

Preclinical Evaluation of the Feasibility, Lesion Durability, and Safety of a Novel Focal and Linear Pulsed Field Ablation Catheter

Yanlin Chen MD¹, Weidong Lin MD¹, Fangzhou Liu MD¹, Hongtao Liao MD¹, Long Huang MS², Yumei Xue MD¹

1. Department of Cardiology, Guangdong Provincial People's Hospital, Guangzhou China 2. EnChannel Medical Inc, USA

Background

Current pulsed field ablation catheters are mostly designed for either circular (single shot) or focal ablation. ¹

Objective(s)

To demonstrate the safety and lesion durability of a novel pulsed field ablation (PFA) catheter with a unique waveform to create both focal and linear lesions. ²

Method

- Ablation was performed in two cohorts of swine (n = 11 in total) and survived for 30 days. Cohort 1 (n=6) received high-dose (HD) ablation. Cohort 2 (n=5) received low-dose (LD) ablation.
- The three-electrode 7F PFA catheter (PFLine, EnChannel Medical, USA) uses the tip and ring-2 for focal ablation and all three electrodes for linear ablation.
- PFA was applied on the RA free wall (RAFW), RA posterior wall (RAPW), cavotricuspid isthmus (CTI), and LA roof line (LARL).
- Pre- and post-ablation voltage mapping (Carto, Biosense Webster) was performed to assess efficacy.
- Lesion durability was assessed, gross examination was performed, and tissue was excised for histologic examination after sacrifice.



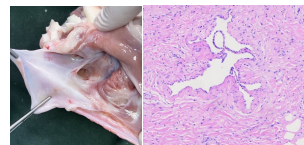
Results

- All animals survived 30 days post-procedure with no reported adverse events.
- In the HD cohort, acute CTI (6/6) and LARL (5/5) success was 100%, while chronic durability was 50% for CTI and 100% for LARL. In the LD cohort, acute and chronic success of CTI was 100% (5/5). The acute and chronic success of LARL was 80% (4/5). The acute success of RAPW was 100% (5/5), with 60% (3/5) chronic success.

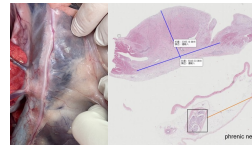
PFA Applications and Lesion Dimensions

PFA Energy	# of Animals	CTI			RAFW		LARL			PWRA	
		# of Apps	Time (ms)	Mean Lesion Dimension (L x W x D*) mm	# of Apps	Time (ms)	# of Apps	Time ms	Mean Lesion Dimension (L x W x D*) mm	# of Apps	Time (ms)
High Dose (13.6-15.2 J)	6	4 (3 - 5)	11.2 (9.6 - 15.2)	25.3 x 8.3 x 3.0	12 (11 - 13)	38.4 (36 - 40.8)	6 (5 - 6)	19.2 (16 - 19.2)	23.3 x 10.9 x 1.8		
Low Dose (7.6-9.6 J)	5	5 (5 - 6)	12.8 (12.8 - 15.4)	23.8 x 11.0 x 3.9			11 (11 -13)	28.2 (28.2 - 33.3)	29.8 x 14.7 x 2.9	9 (8 - 12)	23.0 (20.5 - 30.7)

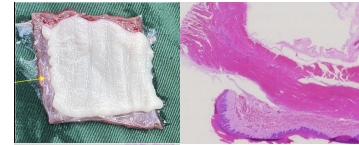
CTI



Phrenic Nerve



Esophagus



Conclusion

- The study confirms the feasibility of a dual-purpose catheter for safely and durably delivering focal and linear PFA with both HD and LD delivery dosages.
- Tissues adjacent to ablation sites showed no evidence of chronic tissue damage.

Disclosure/References

- Di Monaco et al., Pulsed Field Ablation to Treat Atrial Fibrillation: A Review of the Literature J Cardiovasc Dev Dis 2022
- Li et al. European Heart Journal - Case Reports (2024)