

COSY TRIAL

RESULTS

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“We were able to dramatically reduce all of the primary endpoints, most importantly procedure time and radiation dose to both patient and operator. Use of the Surefire Infusion System in the trial was safe without any adverse events up to 30 days. This technology has the potential to improve the safety and efficient delivery of SIRT in our liver cancer patients.”

– Aaron Fischman, MD, Principal Investigator and Assistant Professor of Radiology and Surgery at the Icahn School of Medicine at Mount Sinai in New York City, New York

A prospective, randomized study of

Coiling vs. Surefire Infusion System

in Y90

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The purpose of this study was to prospectively compare standard coil embolization (CE) versus the use of a Surefire anti-reflux infusion system (SIS) in patients undergoing planning angiograms for selective internal radiation therapy (SIRT).

CONCLUSION:

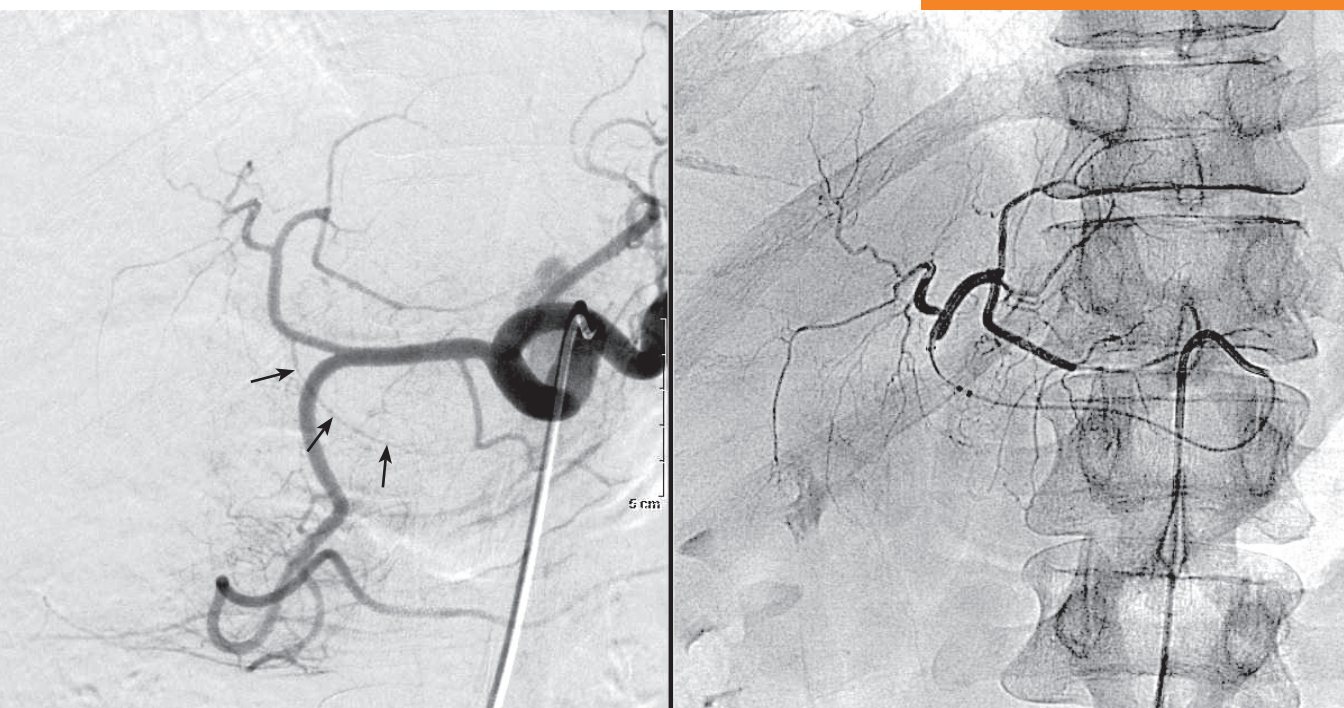
Use of SIS during planning angiogram resulted in significantly reduced Fluoroscopy Time, Procedure Time, Dose Area Product and Contrast Dose in comparison to conventional Coil Embolization. Use of the Surefire System can safely eliminate Coil Embolization and significantly reduce procedure time and radiation exposure to both operator and patient during Selective Internal Radiation Therapy.

47%
decrease in
procedure time

73%
decrease in
fluoroscopy time

39%
decrease in
contrast dose

77%
decrease in
deploy time



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RESULTS:

• **Nine month period, 30 consecutive patients were randomized into two groups.**

- Group 1 (n=15) underwent standard planning angiogram with Coil Embolization (CE) with a standard micro-catheter + Interlock 018 coils (Boston Scientific, Natick, MA)

- Group 2 (n=15) underwent planning angiogram only with the SIS (Surefire Medical, Westminster, CO) without CE

- Both groups were treated with SIRT

• **Tumor types:**

- HCC (n=16, 53%)

- Metastatic (n=14, 47%).

• **Significant Reduction observed in the Surefire group:**

- Fluoroscopy Time (FT), the primary endpoint

- Deployment Time (DT)

- Procedure Time (PT)

- Dose Area Product (DAP)

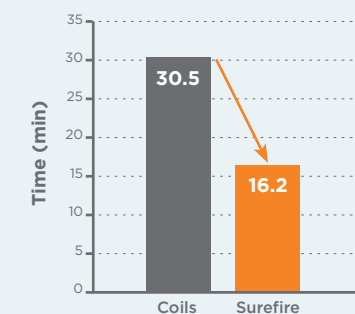
- Contrast Volume

• **Mean number of coils used in Group 1 was 3.4 (range 2-7)**

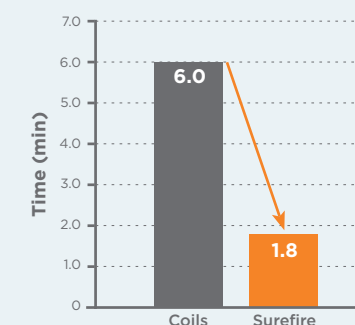
• **There were no major or minor Adverse Events at 30 days in either group**

• **The Surefire Infusion System was used in both groups during the Y90 administration procedures**

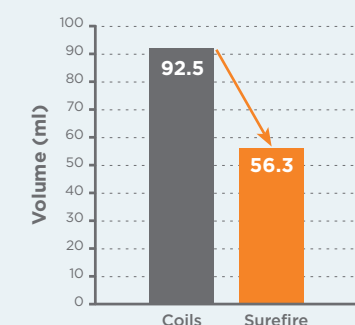
Procedure Time



Fluoroscopy Time



Contrast Agent Dose



Deploy Time

