BofA SECURITIES

Medical Technology

AF Symposium takeaways – doctor feedback on heels of Farapulse approval

Industry Overview

PFA all the talk at AF Symposium; on back of Farapulse

Last week we attended AF Symposium in Boston (one day after BSX's Farapulse was approved). PFA was the main discussion topic. From our conversations and the panels doctors are excited to have PFA in the US and they generally expect broad and quick adoption of PFA (50%+ share shift in the next 1-2 years to PFA from both RF and cryo). Farapulse pricing is about a 30%+ uplift vs Rf/cryo; we heard Farapulse at $8,500 pre rebates and $6,500 for the highest volume users (5+ procedures / week). With PulseSelect and Farapulse now both available in the US, doctors seem more interested in Farapulse but are excited about Affera once available (US IDE data results expected in 1H'24, we estimate approval in 2H'24). Below and inside we go through our conference takeaways.

Expected PFA share gains from doc conversations

One US doctor who uses 100% RF for their ablation cases today expects more than 50% of their share to switch to PFA in 1-2 yrs. Which PFA catheter they will use depends on compatible mapping and pricing. Another US doc sees PFA first replacing cryo and then RF but overall in 2-5 yrs sees PFA being 50%+ of the market coming from both cryo and RF. One European doctor prior to PFA used cryo for 60% of ablations / RF 40% and in 1 year post PFA use with Farapulse saw almost 50% of their practice convert to PFA, taking share from both cryo and RF, and now uses PFA for 80% of their practice and the remaining 20% split equally between RF and cryo.

Key panel discussion takeaways ...continued inside

Will PFA improve efficiency and workflows? One panelist noted if PFA is reducing procedure time from 50 to 37 mins it may not result in an additional case per day, especially for those who can do cryo in a similar time for example, but thinks the benefit will be for operators who run longer to bring their procedure times down. Another panelist agreed that the ease of use will narrow the gap between more and less experienced operators and open up more procedures to those who could not do a point by point ablation for example but could do an ablation with PFA.

Patient selection for RF vs PFA? One doctor in Europe argued there is still a role for RF since it is established with predictable outcomes, but the promise of safety with PFA is very powerful. He notes there is no specific patient characteristic for which he would choose PFA vs RF and generally offers patients a choice. Another panelist argued he would be surprised if many PVIs are done with thermal ablation in the short future, even if PFA efficacy is equal (though he believes PFA efficacy is better than thermal). He also notes with the significant ease of use and reduction in procedure time, it is hard to believe he will use anything other than PFA. A European panelist noted they have had PFA since 2021 and are not ablating everyone with PFA, partly because of resources and costs in healthcare systems, but doesn't think the field is at the point yet where it can treat all patients with PFA even if wanted to.

See inside for much more doctors' feedback, new late breaking clinical data, and second gen PFA devices such as ABT's Volt PFA system.

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PFA = pulsed field ablation

RF = radiofrequency ablation

Afib = atrial fibrillation

BSX = Boston Scientific

MDT = Medtronic

PVI = pulmonary vein isolation

Refer to important disclosures on page 5 to 7.

Point by point with Affera vs single-shot? A European doctor who was doing a live ablation case with Affera believes the main use of single shot devices should be in pure PVI cases. They noted Affera is an all-in-one catheter (RF, PFA and mapping) so can ablate beyond PVI. This doctor has been doing more repeat ablations with Affera because they can safely go for additional lesions beyond PVIs which is what most re-do ablation patients need. They like Affera for the safety, effectiveness and time saving of this catheter when doing additional lesions beyond PVI.

Will there still be a role for cryo with the introduction of pfa? "Think there will continue to be a role at least in near term mainly because of the long-term data we have with cryo, experience and cost. In US PFA will be adding $1-$2k of supply cost to every afib ablation which is a big obstacle to adoption at some hospitals."

Is contact force sensing on PFA catheters needed? One doctor argued there are many technologies to assist operators in maintaining good electrode tissue contact such as Intracardiac echocardiography (ICE) and the question is what incremental gains one can get with contact force sensing and is it worth the additional cost. They think with experienced operators the answer is no but with beginners it's helpful to learn where the catheter is in heart but there are other ways of doing that which are less complicated. Another doctor noted there is role for contact force sensing in point by point systems (vs sees contact force sensing more challenging to implement in a single-shot basket catheter) but doesn't think that will be the dominant delivery mode for PFA.

With efficacy for thermal and PFA around 70%, what going to do to capture that other 30%? One doctor thinks the holy grail is still being able to understand mechanism of afib in all patients. He notes some cases are easy to understand and solve but in big picture it's the ability to understand why does this patient have recurrent afib. Another doctor notes there is a lot more needed to do to treat comorbidities of patients.

Need for concomitant LAAC + afib ablation procedure when have continuous monitoring? One doctor believes there is a need to individualize patient treatment since not all patients need to be on anticoagulant longer term and from the OPTION trial we'll find out. This doctor believes nobody wants to keep monitoring forever so if can close the LAAC once and not worry about it (if can close it once and do so safely and cost effectively) then why not. Another doctor thinks a concomitant procedure depends on what the atrial function is, if someone's atrial function is decimated by an ablation then it makes sense to close the appendage, assuming positive OPTION trial. He thinks maybe will end up looking at combination of risk score and residual afib and atrial function.

Second gen PFA devices key points of differentiation

ABT's Volt PFA system

Dr. Atul Verma notes that second-generation PFA devices need to improve on tissue depth (5mm+), contact sensing, and optimizing tissue delivery while minimizing blood pool delivery. With current PFA devices the maximum electric field depth is 3-4mm, not much different than thermal, and Dr. Verma believes lesions should be at least 5mm in depth. Volt's balloon-in-basket based design is designed to improve apposition, alignment and energy transfer efficiency. Computational modeling indicates lesion volume increase of 16-23% with this design. The balloon also insulates against delivery into the blood pool and minimizes microbubbles and hemolysis. The Volt PFA generator with electrode selectivity assesses tissue proximity and integrates with ensite mapping. ABT is also working on TactiFlex PFA therapy delivery with two therapy settings designed to target at least 5-6mm depth with one application. TactiFlex is a large, single point ablation using a flexible tip catheter.

Pulse Biosciences nanosecond PFA

Dr. Vivek Reddy presented a case using a nanosecond PFA catheter from Pulse Biosciences. The catheter features 2 ablation rings through which energy is delivered, the outer electrode ring is 30mm and the inner is 22mm. Dr. Reddy notes pre-clinical

safety seems to show high quality lesions that are 5-6mm in diameter that are quick and reproducible. He notes the system is not really a single-shot design but more a regional ablation catheter. In the case he presented he noted he did not create a lot of redundancy in the lesions because it seems to make effective lesions and he didn't feel he needed a lot of redundancy. In the case he did 10 ablations which resulted in an ablation time of 7 mins and total procedure time was 41.5 mins.

The benefit of this nanosecond technology vs the existing systems which use microsecond technology is with nanosecond technology the number of volts is high (instead of 2k its 7-10k) but because the duration is so short the amount of joules of energy that enter the tissue is much less than microsecond. This matters because it helps with catheter construction and also allows greater flexibility in how energy is delivered (don't need to wait as long). Dr. Reddy notes for ablation in the atrium both nanosecond and microsecond are ok but he thinks there is reason to believe nanosecond may be better in ventricular.

Late-breaking clinical science presentations

Complete 12-month outcomes from inspIRE

The inspIRE study evaluated the safety and effectiveness of the VARIPULSE Platform for the treatment of drug-refractory paroxysmal AFib in Europe and Canada. At AF Symposium 2023 one-year outcomes from the inspIRE clinical study demonstrated early success at the prespecified interim analysis. The primary analysis showed 0% primary adverse events and the primary effectiveness endpoint was 70.9% but this included only a subset of patient data (186 subjects were enrolled in Wave II population and reached 3-month follow up but only 86 patients had reached 12-month follow up). At AF Symposium in 2024 the entire Wave II cohort (186 subjects) outcomes were reported. The primary effectiveness endpoint of acute pulmonary vein isolation and 12-month freedom from atrial arrhythmia recurrence (AFib, Atrial Tachycardia, or Atrial Flutter) was 75.6% (vs the 70.9% in the interim analysis). Among participants receiving optimal PFA applications (≥48 total or ≥12/vein), 80% achieved the primary effectiveness endpoint. The full results also continued to demonstrate a primary adverse event rate of 0% with notably no esophageal injury, PV stenosis, or coronary spasm reported. There was 1 serious procedure-related adverse event (urinary retention) reported and resolved.

Exhibit 1: Summary of 1-yr efficacy data in PFA vs thermal studies

Below we update our summary of 1-yr efficacy data for the inspIRE full cohort 12-month follow up data which showed 75.6% effectiveness in paroxysmal afib patients. This compares to 81.6% seen in the MANIFEST-PF survey for paroxysmal patients, 73.3% in ADVENT, 66.2% for PulseSelect and 78.3% for Affera.

Company	Device	Energy	Clinical Trial / Study	Type of Afib	1-year Afib Freedom Efficacy
Pulsed Field Ablation					
BSX	Farapulse	PFA	MANIFEST-PF survey	Paroxysmal	81.6%
BSX	Farapulse	PFA	MANIFEST-PF survey	Persistent	71.5%
BSX	Farapulse	PFA	IMPULSE, PEFCAT, and PEFCAT II for CE Mark	Paroxysmal	84.5%
BSX	Farapulse	PFA	ADVENT	Paroxysmal	73.3%
JNJ	Varipulse	PFA	inspIRE clinical trial	Paroxysmal	75.6%
MDT	PulseSelect	PFA	PULSED AF clinical trial	Paroxysmal	66.2%
MDT	PulseSelect	PFA	PULSED AF clinical trial	Persistent	55.1%
MDT	Sphere-9	PFA/RF	EU study to support CE Mark	Paroxysmal	78.3%
MDT	Sphere-9	PFA/RF	EU study to support CE Mark	Persistent	77.9%
Other RF / Cyro Trials					
BSX	Cryoablation Arm	Cryoablation	ADVENT	Paroxysmal	73.6%
BSX	RF ablation Arm	Radiofrequency	ADVENT	Paroxysmal	69.2%
BSX	POLARx	Cryoablation	FROZEN AF	Paroxysmal	79.9%
MDT	Arctic Front	Cryoablation	FIRE AND ICE clinical trial	Paroxysmal	65.4%
JNJ	NaviStar ThermoCool	Radiofrequency	FIRE AND ICE clinical trial	Paroxysmal	64.1%
MDT	Arctic Front	Cryoablation	STOP Persistent AF	Persistent	54.8%
JNJ	THERMOCOOL SMARTTOUCH	Contact force–guided radiofrequency	PRECEPT clinical trial	Persistent	61.7%
JNJ	THERMOCOOL SMARTTOUCH	Contact force–guided radiofrequency	SMART SF clinical trial	Paroxysmal	74.9%
JNJ	HELIOSTAR	Radiofrequency balloon	STELLAR IDE	Paroxysmal	67.7%

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Company	Device	Energy	Clinical Trial / Study	Type of Afib	1-year Afib Freedom Efficacy
MDT	Arctic Front	Cryoablation	STOP AF First clinical trial	Paroxysmal	74.6%

Source: Company materials, clinicaltrials.gov. Note FIRE AND ICE primary outcome was recurrent atrial fibrillation which occurred in 34.6% of the cryoballoon ablation group versus 35.9% of the radiofrequency group. PRECEPT had a primary effectiveness success rate of 61.7% and a clinical success rate of 80.4% at 15 months. STOP AF First on Artic Front is the only clinical that led to FDA approval for first line treatment of afib ablations with cryoballoon.

BofA GLOBAL RESEARCH

Early outcomes of the admIRE study

Twelve-month outcomes data from the pilot phase of the admIRE study, which assessed the safety and efficacy of the VARIPULSE Platform among U.S. patients, were presented. Among 20 patients who completed the 12-month follow-up visit, 100% achieved acute success from ablation procedures and 80% remained free from atrial arrhythmia recurrence at one year. No procedure or device-related primary adverse events were reported in the pilot phase of the study. Integration with a 3D mapping system enabled efficient and low fluoroscopy procedures with a medial only 3.5min fluoroscopy exposure and nearly half of the procedures (48%) as performed with zero fluoroscopy.

MANIFEST-PF Registry Sub-Study

The MANIFEST-PF registry sub-study "Impact of Left Atrial Posterior Wall Ablation During Pulsed Field Ablation for Persistent Atrial Fibrillation" is the first and the largest study of its kind to analyze the addition of left atrial posterior wall (LAPW) ablation to pulmonary vein isolation while using pulsed-field ablation technology in patients with persistent AFib. The sub-study looked at a retrospective analysis of the MANIFEST-PF registry and found of the 547 persistent AF patients who underwent PFA, 131 (24%) received adjunctive LAPW ablation. The primary effectiveness outcome was freedom from any atrial arrhythmia of ≥30 seconds. Safety outcomes included the composite of acute and chronic major adverse events (MAE). The 1-year Kaplan-Meier estimate for freedom from atrial arrhythmias was similar between groups (PVI+LAPW: 66.4% vs PVI: 73.1%, p=0.68). There was also no significant difference in MAE between the groups (2.2% vs. 1.4%, respectively, p=0.51). The study concluded in persistent AF patients undergoing PFA, as compared to PVI-alone, adjunctive LAPW ablation resulted in similar effectiveness without increasing complications. This study demonstrates the importance of exploring additional strategies to enhance outcomes and moving away from ablation techniques that may not be effective in this patient group. Limitations of the study include it is a non-randomized, retrospective analysis; completion of the LAPW ablation was determined by the absence of electrograms on the pentaspline PFA catheter (high-density voltage mapping was performed in 41%)l; variability in frequency and/or intensity of follow up; and durability of LAPW ablation is unknown. There are additional ongoing clinical trials studying PVI + LAPW including the ADVANTAGE AF trial (755+ patients) to assess the safety and effectiveness of Farapulse for the treatment of drug resistant symptomatic persistent afib. Another study is the PIFPAF-PFA randomized trial (206 patients) in Europe to compare the efficacy and procedural safety of two ablation strategies for the treatment of persistent AF using PFA: PVI only versus PVI+LAPW.

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Underperform	N/A	≥ 20%

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