Ex-Vivo Evaluation of the Effect of Multiple Electrode Radiofrequency Needle Tip Convergence on the Size of Ablation Zones

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INTRODUCTION

- Radiofrequency Ablation (RFA) is an established therapy for treatment of malignancy in several organs, including the liver.
 One commonly used system, the Cool-tipTM Cluster Electrode, uses three parallel needles fixed in a triangular geometry.
 However, upon insertion, the final geometry of the needle tips can vary.
- In the case of converging needles, ablation volumes have been anecdotally observed to be smaller than expected.
- The study objective is to determine whether needle tip convergence significantly effects ablation zone in an ex-vivo bovine liver model.

MATERIALS & METHODS

- Cool-tip™ Cluster Electrodes were used to perform RFA in an ex-vivo bovine liver to compare parallel and converging electrode needle tip configurations.
- Cone Beam Computed Tomography (CBCT) scans were obtained prior to each ablation to verify needle tip geometry.
- 10 ablations were performed in the parallel and converging configurations using the standard ablation algorithm for a total of 12 minutes.
- Time to first roll-off and the final temperature were recorded for each ablation.
- Ablation zone measurements of the X, Y, & Z axes were obtained by gross pathology. Ablation volumes were calculated using the following ellipsoidal estimation method:

Ablation Volume = $\frac{\pi}{6}$ (length x width x thickness)

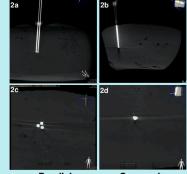
 Mean and standard deviations were calculated for the primary and secondary variables. Statistical analysis performed using an independent, 2 tailed T-test.



Figure 1. Experimental Setup. A: Fluoroscopy arm for CBCT and needle guidance. B: RFA pulse generator (Covidien). C: Cool-tip™ Cluster electrode. D: Specimen holder containing the bovine liver and return electrodes.

Figure 2. CBCT images demonstrating needle geometry for parallel configuration (2a coronal, 2c axial) and converging (2b coronal, 2d axial) configurations.

Figure 3. Representative section of gross pathology specimen post ablation.



Parallel Converging



Table 1: Comparison of Parallel and Converging Ablation Zone Volumes and Time to First Roll Off

	Parallel Configuration (n=10)	Converging Configuration (n=10)	P Value
Ablation Zone (cm³)	34.7 ± 14.8	15.5 ± 4.8	0.001
Time to First Roll Off (min)	4.0 ± 1.3	1.8 ± 0.3	0.00008

RESULTS

- Cone Beam CT demonstrated average distance between needle tips in parallel configuration of 4.9 mm, and in converging configuration 2.8 mm.
- Parallel electrode needle tip configuration resulted in an average ablation zone volume of 34.7 cm³ ± 14.8, while converging needle tip configuration resulted in an average ablation zone volume of 15.5 cm³ ± 4.8.
- The converging electrode needle tip configuration resulted in a significantly smaller average ablation zone volume than the parallel configuration (p=0.001).
- The average time to first roll for the converging configuration was 1.8 ± 0.3 mins, significantly decreased compared to the parallel configuration at 4.0 ± 1.3 mins, (p=0.00008).

CONCLUSIONS

- Ablation zone volume significantly decreases when there is convergence of the electrode tips versus a parallel configuration.
- Confirming needle tip geometry prior to RFA should be performed clinically in order to ensure adequate ablation volumes when using Cool-tip[™] Cluster electrodes and avoid potential undertreatment.

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