Prospective, Randomized Study of Coil Embolization versus Surefire Infusion System during Yttrium-90 Radioembolization with Resin Microspheres

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ABSTRACT

Purpose: To compare standard coil embolization versus the use of an antireflux microcatheter (ARM) in patients undergoing planning angiography before selective internal radiation therapy (SIRT).

Materials and Methods: A prospective, single-center trial was performed in which 30 patients were randomly assigned to undergo SIRT with coil embolization or the use of an ARM. The coil group underwent detachable coil embolization of nontarget vessels, and the ARM group underwent infusion of macroaggregated albumin with use of an ARM system, without coil embolization. Single-photon emission computed tomography (CT)/CT was then performed to assess for nontarget distribution. The primary endpoint was fluoroscopy time during planning angiography. Secondary endpoints included deployment time, total procedure time, radiation dose–area product, contrast agent used, and adverse events. Endpoints were evaluated during planning angiography and SIRT.

Results: Over a 9-month period, 30 consecutive patients were randomized at a 1:1 ratio between coil embolization and ARM groups. Technical success rates were 100% in both groups. Mean fluoroscopy time was significantly reduced in the ARM group versus the coil embolization group (1.8 min [range, 0.4–4.9 min] vs 6.0 min [range, 1.9–15.7 min]; $P = .002$). The planning procedure time ($P < .001$), deployment time ($P < .001$), dose–area product ($P = .04$), and amount of contrast agent used ($P < .001$) were also significantly less in the ARM group than in the coil embolization group. No nontarget distribution was detected in either group. There was no difference between groups in dose delivered on the day of SIRT ($P = .71$). There were no major or minor adverse events at 30 days.

Conclusions: The use of an ARM during planning angiography can significantly reduce fluoroscopy time, procedure time, and radiation dose.

ABBREVIATIONS

ARM = antireflux microcatheter, GDA = gastroduodenal artery, MAA = macroaggregated albumin, SIRT = selective internal radiation therapy, SPECT = single-photon emission computed tomography

In patients with advanced primary liver cancer or liver-predominant metastatic disease, selective internal radiation therapy (SIRT) has been shown to control tumor growth and prolong survival (1–4). Currently, a planning angiogram is routinely obtained before SIRT to prevent nontarget distribution to extrahepatic organs and ensure

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From the SIR 2014 Annual Meeting.

This study was funded by a restricted research grant from Surefire Medical (Westminster, Colorado). A.M.F. is a paid consultant for Terumo (Somerset, New Jersey), Surefire Medical, CeloNova (San Antonio, Texas), and Philips (Eindhoven, The Netherlands). R.S.P. is a paid consultant for Arstasis (Redwood City, California), Sirtex (North Sydney, Australia), and St. Jude Medical (St. Paul, Minnesota). A.A. is a paid consultant for W.L. Gore and Associates (Flagstaff, Arizona), Kimberly–Clark (Irving, Texas), and Surefire Medical, has patent ownership in Surefire Medical, and is a shareholder for Surefire Medical. E.K. is a paid consultant for Biocompatibles (Farnham, United Kingdom), Onyx Pharmaceuticals (South San Francisco, California), and Philips. R.A.L. is a paid consultant for Boston Scientific (Natick, Massachusetts), Cordis (Bridgewater, New Jersey), and Bayer HealthCare (Whippany, New Jersey). Neither of the other authors has identified a conflict of interest.

J Vasc Interv Radiol 2014; 25:1709–1716

http://dx.doi.org/10.1016/j.jvir.2014.08.007

that there is not excessive lung shunting. Although there is currently no standard of care to prevent nontargeted delivery, patients can be pretreated by the permanent placement of embolic coils to prophylactically embolize nontargeted vessels such as the gastroduodenal artery (GDA) and the right gastric artery. However, coil embolization of these vessels increases fluoroscopy and procedural time and is not without risk, as coil migration and arterial dissection may occur. The Surefire Infusion Catheter System (Surefire Medical, Westminster, Colorado) is a new antireflux microcatheter (ARM) with an expandable tip fused to the distal end of an infusion microcatheter that has been recently introduced for the infusion of therapeutic agents. When the ARM is placed in the vessel, with the tip expanded, antegrade blood flow is allowed around the tip while retrograde flow is prevented (5,6). Therefore, our underlying hypotheses was that the use of an ARM may decrease fluoroscopy time, procedure time, procedural radiation dose, and contrast agent volume. To test these hypotheses, we performed a randomized prospective trial comparing coil embolization versus the use of the ARM, with fluoroscopy time as the primary endpoint.

MATERIALS AND METHODS

Patients

All data were handled in accordance with the Health Insurance Portability and Accountability Act. A local institutional review board approved the study. Study data were deidentified and stored on the primary investigator's computer with password protection and digital encryption. Funding for this study was provided by Surefire Medical in the form of a restricted research grant.

This study is a prospective, randomized, nonblinded trial performed at a single academic tertiary referral center. Planning angiography and SIRT were performed as ambulatory procedures by fellowship-trained interventional radiologists with Certificates of Added Qualification in interventional radiology. Patients who were to undergo planning angiography before SIRT with SIR-Spheres (Sirtex, North Sydney, Australia) were randomized at a 1:1 ratio into two groups. A random number table was created by the research coordinator for randomization. Sealed envelopes were pulled from a pool after consent for study participation was obtained.

Between March 2013 and September 2013, 30 patients who met anatomic requirements for the study were randomized, 15 to undergo coil embolization and 15 to undergo treatment with the ARM. All received the randomized intervention. Demographic information is provided in **Table 1**. Patients in the coil embolization and ARM groups were not significantly different in regard to age, sex, type of hepatic malignancy, or lobe treated. No patient in either group had received treatment with bevacizumab or sorafenib before mapping angiography or SIRT. The most commonly treated cancer was hepatocellular carcinoma (n = 16), followed by colorectal cancer liver metastases (n = 6). During the study period, all patients to be treated with SIRT were screened for study eligibility. During the study period, approximately 100 patients were treated with SIRT.

The coil embolization group underwent standard coil embolization of nontarget vessels, macroaggregated albumin (MAA) infusion, and SIRT with the use of a standard microcatheter system. The ARM group underwent MAA infusion and SIRT with use of an ARM, without coil embolization. The ARM used in this study was the Surefire Infusion Catheter System (internal diameter, 0.027 inch; vessel size range, 2–6 mm; Surefire Medical). Informed consent for the procedure and study participation was obtained in all patients.

Table 1. Demographic and Treatment Information

Characteristic	Coil Embolization (n = 15)	ARM (n = 15)	*P* Value
Age (y)	64.7 ± 10.0	62.8 ± 10.7	.60
Male sex	9 (60)	11 (73)	.70
Tumor			
HCC	7 (47)	9 (60)	.72
CRC	2 (13)	4 (27)	.65
NET	4 (27)	1 (7)	.33
Cholangiocarcinoma	1 (7)	0	1.00
Gastric	1 (7)	0	1.00
Appendiceal	0	1 (7)	1.00
Hepatic lobe treated			
Right	11 (73)	12 (80)	1.00
Left	3 (20)	3 (20)	1.00
Whole liver	1 (7)	0	1.00

Values presented as means ± standard deviation where applicable. Values in parentheses are percentages.
ARM = antireflux microcatheter, CRC = colorectal cancer, HCC = hepatocellular carcinoma, NET = neuroendocrine tumor.