

Treatment of Typical Atrial Flutter with a Novel Cryolinear Ablation Catheter



First Experience

Lucas Boersma, MD, PhD, FESC/FEHRA¹, James Cox, MD^{2**}, Alex Babkin, PhD^{2**}, Meital Mazor^{2**}, Tom De Potter, MD FEHRA³

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

Background: Both Nitrous-oxide cryoablation and radiofrequency (RF) ablation systems demonstrate comparable acute and long-term success rates for cavo-tricuspid isthmus (CTI) dependent atrial flutter (AFL) ablation. While previous cryoablation systems show reduced fluoroscopy time and pain perception by the patient, procedure times proved to be significantly prolonged versus RF solutions.

Methods: CryoLinear ablation was performed on 17 AFL patients. The first 9 patients were treated using a Gen-I curved linear catheter with no electrodes, the last 8 patients were treated using an improved Gen-II catheter with 6 electrodes along the freezing element. Acute procedural success was defined as CTI bidirectional block (BDB). Complete conduction block was verified for all lesions 30 minutes after ablation. Patients were evaluated for AFL recurrence at 1 and 3 months.

Acute Efficacy Results:

		All AFL n=17
Acute Success	%	100%
Ablation time to BDB	min.	2.7±3.2
Total Ablation time	min.	5.4 ± 3.4
Procedure time	min.	85±16
Fluoroscopy time	min.	12 ± 5

14/17 (82.4%) of BDB were achieved using the convex approach. Total Ablation times were reduced by 2.7 ± 3.3 minutes with the introduction of the Gen-II catheter.

Shortest ablation times:

CTI BDB	14 sec.
CTI BDB (inc. bonus freeze)	150 sec.

BDB was achieved within the first freeze in 9/17 (53%) of the patients.

Follow-up Results: At the end of final 3 months FU, 16/17 (94.1%) were free of AFL, with no recurrence in 8 patients treated with Gen-II catheter. 3 patients undergoing a second ablation for AF showed durable CTI block demonstrated in EP study.

Conclusion:

- This novel cryo-ablation system using near critical nitrogen at -196C can create long, continuous, transmural, linear lesions in the right atrium safely and effectively within a very short ablation time to achieve durable bidirectional CTI block
- Ablation procedures in the LA to treat AF have already been successfully performed.



Fig. 1: Adagio Flutter catheter Gen-II



Fig. 2: Conduction Block on CTI after 120s of ablation

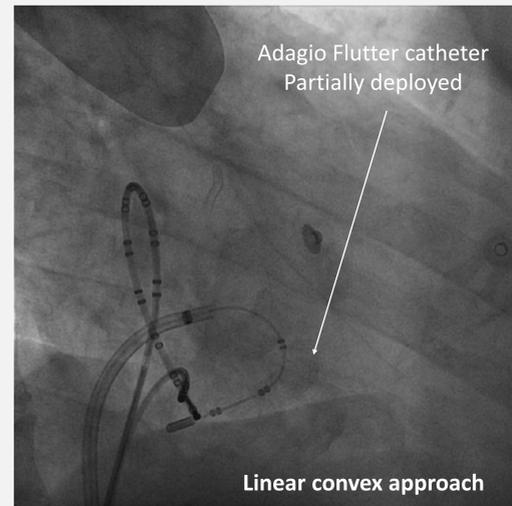


Fig. 2: Adagio Flutter catheter in RAO

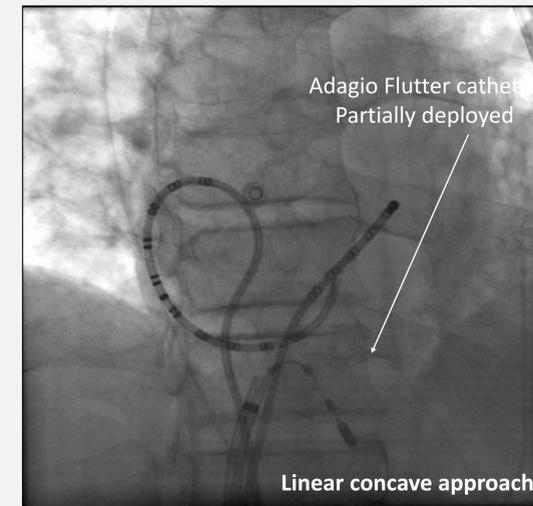


Fig. 3: Adagio Flutter catheter in LAO

Objective: To demonstrate the safety and efficacy of achieving CTI bidirectional block (BDB) using a novel 9 Fr cryoablation catheter system (Adagio Medical, Laguna Hills, CA), designed to create long, continuous, transmural linear lesions in the atria, for the treatment of AFL. The system uses Near Critical Nitrogen as a novel energy source, capable of cooling to -196°C in seconds.

The AFL catheter can be used in a linear convex (left) or linear concave (right) approach. The Convex approach may overcome pouches along the CTI.

Safety Results: One patient had ST elevation for 2 minutes during the procedure (presumed coronary artery spasm) with no sequelae.