

## Feasibility of Unipolar Signal Guided Ablation in Creating Contiguous Lines of Conduction Block: A Proof-of-Concept Study

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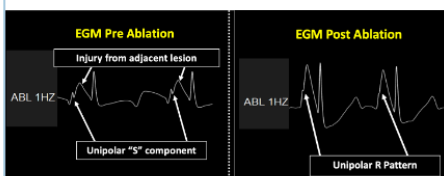
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### Abstract

- Contemporary ablation is guided by non-physiological surrogates such as Ablation index™ (ABI).
- Dynamic changes in local atrial unipolar electrogram (Uni-EGM) with loss of the negative S component or “R-pattern” change, during radiofrequency ablation (RFA) might predict a transmural lesion.

### Objective

- To investigate the feasibility of generating contiguous, transmural lines of conduction block, in atrial tissue, using ablation guided by Uni-EGM modification.



### Methods

- In 10 swine, right atrial (RA) longitudinal ablation line spanning from the SVC to the IVC was created.
- RFA was performed using an irrigated ablation catheter (STSF) using two power settings 30W (N=5, U<sub>30</sub>) and 50W (N=5, U<sub>50</sub>).
- Unipolar EGM signals were processed by the PureEP System (BioSig Technologies).
- RF delivery per lesion was turned off 3 seconds after a stable R-pattern change was seen on the unipolar EGM.
- Inter-lesion spacing was directed by a 2nd operator, blinded to the electroanatomical map, guided solely by Uni-EGM morphology characteristic of viable myocardium contiguous with ablated tissue.

### Methods

- Bidirectional block was assessed by standard EP maneuvers and histopathology.
- U<sub>30</sub> guided lines were compared to a historical cohort of Abl=400 guided transcaval lines created with same power application.

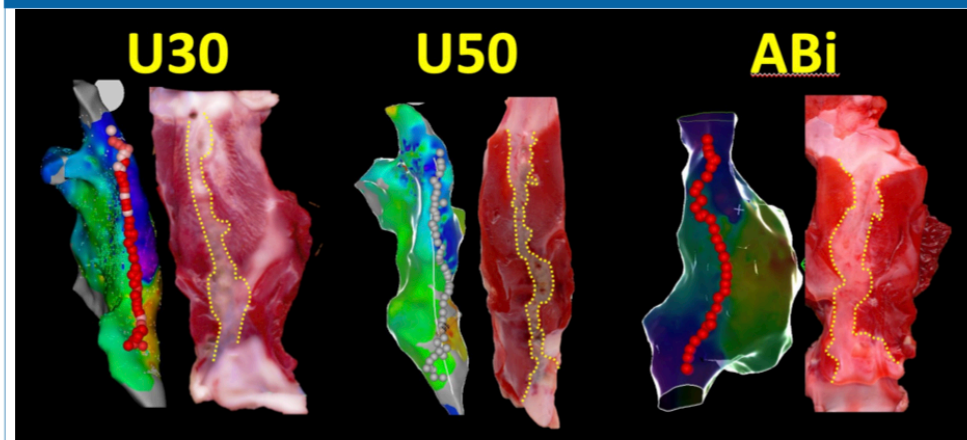
### Results

- Bidirectional block was demonstrated in 4 of 5 U<sub>30</sub> lines (80%) and in all U<sub>50</sub> lines (100%).
- There were no differences in initial impedance, impedance drop or mean ablation line length between U<sub>30</sub>, U<sub>50</sub>, and the ABi guided ablation lines (Table).
- The U<sub>30</sub> lines were narrower compared to both U<sub>50</sub> and Abi group (5.3±1.5mm; 6.7±1.7; 11.7±4.8mm, respectively; p<0.001), and comprised of more closely spaced lesions (2.72±1.3mm; 3.7±1.6; and 3.4±0.5mm, respectively; p=0.001).
- RFA lesion time using U<sub>30</sub> method (14.5±5.7s), was longer compared to U<sub>50</sub> strategy (9.7±4.9s, p<0.001) however, it was shorter compared to ABi strategy (21.9±5s, p<0.001).
- Notwithstanding, the total RF delivery time was shorter while using U<sub>50</sub> strategy compared to U<sub>30</sub> [682s (590-705) vs. 361s (205-441), p<0.001] while Abi strategy had similar overall ablation time [639s (619-693); p=0.92].

### Conclusion

- This study demonstrates that it is feasible to create a transmural line with bidirectional block, using ablation guided solely by unipolar signals.
- Monitoring changes in the local Uni EGM during ablation, offers a real-time physiologic endpoint for titration of RF energy delivery.

### Results



Parameter	U <sub>30</sub> N=5	U <sub>50</sub> N=5	p <sup>1</sup>	<sup>^</sup> ABi lines (control) N=4	p <sup>2</sup>
Impedance (ohm)	139±7.8	137±10.5	0.85	131±8.5	0.3
Impedance drop (ohm)	14±6.8	15.6±6.6	0.12	16.1±5.1	0.1
Ablation index	350±62	403±74	<0.001	400	<0.001
Ablation time per lesion (sec)	14.5±5.7	9.7±4.9	<0.001	21.9±5	<0.001
Total RF time (sec)	682 (590-705)	361 (205-441)	<0.001	639 (619-693)	0.92
Lesions per line	47 (40-49)	34 (27-42)	0.01	27 (26-31)	0.01
Inter-lesion distance (mm)	2.72±1.3	3.7±1.6	<0.001	3.4±0.5	<0.001
Line length (mm)	70 (67-70)	80 (71-89)	0.42	67 (66-75)	0.62
Line width (mm)	5.3±1.54	6.7±1.7	<0.001	12±4.8	<0.001
Transmural	80%	100%		100%	

1: p-value for the comparison between U30 and U50 groups; 2: p-value for the comparison between U30 and ABi groups.

<sup>^</sup> ABi historical group had ablation performed at 30W and thus compared only to U30 group