion of these combined two-stage procedures.

Some of these encouraging sounding studies also included 'success' being defined as freedom from 'AFIB-only' ... not 'freedom from all atrial arrhythmia' ... as is standard outcome language used by the vast majority of AFIB ablation studies over the last ten years. And several of these early promising FIRM + PVI studies also allowed patients to be on AAR drugs at follow-up, if needed to qualify for freedom from AFIB-only ... or freedom from all arrhythmia in those studies that reported this stricter more accepted end-point as well.

Taking all this into account, it is not hard to see why a majority of the EP community have, as yet, remained hesitant to anoint FIRM as a new holy-grail of ablation technology. And indeed, real skepticism has only grown over the last two years, even prior to the OASIS-RCT results being announced. This background helps underscore why this first well-structured RCT on FIRM was so eagerly anticipated. By using only randomized study design and including a control group for the first time in any FIRM investigation, OASIS at last offers us a first more reliable look at what this new technology might really be capable of.

## **OASIS Findings**

After early termination due to futility of Group 1's non-paroxysmal patients who largely failed FIRM-Only ablation, the bulk of OASIS-RCT focused on comparing two separate protocols; Group 2 with a FIRM + PVAI in 42 matched non-paroxysmal patients, in comparison to the control Group 3 in which 42 equally well-matched persistent and LSPAF patients underwent a state-of-the-art extended PVAI + LAPW (left atrial posterior wall isolation) + Non-PV trigger ablation protocol.

OASIS was performed by very experienced AFIB ablationist across the three main centers, with Dr. Natale's world class St. David's Medical Center leading the trail, joined by Dr. Gery Tomossoni's long-established center in Lexington Kentucky, and Dr. Thomas Deneke's respected German center in Bad Neustadt ... the operator's at the latter two centers being very experienced with FIRM + PVI mapping and rotor detection.

And confirmed number of detected rotors (**4.2±1.7**) per patient in Group 2, as well 100% detected rotor elimination confirmed by repeat FIRM mapping in this most challenging cohort of FIRM patients yet studied, are statistically superior to any prior FIRM study to-date. A fact, that unequivocally dismantles a frankly lame excuse a few FIRM-booster EP's floated after the OASIS stats were presented, when suggesting these poor results must be an 'outlier' due to the OASIS teams presumed FIRM ineptitude.

The afibbers in all three groups were 100% non-paroxysmal, consisting of only confirmed true persistent and LSPAF patients. And, 100% of all cases had ablation naive hearts having had no prior ablation procedure at all. Hence, this was a significantly tougher cohort than any previously published FIRM-related study so far, not to mention the greater rigor and demands enforced by all patients being randomized in OASIS via a 1:1:1 randomization allocation, by group.

In addition, OASIS-RCT was the first study to compare a FIRM-guided + PVAI ablation protocol against the Group 3's state-of-the-art persistent and LSPAF ablation technique, described above, that's been well-vetted and proven effective by previous RCTs, and employed by a number of top volume ablation centers around the world. The efficacy of which is confirmed once again below in OASIS Group 3 arm.

The focus being, to not only get a strong indication whether or not FIRM + PVAI might offer clear evidence of added efficacy, over and above, an RCT-vetted PVAI-alone in this challenging population of afibbers, but also to answer the question: 'Does FIRM + PVAI buy us anything above and beyond what is possible to achieve with a front-line state-of-the-art non-paroxysmal ablation protocol already proven effective in other randomized trials? This is exactly the kind of data the bulk of the EP world has been waiting to see on FIRM.

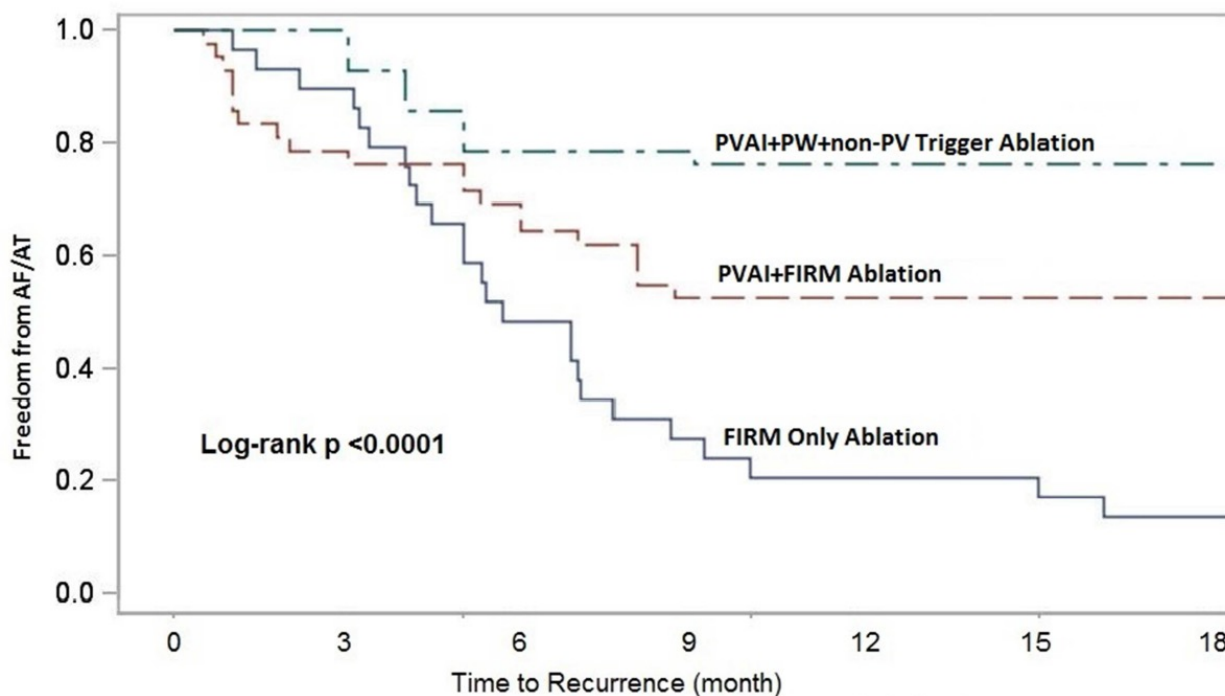
In this first randomized trial comparing efficacy of FIRM ablation, with or without PVAI vs. PVAI + LAPW+ Non-PV trigger ablation in 113 well-matched PersAF and LSPAF patients, the main findings were:

1. Rotor-only ablation had very poor outcome; (14% freedom from all AT and off all AAR drugs at one year), that forced premature termination of Group 1 arm.
2. FIRM-guided rotor ablation + PVAI had significantly longer procedure time and lower efficacy than did PVAI + LAPW + Non-PV trigger ablation.
3. Long term procedure efficacy of the three groups at 12 months +/- 7 months with freedom from all arrhythmia and off all AAR drug from a single procedure in 100% ablation naive hearts and 100% non-paroxysmal PersAF and LSPAF patients, were as follows:

**Group Success Rates (bolded and underlined):**

- A. **Group 1: FIRM-Only = 14%** (4 of 29 patients - 69% persistent, 31% LSPAF)
- B. **Group 2: FIRM + PVAI = 52.4%** (22 of 42 patients – 71% persistent, 29% LSPAF)
- C. **Group 3: PVAI + PW + Non-PV triggers = 76%** (32 of 42 pt.- 69% PersAF, 31% LSPAF)

**OASIS-RCT Long Term Outcomes**





Kaplan-Meier curve comparing freedom from recurrence across the study groups. After 12±7 month follow-up, 4 (14%), 22 (52.4%) and 32 (76%) patients in groups 1, 2 and 3 were AF/AT-free off AADs (log-rank  $p < 0.0001$ ).

**Graphic Legend:**

Group 1 = 'FIRM Only Ablation'

Group 2 = 'PVAI+FIRM Ablation'

Group 3 = 'PVAI+PW+Non-PV Trigger Ablation'

Note: In addition to OASIS-RCT Group 1 FIRM-Only in non-paroxysmal outcome failure with only 14% success at one year, the recent *Berntsen et al.*, Norwegian FIRM-Only study in 100% paroxysmal cases showed an equally dismal lack of efficacy as was found in OASIS-RCT, with only a 15% overall freedom from all AT and off all AAR drugs at  $15.2 \pm 3.2$  months.

However, this Norwegian report used an even easier, more liberal end-point requiring a longer period of AFIB/AT recurrence of  $\geq 30$  minutes duration of AT to equal failure, whereas OASIS-RCT used the more typical and stringent metric of any AFIB/AT episodes  $\geq 30$  seconds over the full follow-up period to denote failure.

In any event, the ineffectiveness of this second recent FIRM-Only ablation result also forced early study termination due to futility, further corroborating the OASIS FIRM-Only Group 1 outcome, in this well-done single center, single operator Norwegian study published in Heart Rhythm Journal, April 2016: <http://dx.doi.org/10.1016/j.hrthm.2016.04.016>

**Addendum: PRECISE Trial mystery**

There are two brief abstracts reported by the FIRM developer reflecting results from the PRECISE Trial<sup>4</sup> of FIRM-Only ablation with no PVI on 31 paroxysmal-only patients showing an amazing 82.6% success defined as freedom from 'AFIB-only' at 6 months (190 days), from the 2013 HRS conference in a mysterious reference nearly impossible to find on PubMed. And the same PRECISE study followed-up long-term in a second, equally hard to find poster presentation abstract from HRS 2015<sup>5</sup> showed purported FIRM-Only freedom from AFIB of 80.6% at 365 days and 74.2% at 561 days. Truly extraordinary, even with 'AFIB-Only' defining success.

Both of these very impressive sounding PRECISE outcomes published so far via only 'mini-abstracts' with very sparse data from 2013 and 2015 HRS presentations, have *never* been published in any peer-reviewed journal that I could find after exhaustive research over the last 6 months.

For over 3 years now, these PRECISE results have been touted and reinforced in presentations by FIRM proponents at every AFIB conference I have attended as proof of concept that FIRM mapping and ablation alone results in long-term freedom from AFIB. The question then arises, if these outstanding numbers using FIRM-Only ablation can withstand critical scrutiny of a peer-review process, why on earth has neither of these studies have ever been formally published in any cardiology/EP journal showing complete detailed data plus study design and structure?

Certainly, repeated reference to these outstanding sounding results at the various conferences has served to give skeptical EP's pause, and forced many EP's and lay afibbers alike, including myself, to assume FIRM must fundamentally detect and eliminate AFIB sources if a FIRM-Only ablation can reproducibly and consistently produce such results. If so, where is the beef, as they say? After over 3 years and plenty of time since PRECISE was briefly first described with very few details at HRS 2013.

Perhaps there is a good explanation for this mystery of where the full PRECISE study can be found. Certainly, when and if, I'm able to discover this, so far, unsolved mystery ... I'll gladly inform all

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<sup>4</sup> Narayan SM, et al. Precise rotor elimination without concomitant pulmonary vein isolation for the successful elimination of paroxysmal atrial fibrillation. *Heart Rhythm* 2013;10:1414.

<sup>5</sup> Narayan SM, et al. Long-term freedom from paroxysmal atrial fibrillation by eliminating localized sources without pulmonary isolation. *Heart Rhythm* 2015;12:S107 (PO01-29)

readers via newsletter and forum clarifying such a welcomed revelation. In the meantime, I cannot in good conscience consider the very limited PRECISE data I've seen so far as reliable.

I'm still open to being convinced with proper evidence, though I cannot reconcile why such stunningly good sounding results from FIRM-Only ablation would not have been literally shouted from the roof tops by EPs everywhere by now, and why FIRM-Only procedures would not dominate the AFIB ablation landscape by now, at least for paroxysmal AFIB, if these results were universally replicable. Furthermore, if this were truly reliable information, then why on earth would there be almost no FIRM-Only ablation procedures being offered as front-line treatment for their own patients by the majority of those EP's that are still staunch FIRM ablation supporters?

I only read and hear of FIRM + PVI ablations being done for the most part, and outside of these PRECISE trial references, there is precious little successful FIRM-Only ablation evidence seen in any of the other positive FIRM-based non-randomized studies. And now, with the two recent independent FIRM-Only ablation studies to be published to-date, including the first full RCT on FIRM addressing both non-paroxysmal and paroxysmal cases, and both showing equally dismal failure of FIRM-Only ablation ... I'm sorry, but the PRECISE story just does not add up! At least not based on all available evidence I've been able to find to-date.

For now, afibbers faced with an ablation decision, the FIRM story so far underscores our long term recommendation never to choose the exciting sounding technology first, and only then seek out ablation EPs who are willing to use the tech you prefer. Always seek out the most experienced and well-vetted ablation EP you can possibly arrange for yourself, even if a week of travel might be necessary to put your hearts care in your best possible option's hands. Then trust that he or she will choose the very best tools for your procedure. There is great wisdom and a long history of experience behind this approach to insuring the best results with least risk possible.

### **Conclusion & Editor's Comments:**

*In drawing to a close this important, controversial and complex two-part review of FIRM studies so far, I want to emphasize that in spite of the apparent mystery around PRECISE, and the very poor outcomes from the only reliable and published FIRM-Only ablation evidence so far, this does not necessarily mean FIRM ablation added to a PVI/PVAI is bereft of any merit. Nor does it confirm that all algorithmically-detected rotors are inherently ineffective ablation targets, nor does anything seen so far rule-out the possibility that these mathematically-conceived rotors really do drive AFIB in humans*

*However, the wave of largely disappointing FIRM + PVI research published over the last 18 months may well be telling us (paraphrasing both Drs. Berntsen, Buch/Shivkumar and Mohanty/Natale in summation of their own FIRM investigations when they separately, yet collectively, posit the very real possibility that): '... the observed rotor-like activity produced by the proprietary FIRMap software may just be an epi-phenomenon of fibrillatory conduction over-interpreted by a complex algorithm processing suboptimal data.' Rather than directly revealing consistent ablation targets.*

*The jury is still decidedly out on this hypothesis, and rotor detection and ablation may yet bare sweeter fruit, either by other possibly more mature or effective approaches at rotor mapping and detection, such as possibly Cardio-Insights non-invasive body surface mapping vest, or even by future more effective iterations of the FIRM software and method that perhaps includes more effective basket mapping catheters than the one's currently used in FIRM ablations.*

*With the huge resources of Abbott Medical now behind FIRM, the odds are good that if there really exists a fundamental advantage in targeting such rotor-like patterns, their large team should be in good position to take advantage of this scenario. But only if the 'rotors as AFIB drivers' theory fully pans out in the coming years of research. All bets depend on whether or not this theory is fundamentally right, which is now honestly in doubt.*

*Regarding the Cardio-insight vest, while there is preliminary promising data out using this interesting approach to such individualized substrate driver detection, so far, most of this data also includes a well-done PVI ablation too, thus leaving it still unclear just how much of any long-term good results can be attributed to the vest-based driver ablation phase.*

For example, “in a study using such a non-invasive body surface mapping vest with derived electrograms from the inverse solution, Haissaguerre et al. found that rotors were short-lived and meandered considerably, but recurred repeatedly in the same regions (of the LA & RA). Although ablation of regions with high rotor density resulted in a significantly earlier termination of AF compared to a standard step-wise approach, freedom from AFIB at 12 months were similar in both study groups; suggesting no specific additional effect of rotor ablation when combined with PVI which was performed in all patients as well”. *Heart Rhythm Journal*, pg. 9 April 2016: <http://dx.doi.org/10.1016/j.hrthm.2016.04.016>

All this data is still only non-randomized ‘hypothesis generating’ evidence so far. Not solid proof of concept, just yet. And now, after the experience with FIRM, I suspect everyone will demand several well-structured independent RCTs confirming reliable efficacy for any all new mapping approach before the majority of the EP world is willing to jump on board.

### **Where does FIRM + PVI go from here?**

When carefully vetting the bulk of existing positive and more disappointing reports on FIRM, it is clear that there is, as yet, no convincing evidence that FIRM + PVI truly buys us much more than a well-executed PVI/PVAI alone.

Once all the looser design structure coupled with generally more liberal endpoint and outcome language used in a majority of the positive non-randomized FIRM studies is more accurately aligned and compared as close as possible with the much stricter RCT of OASIS, as well as the rest of the negative reports of late, there just is no compelling evidence that adding FIRM to PVI/PVAI clearly increases conservative long term success ... that is the bottom-line from my 9-month long research.

How do we then reconcile the fervent insistence and confidence expressed by many FIRM supporting EPs that they see better overall results in patients with FIRM + PVI, compared to older PVI-only patients they used to treat? I have no doubt each of these EPs is entirely sincere and earnest in that belief and self-assurance in a distinct FIRM-added benefit in their patients. And such is the inherent catch-22 set-up by including a well-executed PVI/PVAI with each FIRM rotor detection ablation phase.

I can imagine, too, that most do notice some degree of benefit, although how much is due to their own improving skill and increased precision in PVI/PVAI over the ensuing years from constantly advancing catheters, mapping systems and progression of ablation understanding now, compared to those earlier patients they may largely be recalling anecdotally?

Also, there might be some degree of expected modest benefit in outcome simply from the fact of adding Non-PV lesions at FIRM detected regions, beyond the PVI. And not surprisingly, these rotor areas tend to coincide with 4 to 5 LA/RA zones where almost all AFIB triggers reside ... by whatever name you call them. Even if a modest increase in ‘hits’ simply by ablating in other areas of the LA/RA were purely a random result (aka a blind man pinning a tail on the donkey), as might be expected to happen simply from adding additional lesions via FIRM-guided ablation.

Regardless of the influence, so far objective cross comparisons do not suggest a significant FIRM + PVI advantage over other well-vetted RCTs on PVI/PVAI-alone for matched classes of afibbers. For example, one of our members who consulted with a highly-respect FIRM researcher, Dr. John Miller, at Indiana University Health Methodist Hospital, recounted how this deservedly appreciated clinical EP and educator assured him that his PVI success rate ‘jumped from around 60% to 80% over the last 5 years from adding FIRM to his PVI’ (paraphrased 2<sup>nd</sup> hand conversation).

Yet, when you look at Dr. Miller’s latest published FIRM + PVI study, also released at this HRS, his actual FIRM + PVI stats lists a **79%** freedom from ‘AFIB-Only’ at 15 months, from an evenly split paroxysmal (37%), persistent (31%) & LSPAF (32%) cohort. However, when including the far more relevant ‘freedom from all AT’ the success drops to a more typical **64%** at 15 months, not to mention that **42%** of all cases had at least one prior PVI before the FIRM + PVI ablation. Still decent for this group, but not any better than other PVI/PVAI studies using strict RCT design guidelines, while Dr. Miller’s study used non-randomized ‘look-back’ retrospective data that may inadvertently inflate stats to a degree compared to randomized control design using a similar cohort. (**Study numbers from HRS 2016 poster abstract: ‘Termination of AFIB-Guided by Rotor Mapping: Impact on Long-term Outcomes’**).

Compare that to STAR-II-RCT that showed roughly a **59%** freedom from AF at 18 months from a PVI-alone in 100% persistent, with a mean of 2.2 years of persistent AFIB (partly an LSPAF group), done at over 40 centers world-wide. And when you include 2 PVIs per patient, the success goes up to **72%**. Dr. Miller's mixed group of 37% paroxysmal 63% non-paroxysmal had **79%** 'freedom from AFIB' using looser less confidence-inspiring retrospective data, and **42%** of patients had at least one prior PVI ... you can quickly see how the numbers game starts to even out here.

Dr. Tomossoni, another leading FIRM researcher that is included in OASIS-RCT, posts some of the best results in his FIRM + PVI studies, and showed in his own recent non-randomized FIRM study<sup>6</sup> a single procedure FIRM + PVI freedom from AT and off all AAR drugs at **58%** in PersAF and only **25%** in LSPAF, (note: how the added 37% paroxysmal cases in Dr Miller's study above might help swell his stats a bit).

All of the above, compared to OASIS-RCT Group 2: FIRM + PVAI at **52.4%** freedom from all AT and zero AAR drugs at 12 months in 100% non-paroxysmal, 100% ablation-virgin hearts via all randomized data; and giving a **76%** success from GROUP 3's advanced non-paroxysmal ablation protocol of PVAI+LAPW+Non-PV trigger ablation. This clearly underscores the non-inferiority of OASIS-RCT Group 2 and clear superiority for OASIS-RCT Group 3 compared to any of the non-randomized FIRM + PVI studies to-date. Especially when all variables are given their proper weight and due consideration.

### **The End Game**

In the final analysis, the only way we will get further clarity on what role FIRM may, or may not, have going forward, and confirm if there is any reliable added benefit from FIRM + PVI/PVAI, will depend on at least several more conservatively-designed RCTs on FIRM, preferably from independent centers, all confirming a repeatable, consistent benefit to adding FIRM to PVI/PVAI going forward.

None of us want to see more non-randomized FIRM studies at this point, just reinforcing the same rather unconvincing story we have seen so far. If this version of FIRM, or a future iteration, can truly prove itself under the rigorous light of such reliable RCTs, then there may well be hope that FIRM yet finds a key place in the EP Lab. The current outlook makes that a tall order, but not impossible.

**Mohanty S, et al. Impact of Rotor Ablation in Non-Paroxysmal AF Patients: Results from a Randomized Trial (OASIS), JACC. July 2016. <http://dx.doi.org/10.1016/j.jacc.2016.04.015>**

## **Brain Benefits of L-Theanine** *By Jackie Burgess*

Many, find the supplement L-Theanine can help terminate an AF episode when taken at the onset. This amino-acid, found in green tea, is also useful to help relax during AFIB events since it increases the brain's alpha wave calming activity, or for just relaxing at bedtime to diminish that 'wired' or restless feeling. A most important property for L-Theanine is that while it produces a relaxing calm, it does not cause drowsiness or motor impairment compared to pharmaceutical stress-relievers such as Xanax, Valium, Restoril, Lunesta or Ambien. In 2006, Michael T. Murray, N.D. wrote about L-Theanine as a: "gentle, natural alternative" in his newsletter and gave dosing guidelines which were reported in various posts on our AFIB forum.

New discoveries over the past two years indicate L-Theanine may reduce the risk of stroke and protect against brain damage of ischemic strokes .... important news and not just for Afibbers.

A few of the referenced study highlights from a report on the Benefits of Theanine are published in the March 2016 issue of Life Extension Magazine linked to below and include:

- L-Theanine supplementation may help prevent the abrupt rise in blood pressure that some experience with stress.
- Excessive glutamate stimulation of brain cells (excitotoxicity) factors into development of neurodegenerative disorders including stroke and schizophrenia and L-Theanine helps lower

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<sup>6</sup> Tomassoni G, et al. Long-term Follow-up of FIRM-guided Ablation of Atrial Fibrillation: A Single-center Experience. *Journal of Innovations in Cardiac Rhythm Management*, 2015;2145-2151

excess glutamate.

- There is a link between anxiety, reactions to stress and the brain's function of maintaining cognition. L-Theanine may help support cognitive function and may possibly help slow early onset progression.
- Chronic glutamate-driven excitotoxicity can result in profound and long-lasting cognitive decline including neurodegenerative disorders such as Alzheimer's, Huntington's, Parkinson's and ALS.
- Animal studies over three years indicate the protective effects of L-Theanine may help mitigate these disorders to some degree in early stages.
- Recent studies show L-Theanine may prevent both biochemical and structural damage to brain cells induced by aluminum, which can then prevent or slow cognitive decline.
- Significant nitric oxide production in endothelial cells, offering the potential to lower stroke risk.
- Animal studies show that administration of L-Theanine up to 12 hours after induced stroke reduces brain damage size.
- 400 mg L-Theanine daily along with regular meds helped schizophrenic patients reduce anxiety and general symptoms.

Be sure to read the complete Life Extension Magazine Report:

### ***Brain Benefits of L-Theanine***

<http://www.lifeextension.com/magazine/2016/3/brain-benefits-of-l-theanine/page-01>

Look for the identification of Suntheanine® on the label of supplements to ensure reliability and purity.

## **An Inspiring Patient's Story** *by Richard D.*

On June 26, 2014 I had triple by-pass surgery at the Foothills hospital in Calgary. I was quite fortunate in that the resident surgeon who performed the surgery was Dr. William Kidd. He had excellent communication skills, and instilled great confidence. This, he followed up by doing a flawless by-pass procedure. Since I was quite fit, my recovery proceeded quickly and I was home less than a week later on July 1st. As I healed and went for walks, I could immediately feel that the shortness of breath, which I had experienced leading up to the surgery was gone. I could climb stairs effortlessly, and when I resumed going for my workouts, I could put in 30 minutes at a brisk pace on the elliptical machine. Soon I was back playing golf, and I felt I had clearly been given a second lease on life.

After three months, I went back to my cardiology centre (Total Cardiology) and was put to work on the stress EKG. I was still going strong well after 12 minutes, and the technician said she could stop the test. No need to go any further. She told me that it was the strongest performance she had seen after a by-pass that year. And I was exhilarated.

This feeling of euphoria lasted for 6 months. Almost overnight, I again noticed the dreaded shortness of breath. Could the blockages have returned?

A little later, I noticed something else. I would wake up at night gasping for air, as if the windows needed to be opened to let in fresh air ... it felt like the room was lacking oxygen.

I called my cardiology clinic to make an appointment, but the waiting time was two months. In the meantime, I decided to go to another walk-in cardiology clinic down town, operated by Dr. Gary Bloomberg, and saw him literally the next day. His staff performed an EKG, and he gave me the news. I was in "AFIB"... Atrial Fibrillation. I had never heard of AFIB. He said it was not uncommon for by-pass surgery patients to develop this condition following their surgery. And he recommended that I keep my appointment at my regular clinic, and that my regular cardiologist would advise me as to the proper treatment.

Since that was in a couple months, I called the office of cardiac surgeon, Dr. Kidd, and booked an appointment with him. I was able to see him within two weeks and he was happy to see how well I had healed up, and told me that the by-pass was successful. The shortness of breath and the other symptoms were due to the fact that I had developed AFIB. But, he said that the treatment of AFIB was

not in his department. The Hospital had an “Arrhythmia” unit, and he made an appointment with the department head (without a long waiting period).

At this appointment, I was given a very detailed explanation of what AFIB really was – in terms of the functioning of the heart. Among other things, I learned that I was in much greater risk of having a stroke ... and Dr. Mitchell explained why. After reviewing the medication options available, we decided I would immediately start taking the blood thinner, ‘Eliquis’.

I wanted to know how to ‘cure’ this problem. He was not very encouraging, but he did say that some patients have had their normal heart beat restored by “Cardioversion”, literally by the application of an electrical shock to the heart. He said that if this didn’t work, many other patients have a pacemaker installed, which they then live with for the rest of their lives.

We agreed that I would go to my appointment with my cardiologist, and in the interim, he would write a letter to my cardiologist recommending we try the cardioversion.

At this stage, I wanted to learn all I could about AFIB. I was always short of breath, and could basically only walk on flat surfaces. If I encountered any stairs, a small rise, or had to perform any cardio activity, I was panting for air and had to stop to catch my breath.

On the internet, I came across a reference to a book written by Steve S. Ryan, PhD titled **“Beat You’re AFIB”**. I ordered it on-line and it arrived in three days.

This book provided me with quite a different insight. Here was a guy who had AFIB and beat it! He detailed his own experiences with his cardiologists, and I could relate. I highlighted in yellow two lines in his book:

“Cardioversion offers immediate, but short lived results”  
“In general, pacemakers are not very effective for controlling AFIB”

However, I did proceed with the cardioversion. It successfully restored my normal heart beat. I felt great again! But, alas, in about 6 weeks the A-Fib was back.

I asked my cardiologist if we could redo the cardioversion. I asked if ablation was an option (I had read all about this procedure in Steve Ryan’s book, and the success achieved at the Bordeaux clinic). He replied “We aren’t doing cardioversion, or ablation ... you need a pacemaker.”

***(Editor’s note: This is an all too often seen recommendation as the best, or only, alternative given to far too many persistent and long standing persistent AFIB patients we have seen on our forum by otherwise well-meaning, though clearly not up-to-date EPs and Cardiologists. Even including advice to such patients to get an AV-Node ablation and become pacemaker dependent for life which still only reduces AFIB symptoms, but not stop AFIB itself.)***

I agreed to have the pacemaker installed, but now I started to stall the process. I had additional holter monitor tests done by Dr. Bloomberg to see how low my heart rate dropped at night. On the advice of another cardiologist, I stopped taking the blood pressure medication (Valsarten) which I had been taking since the by-pass operation. This immediately raised my heart rate to the point that the holter test now indicated a pace maker was not needed. But I still had that extreme shortness of breath, and difficulty in climbing stairs.

I wrote to the website “The AFIB Report” with my story, asking if I should consider ablation and perhaps go to the Bordeaux Clinic. I received an email from Shannon Dickson, another person who “beat” his A-Fib, and who was now providing information to victims of AFIB. This was a game changer for me.

A little later, Shannon called me and I told him that I had reluctantly agreed to have a pacemaker installed. He told me that there was a clinic relatively closer compared to France in Austin, Texas that was very successful in performing the ablation procedure, and was particularly recommended for persistent and long standing persistent cases like mine.

Shannon said that in 8,000 plus AFIB ablations performed by Dr. Andrea Natale, head of the clinic in Austin, he had never had to resort to use of AV-Node ablation plus required pacemaker to address AFIB, nor to using just a pacemaker without AV-node ablation to control atrial arrhythmias.

He also mentioned that Dr. Natale was Director of the largest AFIB research and ablation center in the world there at St David's. Shannon expressed his view that Dr. Natale might be the best surgeon performing ablation on the planet, although he did say that the team at the Bordeaux Clinic was excellent as well and that he often referred patients from Europe to Bordeaux for Drs. Haissaguerre, Jais or Hocini to treat. I remembered Dr. Natale being referred to in Steve Ryan's book.

I asked Shannon what would be involved in getting on the waiting list at St. David's in Austin. He said that it could be two to three months, but that he would call them to find out what the current waiting list might be. He called back the next day (Thursday May 12<sup>th</sup>) and told me that St. David's just had a cancellation on the very next Tuesday, May 17<sup>th</sup>, and I could have the slot. I said "I am in"!

***(Editor's note: In this case, when Dr Natale heard that Richard was already scheduled that next week to have a pacemaker installed for his AFIB-induced bradycardia, he worked with his schedulers to see what was possible. Fortunately for Richard, a cancellation had just occurred at St. David's for the next Tuesday to enabling him to avoid having a pacemaker installed unnecessarily in Canada.)***

This seemed so improbable, I started to wonder if this was just an internet scam, where I would next be asked to send the cash up front. However, a few hours later I started to receive emails from St. David's which proved this was for real. I sent my medical records and agreed to the fee (\$40,000 USD) that I would pay at the clinic, since I had no US medical insurance.

I flew to Austin on Sunday with a very close friend, and reported to St. David's Arrhythmia Clinic at 9:30 on Monday morning (May 16<sup>th</sup>). They took blood samples and an echocardiogram and gave me a thorough check up. Everything was highly professional, and the staff were extremely friendly and helpful. I looked forward to meeting Dr. Natale. He did not disappoint. He was calm, and humble, with kind, receptive eyes and yet he imbued overwhelming confidence when he spoke and explained what he would be doing. I knew I had come to the right place.

On the 17<sup>th</sup> the operation was scheduled for 7:30 am, and it proceeded as planned. Successful Ablation requires two elements. Firstly, the science and technology has to be state of the art, which the St. David's Cardio Unit clearly has.

However, it is very clear that the procedure demands a high degree of art as well. The surgeon must be extremely skillful to have the dexterity required to manipulate a camera plus mapping and ablation catheters on the end of a four-foot cable, which are inserted into the heart via openings in femoral veins at the right and left groin and right jugular vein.

It is like the difference between Michelangelo and a top artist, or Leonardo da Vinci and one of his top students. Dr. Natale is a real master.

I came too after about five hours. Not much later I was staring at a heart monitor above my bed showing a nice, normal sinus EKG which my Calgary EP had said I would never see again under any circumstance. Later that afternoon Dr. Natale dropped by to see how I was feeling and to explain how the procedure went from his perspective. He indicated that the one-year delay in doing the ablation definitely made it more difficult. He told me that he tried his best to cauterize all of the misfiring spots in that single session.

However, he did say that if the AFIB came back, he would have to go back in. Such a second session which would generally be far shorter than the first ablation would then eradicate any remaining arrhythmia. I had agreed to have a Medtronic 'Reveal LINQ' implantable heart monitor installed under my skin. This is really a computer chip which monitors my heart rate 24/7 and the data is transmitted to St. David's unit every day. All wireless via Wi-Fi. The added cost for this was \$4k.

I was kept overnight and released at noon on Wednesday. My dear friend and I stayed in Austin another night and we flew back to Calgary on Friday. When we left the plane and we walked up the

gangway bridge to the terminal I did not labor for lack of breath as I did earlier. As I walked up, I felt I was floating on a cloud! AFIB no more!

### **June 18<sup>th</sup>**

It has now been one month since Dr Natale performed my ablation. In spite of having been in continuous long-standing persistent AFIB for well over a year, I have been in normal sinus rhythm since waking from the procedure on May 18<sup>th</sup>.

I am now sleeping through the night for the first time in almost two years. During my time with A-Fib, my heart rate would fall as low as 20 beats per minute and often with long pauses of several seconds while I was asleep. Invariably, I would wake up gasping for air. I would have to get up and move around to get my heart rate up several times every night. Now I am finally feeling well-rested and no longer wake up with a head-ache. The "LINQ" implanted heart monitor is transmitting my EKG to St. David's Cardio group every day, and they report that my results are excellent.

A week after the procedure in Austin, I was back playing golf with my regular group. I am no longer short of breath, and have no fear of climbing stairs, or hills on the golf course. Last week I hit a tee shot 320 yards (I am 68). That was longer than I had ever previously hit a drive on that particular hole.

On June 16<sup>th</sup> I kept an appointment I had with local head of the arrhythmia department at the Foothills hospital. This EP had advised me earlier that I would have to live with A-Fib for the rest of my life and would be taking blood thinners for the rest of my life as well, Not only that, but he insisted that I needed to be fitted with a pacemaker without delay, which I would also have for the rest of my life.

He was surprised during our meeting, to say the least, when I showed him an EKG taken a few days earlier showing a normal sinus rhythm. I told him that I felt I had to find an actual cure, and not merely treat one or two of the symptoms. I explained how I had contacted the "A-Fib Report" web site, and how Shannon Dickson was able to get me into the queue at St. David's almost immediately due to a cancellation, and thus I was urgently moved up to help avoid the scheduled pacemaker installation unless absolutely necessary. Dr. Mitchell indicated that he knew Dr Natale, and offered me his congratulations.

I realize that it has only been a month now, but every day without A-Fib is a victory!

**Richard D. - Calgary**

*Editor: Shannon W. Dickson*

*THE AFIB REPORT is published 6 times a year by  
Shannon W Dickson, PO Box 1016, Sedona, Arizona, 86339 USA  
E-mail: [editor@afibbers.org](mailto:editor@afibbers.org) World Wide Web: <http://www.afibbers.org>*

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