

Novel Linear Cryoablation Catheter to Treat Atrial Fibrillation*



Tom De Potter, MD, FEHRA¹, Lucas Boersma, MD, PhD, FESC², Alex Babkin, PhD^{3**}, Meital Mazor, PhD^{3**}, James Cox, MD^{3**}

1 – OLV, Aalst, Belgium, 2 – St. Antonius, Nieuwegein, The Netherlands, 3 – Adagio Medical, Laguna Hills, USA **Financial disclosure



Background: A novel 8.5 Fr cryoablation catheter system (Adagio Medical) designed to create long, continuous and focal transmural lesions was used to treat Paroxysmal, Persistent and Long Standing Persistent Atrial Fibrillation (PAF, PsAF and LSPsAF). The system uses Near Critical Nitrogen capable of cooling to -196°C.

3 catheter generations were used. The first 26 Pts (10 PsAF) were treated using Gen-I and Gen-II catheters with a fixed loop shape, adjustable to a diameter of 25-40 mm with 8 electrodes along the freezing element of 126mm.

Last 6 Pts, (2 PAF, 3 PsAF and 1 LSPsAF), were treated using an improved Gen-III catheter with 20 electrodes, capable of adopting multiple shapes and deflections with pre-formed stylets. This enabled flexibility and more accurate catheter positioning during continuous or focal lesion creation. Specific stylets were made for large common antrum, CTI and assure direct access to the right inferior pulmonary vein. In average, 3 different stylets were used per patient, including the CTI shape. Focal ablation was performed in 4 patients.

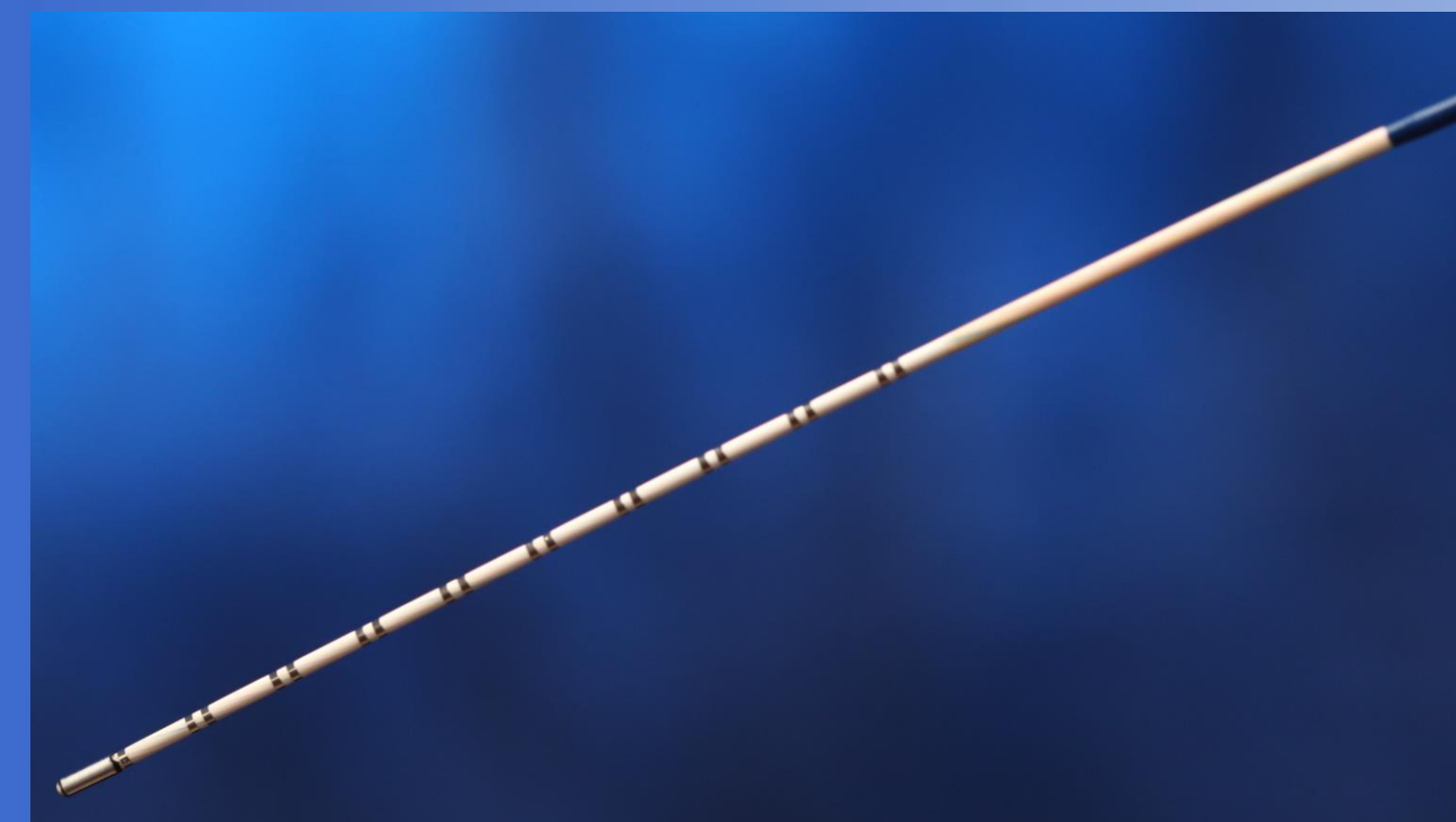


Fig. 1: Adagio AF catheter Gen III*** With Straight Stylet

Fig. 2: Adagio AF catheter Gen III*** With 30mm loop and 90° pre-deflection stylet



Fig. 3: Adagio AF catheter Gen III*** With 8.5mm freezing tip

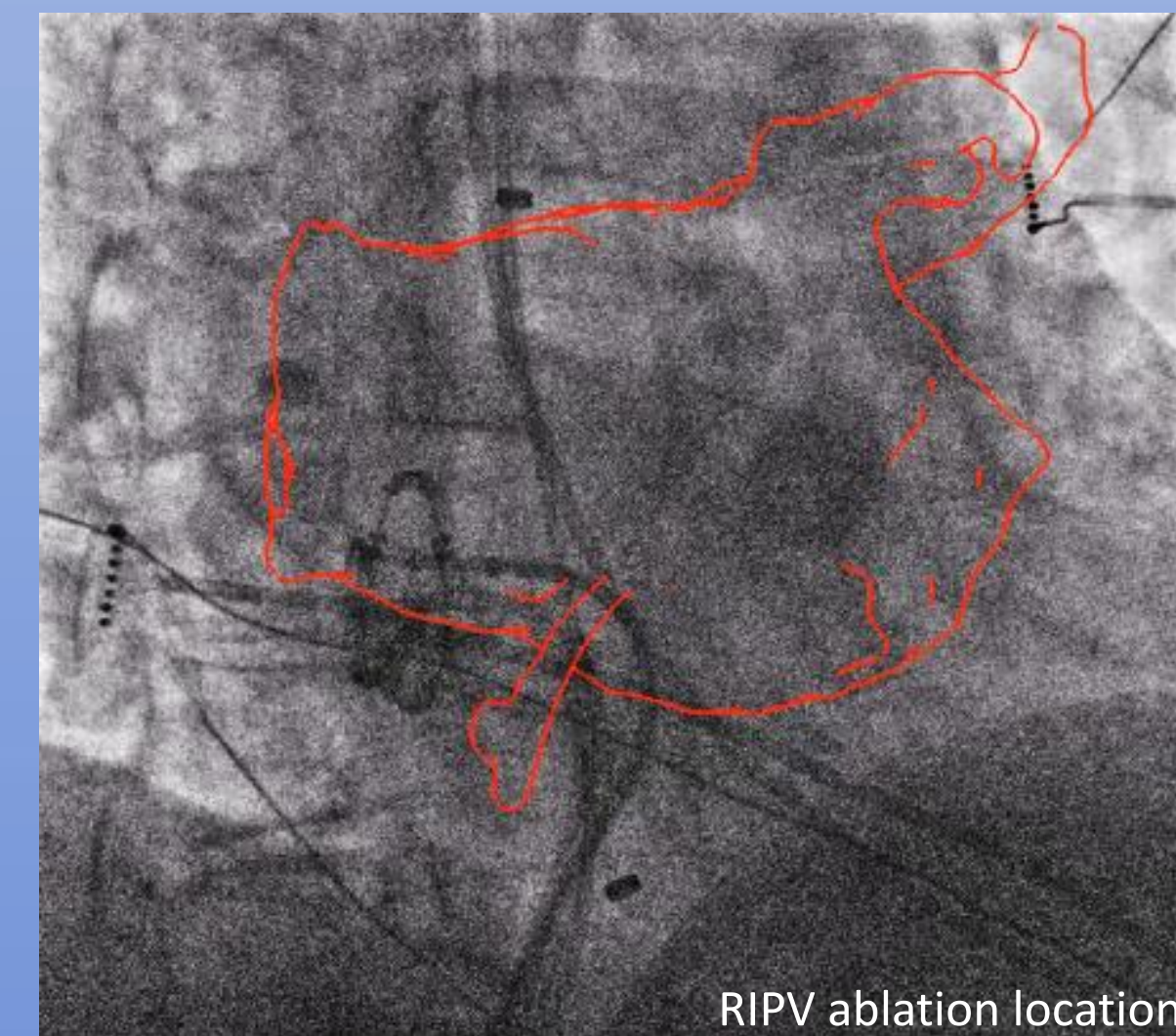


Fig. 4: Adagio AF catheter Gen III*** With dedicated RIPV stylet, no sheath support

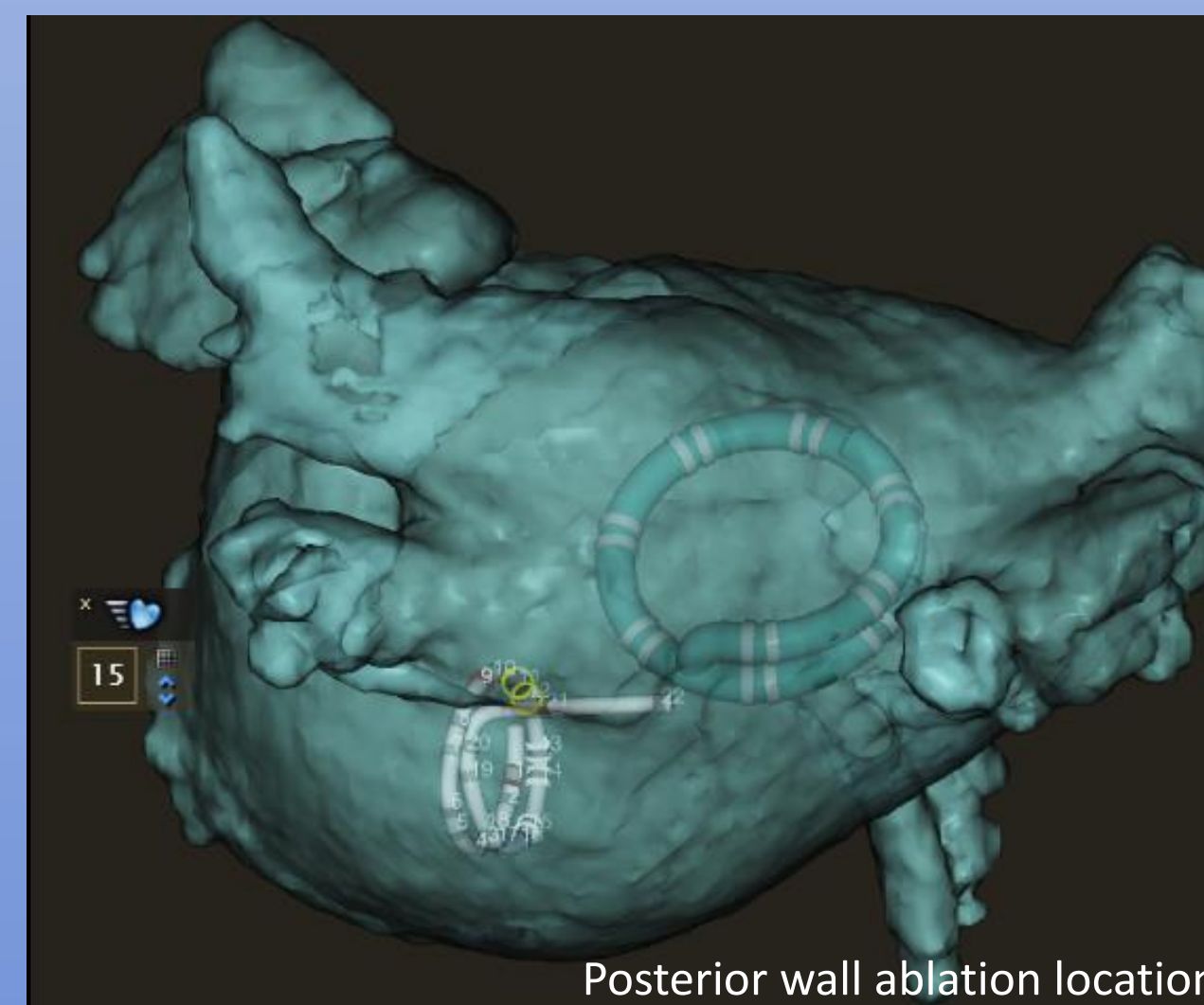


Fig. 5: Adagio AF catheter Gen III*** Position on the posterior wall

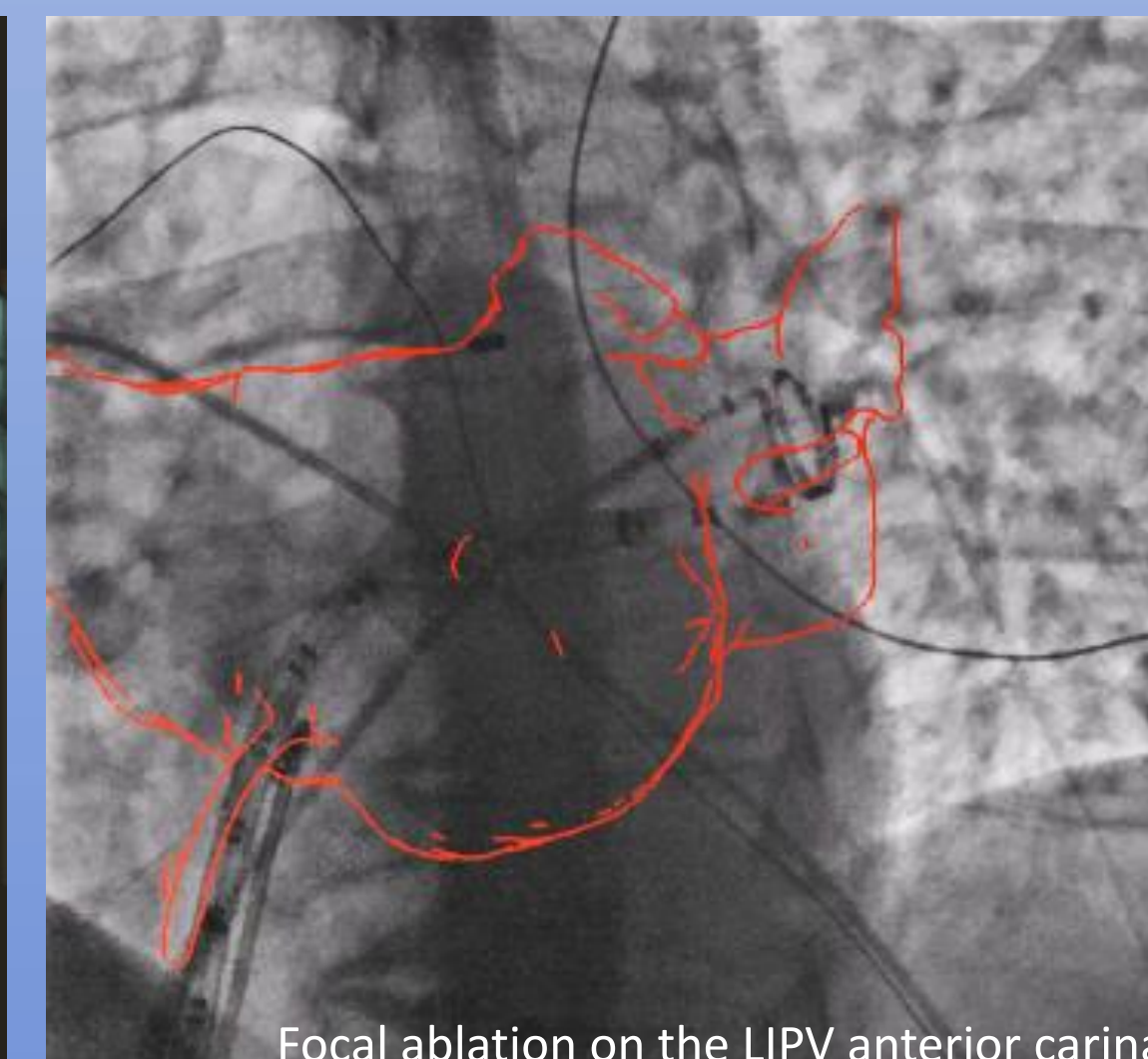
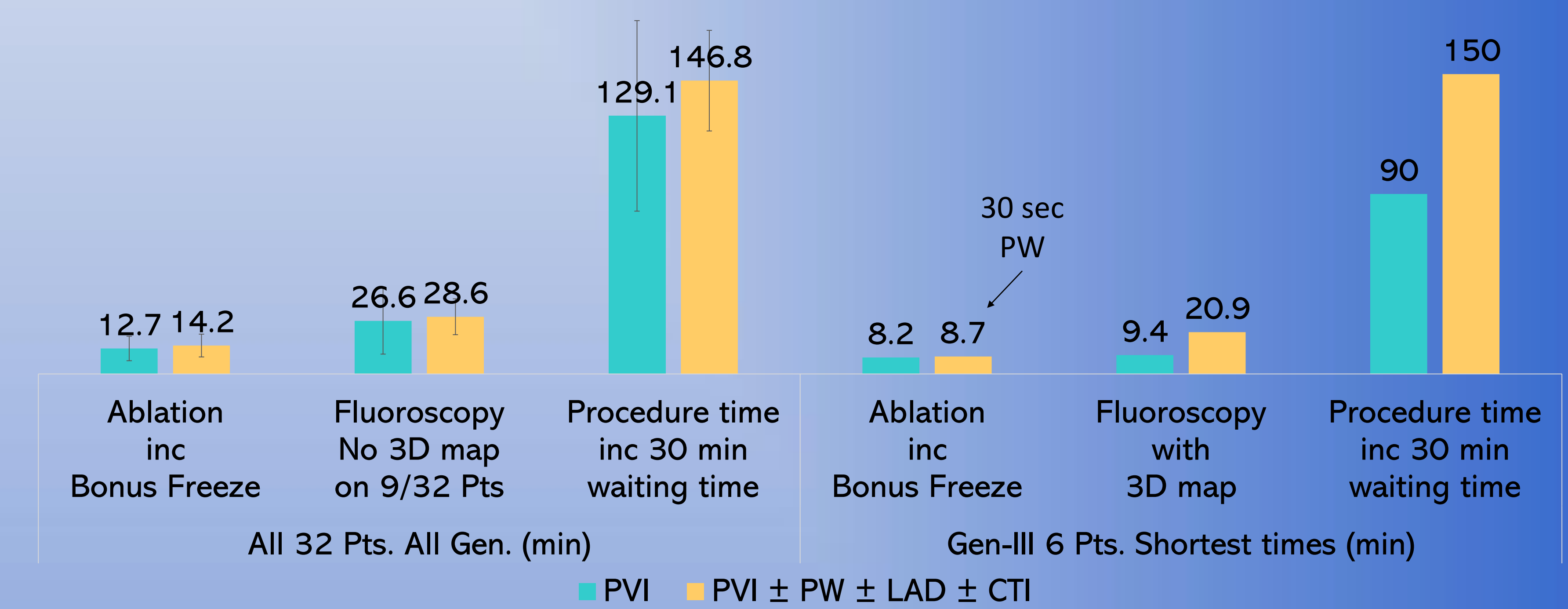


Fig. 6: Adagio AF catheter Gen III*** Focal approach



Fig. 7: Adagio Esophageal Warming Balloon



Follow-up Results: After the initial experience with Gen-I, from the 13 Pts treated with Gen-II, 90% (10/11) remain free of AF at 6 months FU. No other atrial tachycardia was documented in these Pts. Among the 6 Pts treated with Gen-III, 1 PsAF Pts has already completed the 3 month blanking period, remaining free of AF.

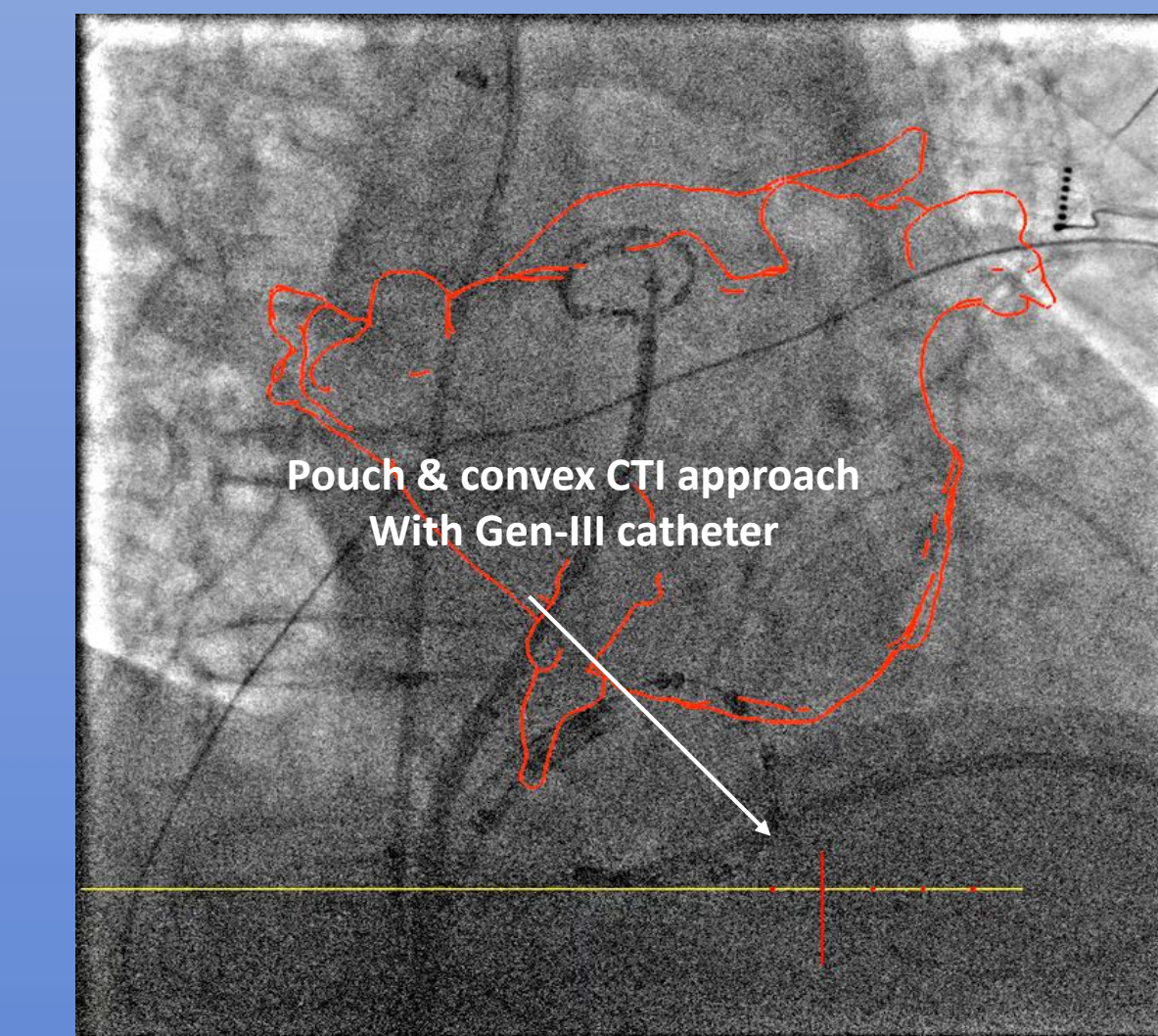


Fig. 8: Adagio AF catheter Gen III*** With dedicated CTI stylet, convex approach

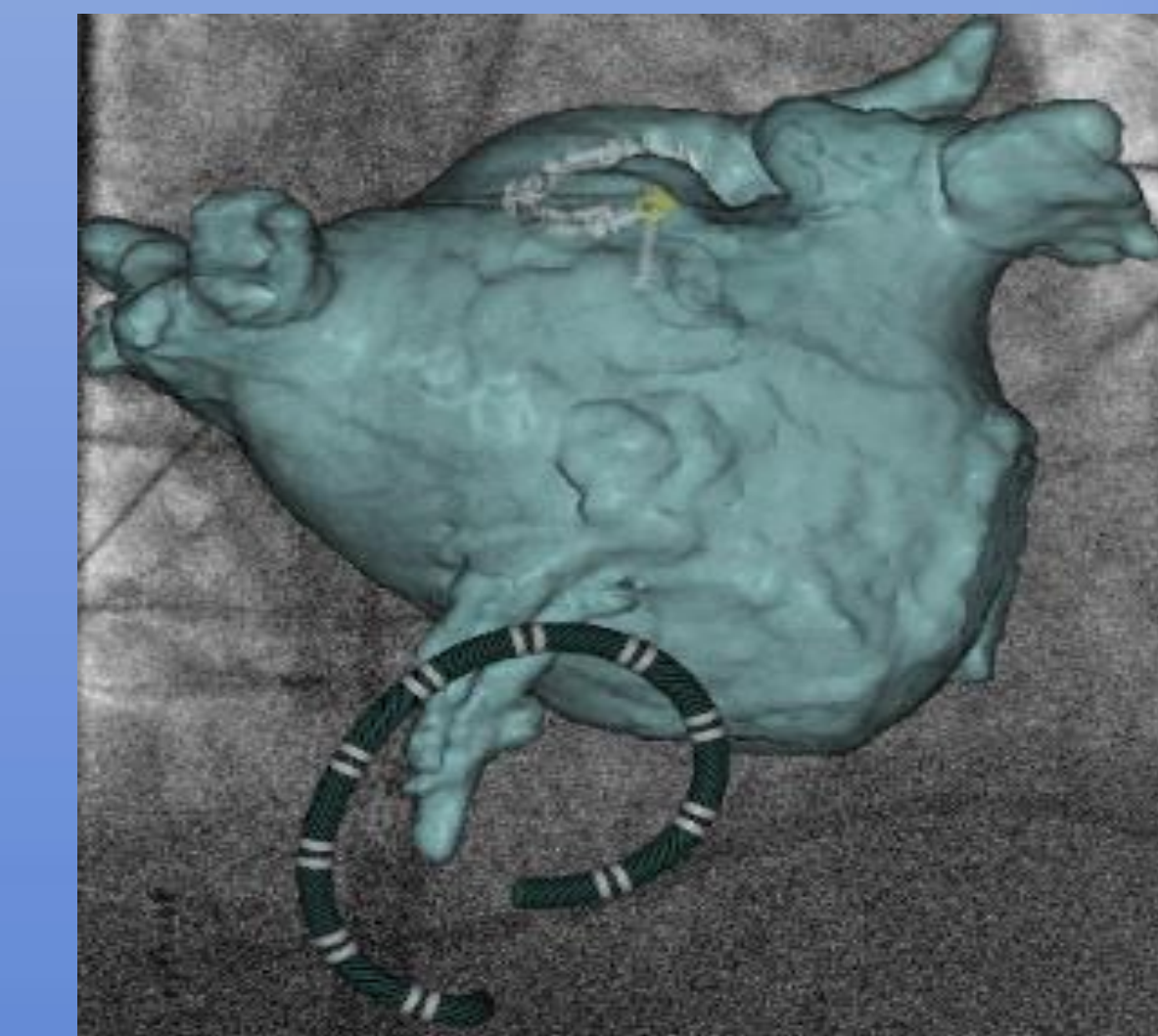


Fig. 9: Adagio AF catheter Gen III*** With dedicated CTI stylet visualization on 3D map

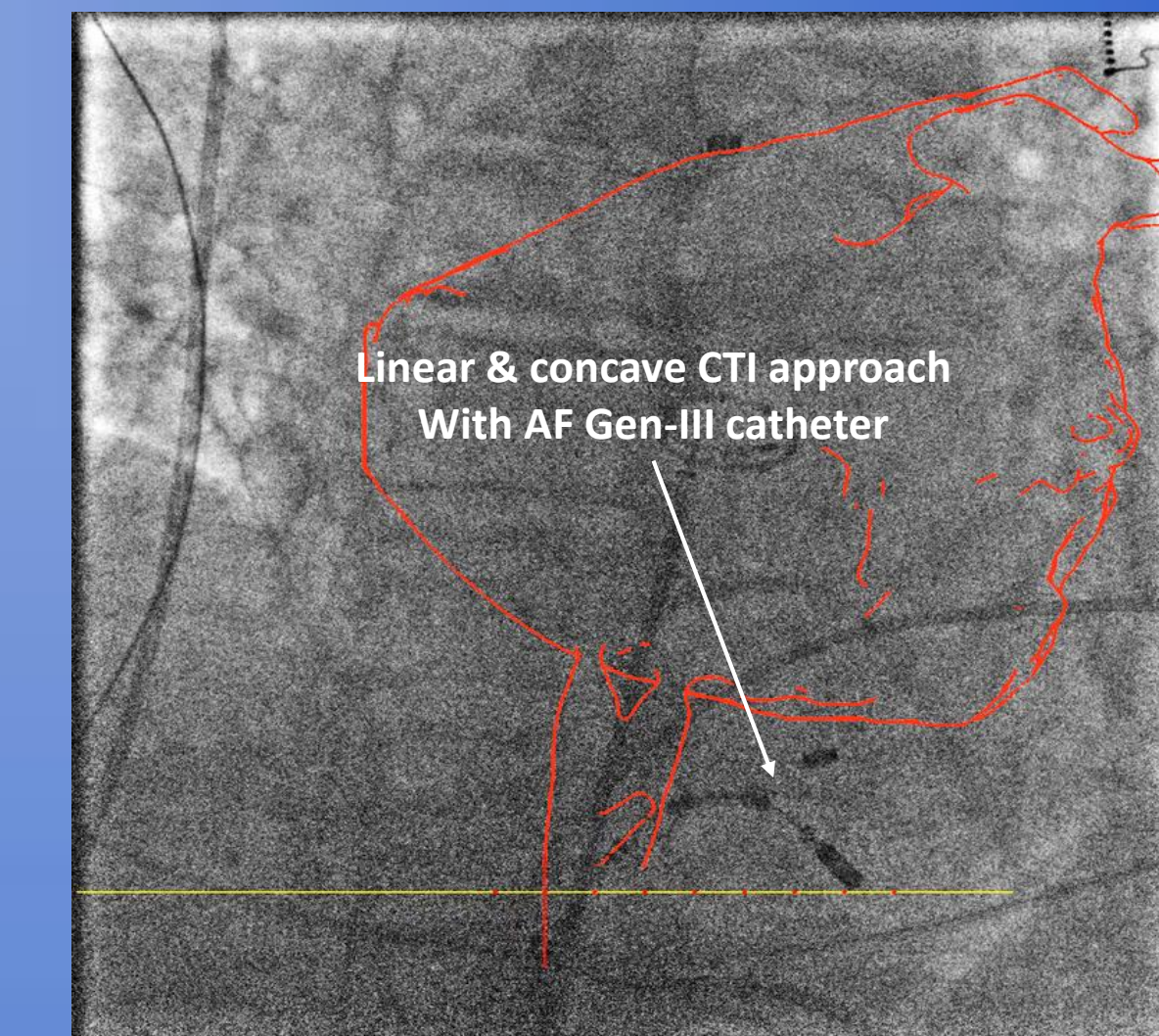


Fig. 10: Adagio AF catheter Gen III*** With dedicated CTI stylet, Convex approach

Methods: 32 Patients (Pts) have been enrolled (18PAF, 13 PsAF and 1 LSPsAF). All Pts received an antral pulmonary vein isolation (PVI). Additional non-PV triggers were ablated in 12 Pts, with posterior wall “box” lesion set (PW) in 10 Pts and left atrial defragmentation (LAD) in 2. A Cavo-tricuspid isthmus (CTI) line was included in 9 Pts. Multiple 3D mapping systems were used in 23 Pts. 1 patient was treated under conscious sedation. Acute procedural success is defined as complete PVI, verified 30 min. post ablation. Pts are being followed at 1, 3, 6, 9 and 12 months with continuous ECG monitoring.

Esophageal temperature was preserved during the cryo-applications by continuously circulating body temperature saline through a compliant intra-esophageal balloon.

Safety Results: There were no deaths, AE fistulas, strokes, cardiac perforations or major bleedings. 2 cases of temporary phrenic nerve palsy (PNP) were observed and completely resolved. Since the introduction of a Cryomapping safety feature, PNP was successfully prevented in the last 19 procedures.

Acute Results: Overall ablation, fluoroscopy and procedure times gradually reduced with the introduction of improved catheter versions as well as an increased physician experience with this device.

Conclusions

- Ultra-low temperature cryoablation is technically feasible in a percutaneous setting
- Multiple catheter shapes using pre-formed stylets allow versatility to ablate anywhere in the atria without catheter exchanges.
- Safety measures mitigate unwanted damage (Cryomapping, esophageal warming)
- Clinical results demonstrate that the novel near critical nitrogen cryoablation system can deliver long continuous linear and focal transmural lesions to treat AF with excellent safety and efficacy outcomes.
- Initial follow-up results are promising for PAF and PsAF Pts.

** Latest Generation of the Adagio AF catheter used in clinical trials, with the capability to acquire Multiple Shapes

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