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EDITORIAL

Pulmonary vein isolation with composite index tagging: are we making ablation simpler or simple?

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This editorial refers to 'Acute and mid-term outcomes of ablation for atrial fibrillation with VISITAG SURPOINT: the Japan MIYABI registry' by K. Okumura *et al.*, https://doi.org/10.1093/europace/euad221

Pulmonary vein isolation (PVI) is the cornerstone rhythm control strategy for atrial fibrillation (AF) catheter ablation and improves patient symptoms and quality of life.[1] Although technological advances in ablation tools and strategies over the past two decades have propagated the success of PVI in modern AF management, streamlining the AF ablation workflow while maintaining durable and long-term PV isolation remains the next quest to further improve patient outcome and experience.

Composite ablation indices (AIs) are novel intraoperative tools that can assist operating electrophysiologists understand the quality and durability of their radiofrequency (RF) lesion sets. Currently available indices include: VISITAG SURPOINT (VS) (CARTO, SmartTouch CF ablation catheter, Biosense Webster) that incorporates power, contact force (CF), and RF time in a weighted formula; ForceLesion Index (EnSite, TactiCath CF ablation catheter, Abbott) that combines CF, RF application duration, and RF current; Force Time Integral (EnSite, TactiCath CF ablation catheter, Abbott) that calculates CF over time; and DIRECTSENSE local impedance (Rhythmia, IntellaNav MIFI OI ablation catheter, Boston Scientific) that estimates lesion properties using generator impedance.

One of the most studied and widely utilized composite AI is the VS AI. Small single-centre experience and corresponding meta-analysis have demonstrated the safety and long-term effectiveness of AI-guided ablation not only in preventing AF recurrence but also in reducing procedure and ablation times.[2–5] Two recent large prospective multi-centre studies from both Europe and the USA have confirmed the reproducibility of clinical safety and effectiveness of the PVI workflow guided by AI in patients with paroxysmal AF.[6–8] However, evidence of its wide application in the Asian population was lacking.

In this issue of *Europace*, Okumura *et al.*[9] conducted a prospective, multi-centre, observational study that included 50 participating centres in Japan to investigate the safety, efficacy, and generalizability of the VS AI in the Asian population. The study included adult patients with drug-refractory symptomatic paroxysmal or persistent AF for less than 6 months. Key exclusion criteria were persistent AF with a continuous episode lasting ≥6 months, a previous AF ablation procedure, patients who were or planned to become pregnant during the study, and those with a life expectancy of <12 months. Patients in this study received AF ablation using Thermocool SmartTouch/SF (Biosense Webster, USA) catheters with CF-sensing capability. The VS AI as part of the CARTO 3 VISITAG module provided visual guidance. In this study, no VS cut-off values were pre-defined for PVI throughout the participating centres, and each centre determined their own VS values for ablation of anterior or posterior wall of the left atrium (LA) and for oesophageal region based on previous experience to achieve higher first pass isolation rate. Safety outcomes included primary adverse events (PAEs) that included device- or procedure-related serious adverse events that occurred within 7 days following the procedure as well as PV stenosis and atrio-oesophageal fistula even if they occurred >7 days post-procedure. The primary effectiveness endpoint was acute success of PV isolation at the end of the procedure. Mid-term effectiveness at 12 months after the procedure was evaluated by freedom from documented atrial arrhythmias (AF, atrial tachycardia, and atrial flutter) lasting ≥30 s after the 90-day blanking period. The recurrence of atrial arrhythmias was checked by periodic 12-lead electrocardiogram (ECG), 24-h Holter ECG monitoring, and/or mobile ECG at the discretion of the treating physician. A total of 1011 patients were enrolled and 1002 underwent VS-guided ablation, with 93.3% finishing 12-month follow-up. Mean age was 66.7 years, and 67.7% of patients were male. Unlike the US and European studies, the current study did not specifically exclude patients with LA size > 50 mm or left ventricular ejection fraction (LVEF) < 40%; however, mean LVEF in this study was 62.4%, and mean LA diameter was 39.2 mm. There were 801 patients (79.9%) with paroxysmal AF and 201 patients (20.1%) with persistent AF. The mean VS index value was 428.8 on the anterior wall and 400.4 on the posterior wall. Acute PV isolation was achieved in 99.7% of patients, and 12-month freedom from atrial arrhythmia recurrence was 88.5%. At repeat ablation, 54% of RSPV, 73% of RIPV, 70% of

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LSPV, and 86% of LIPV evaluated remained durably isolated. Nine patients (0.9%) experienced PAEs including cardiac tamponade/perforation, major vascular bleeding/complication, pericarditis/pericardial effusion, and pulmonary oedema.

This is the third large-scale multi-centre prospective study carried out in a different continent that demonstrated the safety and efficacy of guiding PVI with VS AI. Okumura *et al*. should be commended on completing this important large prospective trial and expanding the evidence of AI into the Asian population. This current study not only reiterated the reproducibility of the results compared with the VISITAX trial in Europe and the post-approval study in the USA but also offered unique perspectives on utilizing AI in the AF ablation workflow. One of the most important distinctions of this study is that no specific AI targets were mandated in this protocol whereas both the European and American studies set pre-defined AI goals for anterior (Europe/US: 550) and posterior walls (Europe: 400; US: 380) of the LA. Similar to the European and US studies,[6–8] two types of ablation catheters (both THERMOCOOL SMARTTOUCH and THERMOCOOL SMARTTOUCH SF) were utilized in this trial. The mean anterior wall AI achieved was significantly lower in this study (428.8 vs. 519.3 US study). This likely accounted for the lower first-pass isolation rate reported in this study: 749/1002 patients achieved first-pass isolation and only 533 patients had isolated PVs at the end of the waiting period and pharmacological challenge, vs. 82.4% of patients in the European study and 83.1% targeted PVs in the American study. Nevertheless, similarly high percentage of successful PVIs was achieved at the end of procedure presumably due to redo isolation attempts after the waiting period and pharmacological challenge, as represented by almost double the mean RF application time (60.6 vs. 35.2 min in Europe vs. 29.0 min in the USA) and significantly longer mean fluoroscopy time (22.4 vs. 7.9 min in Europe vs. 2.2 min in the USA) in this study. While previous single-centre observations may have suggested lower AI targets to achieve first-pass isolation in the Asian population,[10] the results from this study appeared to demonstrate the opposite. Another unique aspect of this study design is the inclusion of patients with persistent AF who also underwent AI-guided RF ablation, which accounted for 20% of the enrolled population. In this study, patients with persistent AF had slightly lower first-pass rate (66.0% vs. 72.5%) but comparable freedom from atrial arrhythmias at 12 months. Most importantly, PAEs only occurred in less than 1% of patients, which is the lowest across all three studies.

The overall 12-month freedom from arrhythmia rate across all three studies was comparable, with the current study reporting the highest percentage of arrhythmia-free survival at 88.5% (81.5% in the USA vs. 78.3% in Europe). However, both the US and European studies implemented stringent arrhythmia monitoring with weekly/monthly trans-telephonic monitoring at pre-specified intervals, which was not apparent in the design of this study. Comparing stringent and standard-of-care monitoring techniques, close to 10% absolute increase in recurrence was captured in the other two studies. This needs to be taken into consideration when interpreting the results of this study and whether lower AI targets are truly applied in the Asian population.

Overall, the study by Okumura *et al*. extrapolated the applicability of using VS AI to guide AF ablation in the Asian population with both paroxysmal and persistent AFs. For the third time in a row, an excellent safety profile was demonstrated, and both acute PVI success and 12-month freedom from arrhythmias were again reported. Composite index tagging is well on its way to be further integrated into everyday AF ablation workflow to improve procedure uniformity, reduce procedure time, promote therapeutic efficacy, and refine patient experience. Just as Albert Einstein has said, 'Everything should be made as simple as possible, but not simpler'.

Conflict of interest: L.D.B. is a consultant for Stereotaxis, Biosense Webster, I-Rhythm and Boston Scientific, and Abbott Medical and has received speaker honoraria/travel from Medtronic, Atricure, Biotronik, Baylis Medical, and Zoll. F.Z. reports no conflict of interest.

Data availability

All relevant data are within the manuscript.

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