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Downstream Hepatic Arterial Blood Pressure Changes Caused by Deployment of the Surefire AntiReflux Expandable Tip

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Abstract
Purpose The purpose of this work was to evaluate blood pressure changes caused by deployment of the Surefire antireflux expandable tip. The pressure measurements are relevant because they imply changes in hepatoenteric arterial blood flow within this liver compartment during hepatic artery delivery of cytotoxic agents.
Methods After positioning the Surefire antireflux system in the targeted hepatic artery, blood pressure was obtained initially with the tip collapsed (or through a femoral artery sheath), then again after the tip was expanded before chemoembolization or yttrium 90 (^{90}Y) radioembolization.
Results Eighteen patients with liver malignancy underwent 29 procedures in 29 hepatic arteries (3 common hepatic, 22 lobar, 4 segmental). Systolic, diastolic, and mean blood pressure were all decreased by a mean of 29 mm Hg ($p = 0.000004$), 14 mm Hg ($p = 0.0000004$), and 22 mm Hg ($p = 0.00000001$), respectively.
Conclusion When the Surefire expandable tip is deployed to prevent retrograde reflux of agents, it also results in a significant decrease in blood pressure in the antegrade distribution, potentially resulting in hepatopedal blood flow in vessels that are difficult to embolize, such as the supraduodenal arteries.

Keywords Liver cancer · Hepatocellular carcinoma · Chemoembolization · Radioembolization · Embolization

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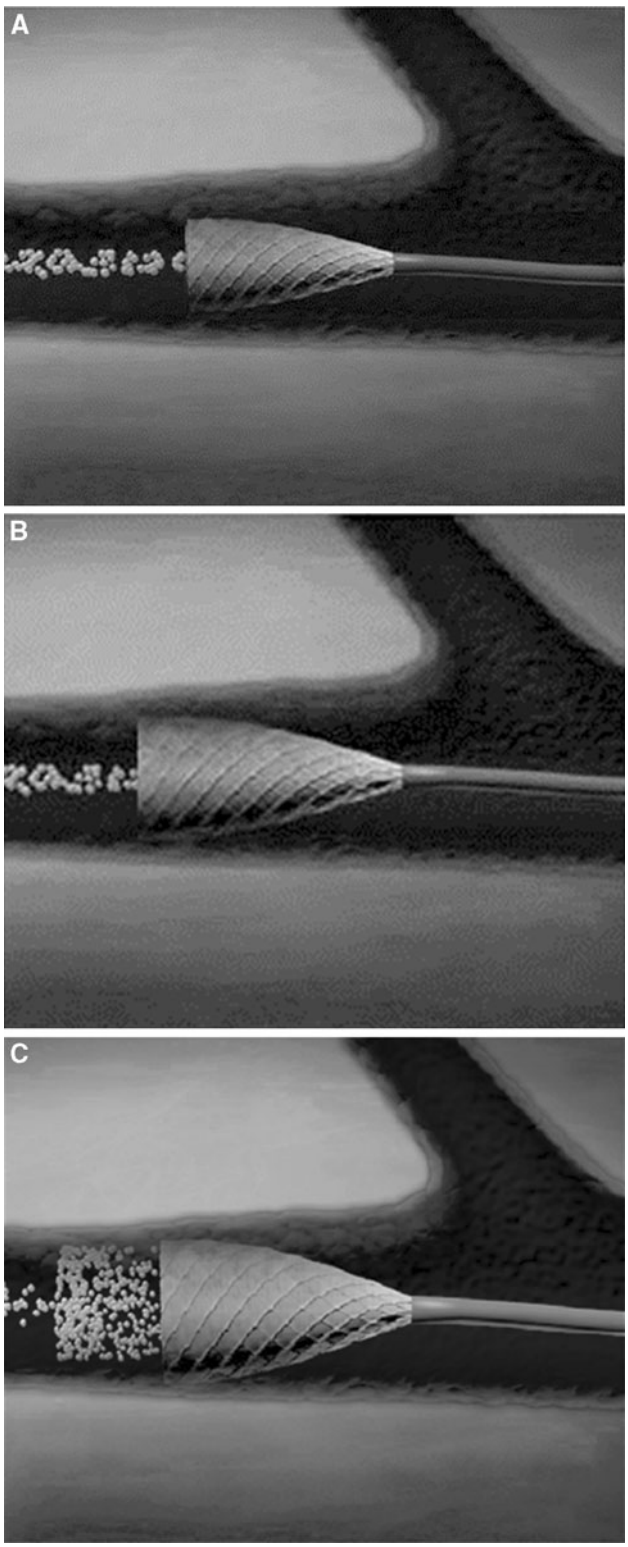
Introduction

One potentially serious risk of transarterial therapies, such as chemoembolization or yttrium 90 (^{90}Y) radioembolization, used to treat hepatic malignancies is the unintended delivery of the therapeutic agent into nontarget structures resulting in complications, such as ulceration of the gut [1]. The reported incident of gastrointestinal ulceration after ^{90}Y radioembolization varies widely from 0 to 25 % (with mean values 6–8 %) likely depending on angiographic preparation, ^{90}Y dose–delivery techniques, vigilance of clinical follow-up, and threshold for performing endoscopy [2–7]. These ulcers are frequently severe, may require surgical resection, and occasionally are fatal. The mechanisms can be due to either retrograde reflux of agent into upstream arterial branches or antegrade flow into more distal hepatoenteric arteries with hepatofugal blood flow. To prevent these events, considerable diligence, effort, and expense is frequently invested in permanent coil occlusion of the relevant arterial branches to ensure that the agent, especially ^{90}Y microspheres, remains within the targeted portion of the liver [8, 9]. Not infrequently, patients are left partially unprotected despite extensive efforts because the hepatoenteric arterial branches, such as the supraduodenal arteries, are too small, too tortuous, or have a severe angle of origin that does not allow catheterization for protective embolization.

Recently a microcatheter with a pliant braided polymer funnel-shaped, self-expending tip (Surefire Infusion System [SIS]; Surefire Medical, Inc., Westminster, CO) has been made commercially available. The degree of blood vessel occlusiveness is dynamic and is dependent on the phase of the cardiac cycle and amount of downstream embolization. The tip is partially collapsed during forward blood flow of cardiac systole (Fig. 1A) with a minor degree



◀**Fig. 1** Conceptual drawing of the SIS. **A** During systole, forward blood flow partially collapses the expandable tip, thus allowing forward delivery of the embolic particles. **B** During diastole, forward flow collapses the expandable tip less due to the lower pressure, but forward flow persists. **C** During retrograde flow conditions, the blood flow reversal causes the expandable tip to open and occlude the arterial lumen, thus prohibiting retrograde passage of embolic particles

of expansion during cardiac diastole that is subocclusive (Fig. 1B), thus allowing antegrade delivery of the agent. During this phase, the spring-like, self-expending properties of the tip cover a relatively large portion of the vessel cross-sectional area, somewhat analogous to a high-grade stenosis. The tip fully expands if the blood pressure at the tip of the microcatheter plus the self-expandable forces of the funnel-shaped tip is greater than the blood pressure in the upstream portion of the blood vessel, usually during the course of embolization with occlusion of downstream arterial branches, thus preventing reversal of blood flow and retrograde reflux of the agent into upstream arterial branches (Fig. 1C) [10]. This later phase would be analogous to a vessel occlusion or an expanded occlusion balloon [11].

Because this membrane tip occupies a large proportion, if not all, of the arterial cross-sectional area, we hypothesized that when the tip is expanded, blood pressure in the downstream hepatic arterial compartment would be significantly lower than the blood pressure in the rest of the body. If true, the implication would be that blood flow in the hepatoenteric arteries may reverse and become hepatopedal, thus flowing toward the hepatic artery compartment with a lower blood pressure. Potentially this could provide a measure of protection against nontarget delivery of agents in the downstream vascular bed as well.

Methods

Subjects

Since October 2011, when the SIS became available at our institution, all patients with liver malignancy being treated with chemoembolization or ^{90}Y radioembolization with arterial anatomy at high risk of nontarget delivery of agent were deemed candidates for use of the SIS. High-risk anatomy was defined as replaced right or left hepatic arteries, nearby gastroduodenal artery, bifurcation of the right and left hepatic arteries upstream to the gastroduodenal artery, nonembolizable right gastric artery, or nonembolizable distal hepatoenteric artery (e.g., supraduodenal or accessory left gastric artery). Before embolization, recording of blood pressure has been our institutional standard practice to ensure both adequate expansion of the expandable tip as well as estimation of the degree of potential distal protection by direction. This protocol was derived from our institutional experience using temporary balloon occlusion of the splenic artery during partial splenic embolization procedures [11]. Our Institutional

Review Board has given approval of retrospective collection and analysis of depersonalized data.

By intention to treat using this device, between October 2011 and June 2012, 27 patients were candidates. In nine patients (33.3 %), the 4.8F guide catheter could not be delivered to the targeted hepatic artery, primarily due to a sharp aorto-celiac or aorto-superior mesenteric artery angle [12]. Of the 18 patients in whom there was successful deployment of the SIS, 15 had hepatocellular carcinoma, 2 had primary nodular intrahepatic cholangiocarcinoma, and 1 had hepatic metastases from a colorectal adenocarcinoma. Fourteen patients were male, and 4 were female. Ages ranged from 52 to 82 years (mean 66.7). In these 18 patients, 29 procedures were performed: 14 drug eluting–bead chemoembolizations (four with lipiodol), 4 hepatic angiography and embolization in preparation for ^{90}Y radioembolization, and 11 ^{90}Y radioembolization (glass microspheres = 8 patients; resin microspheres = 3 patients).

Technique

All patients underwent initial selective angiography of the celiac artery and superior mesenteric artery using a 5F reverse-curve angiographic catheter (Torcon NB Advantage Catheter; Cook, Bloomington, IN) and power injection of iodinated nonionic contrast material (Visipaque 320; GE Health Care; Princeton, NJ) at 5 to 6 ml/s using anteroposterior digital acquisition (AXIOM Artis dTA; Siemens AG Medical; Muenchen, Germany). In those patients deemed to have arterial anatomy at risk for nontarget delivery of agent, use of the SIS was attempted. Over a heavy, torquable angled–tip 0.035-inch guidewire (Glidewire Advantage; Terumo; Somerset, NJ) positioned into the targeted hepatic artery, the 5F angiographic catheter was replaced with a 4.8F straight-tip guide sheath (Surefire Guide Sheath; Surefire Medical). Once positioned, repeat selective angiography was performed with anteroposterior digital subtraction acquisition followed by cone beam computed tomography (CT) angiography (Dyna CT, Siemens Medical) to ensure that the tumors were included within the treatment area and that the desired portion of the liver had been selected. The coaxial 3.0F Surefire microcatheter with the expandable antireflux tip was coaxially repositioned over a straight-tip microguidewire (Fathom-16; Boston Scientific, West Valley City, UT) such that the tip of the antireflux microcatheter was positioned at the tip of the guide sheath.

Blood pressure was obtained using standard electronic physiologic monitoring transducers (Pressure Monitoring Kit; Edwards Life Sciences, Irvine, CA) with saline-filled plastic tubing connecting the hub of the microcatheter to the pressure transducer. The transducers were attached to an angiographic table mount and adjusted to the level of the midaxillary line using laser sights. This is our institutional standard for intravascular recording of blood pressures, such as hepatic venous pressure measurements. After approximately 1 minute to allow readings to stabilize, values recorded included systolic, diastolic, and mean arterial blood pressures. Beginning April 2012, our protocol was expanded to using 6F femoral artery sheathes rather than 5F sheathes to obtain real-time systemic blood pressure changes during embolization in addition to pre-embolization blood pressure readings with the SIS tip closed. Under fluoroscopic observation, the guide sheath was then retracted approximately 2 cm relative to the microcatheter to allow the expandable tip to open fully. Contrast material was hand-injected to ensure full tip expansion and suitable tip location. After flushing the microcatheter with heparinized saline, the same blood pressure values were obtained and recorded before embolization. The anatomic location and the diameter of the hepatic arterial branch at the tip of the SIS were recorded. The diameter was measured from the proprietary electronic calipers and measurement function (Siemens Medical) using a representative selective digital subtraction angiogram.

Clinical Follow-Up

Clinical follow-up using the electronic medical records and archived digital imaging was recorded on August 1, 2012, on all patients in whom use of the SIS device was attempted. Specifically, evidence of potential nontarget delivery of cytotoxic agents (e.g., gastrointestinal or skin ulceration) was sought. In accordance with the limitations of the Institutional Review Board, telephone contact with the patients was prohibited. The effects of embolization on the tumors and liver was outside the scope of this project and is the subject of a separate evaluation.

Statistical Analysis

We assumed that the blood pressure measured with the microcatheter tip closed was a reasonable approximation of the systemic arterial blood pressure and that there was not a significant upstream change after the antireflux tip was expanded. Although the 4.8F guide sheath would occupy a portion of the cross-sectional area of the targeted hepatic artery, this remained constant between the two measurements. The difference in blood pressure parameters (systolic, diastolic, and mean) between that recorded with the microcatheter tip collapsed and that recorded with the microcatheter tip expanded was calculated. The significance of differences was assessed using standard Student *t* test, one tailed, and assumed Gaussian distribution and unequal variance. Blood pressure differences were

Table 1 Baseline pre-embolization blood pressure values with the tip closed and expanded as well as differences plus vessel location and diameter on a per-patient and per-procedural basis

Patient no.	Target artery	Diameter (mm)	Tip closed (mm Hg)		Tip expanded (mm Hg)		Decrease (mm Hg)	
1	Segment II/III	3.0	[a]	83	[a]	50	[a]	33
2	RHA	3.1	124/64	91	87/48	63	37/16	28
3a	RHA	4.4	118/62	85	106/53	75	12/9	10
3b	CHA	6.6	114/61	82	98/53	71	16/8	11
4	Segment IV	3.2	117/70	89	99/64	75	18/6	14
5	RHA	5.6	70/50	59	38/35	36	32/15	23
6a	(r) RHA	4.5	97/85	92	60/50	55	37/35	37
6b	(r) RHA	4.5	92/74	84	65/22	58	27/22	26
6c	(r) RHA	4.5	77/64	71	49/47	48	28/21	23
6d	(r) RHA	4.5	128/75	96	64/54	59	64/21	37
6e	(r) RHA	4.5	104/64	80	76/54	63	28/10	17
7	Seg VII	2.5	98/58	74	48/41	44	50/17	30
8	LHA	4.0	82/53	64	69/37	49	13/16	15
9	LHA	4.9	120/66	86	87/53	66	33/13	20
10	RHA	6.0	78/52	59	47/33	38	31/19	21
11a	CHA	5.2	136/63	91	118/53	77	18/10	14
11b	RHA	4.9	86/67	77	86/41	57	0/26	20
11c	RHA	4.9	103/52	72	83/46	60	20/6	12
11d	RHA	4.2	105/50	71	77/38	53	23/12	18
11e	RHA	4.3	137/58	85	86/38	54	51/20	31
12a	(r)LHA	3.4	137/62	90	87/34	52	50/28	38
12b	(r) LHA	3.4	121/91	97	76/47	62	[a]	35
13	RHA	6.6	118/63	86	90/50	67	28/13	19
14.	RHA	4.1	122/50	87	103/48	69	19/2	18
15	SEG VIII	2.3	91/63	76	61/49	54	30/14	22
16	RHA	5.8	101/50	65	68/43	50	33/7	15
17a	RHA	5.9	142/73	103	130/77	90	12/-4	13
17b	RHA	5.2	142/73	102	128/60	87	14/13	16
18	CHA	5.9	118/62	84	96/47	65	22/15	19

[a] Not recorded, no discernible arterial wave form

stratified by arterial location (common hepatic artery *vs*. lobar hepatic artery *vs*. segmental hepatic artery).

Results

The changes in blood pressure values between those obtained with the SIS tip collapsed and the tip expanded are listed in Tables 1 and 2. The decrease in blood pressure values were highly significant ($p = 0.000004$, 0.0000004, and 0.00000001, respectively) for systolic, diastolic and mean arterial blood pressure. Mean arterial blood pressure changes stratified by anatomic hepatic arterial location are listed in Table 3. The decrease in blood pressure was significant at the common hepatic, lobar, and segmental levels. The difference in the mean arterial blood pressure between anatomic location did not reach statistical significance (between the common hepatic arteries and lobar arteries, $p = 0.3$; between the lobar and segmental arteries, $p = 0.07$; and between the common hepatic arteries and the segmental arteries, $p = 0.14$).

Table 2 Mean blood pressure values (± SD) with the tip closed and tip expanded as well as *p* value for decrease in mean blood pressure

B/P values	Tip closed (mm Hg)	Tip expanded (mm Hg)	Decrease (mm Hg)	*p*
Systolic	101 (±25)	76 (±25)	25	0.004
Diastolic	64 (±9)	47 (±9)	17	0.00002
Mean	79 (±11)	58 (±14)	21	0.00003
Pulse amplitude	37 (±20)	29 (±20)	8	0.134

Table 3 Mean arterial blood pressure stratified by vessel location

Vessels	Tip closed (mm Hg)	Tip expanded (mm Hg)	Decrease (mm Hg)	*p*
All	81.3	59.5	21.8	0.00000001
Common hepatic	85.7	68.0	17.7	0.07
Lobar	80.9	59.0	21.9	0.0004
Segmental	80.5	55.8	24.8	0.03

The diameter of the hepatic arteries at the location of SIS deployment ranged from 2.3 to 6.6 mm. The mean decrease of the mean arterial blood pressure was 27.3 mm Hg (standard deviation [STD] 7.8), 21.7 mm Hg (STD 8.3), and 17.8 mm Hg (STD 5.4) for arteries with a diameter <4 mm, 4 to 5 mm, and >5 mm, respectively. The p values were 0.08, 0.10, 0.01, and 0.03 when comparing mean blood pressure decreases of <4 versus 4–5 mm, 4–5 versus >5 mm, <4 versus >5 mm, and <4 versus ≥4 mm, respectively.

After April 2012, simultaneous blood pressure recordings were obtained through a 6F femoral artery sheath in seven patients undergoing nine procedures. The difference in estimations of pre-embolization mean systemic blood pressure (sheath minus SIS tip closed) were as follows: range −14 to +9 mm Hg (mean 1.9 [SD 6.7; $p = 0.35$]). The differences in systolic blood pressure readings ranged from −20 to +28 mm Hg (mean 11.9 [$p = 0.19$]), and diastolic blood pressure values ranged from –14 to +15 (mean 0.78 [$p = 0.95$]).

Clinical and imaging follow-up was available in all patients in whom use of the SIS was attempted. In the 18 patients in whom SIS was successfully deployed, follow-up ranged from 0.2 to 9.5 months (mean 4.9). No patients had symptoms suggestive for nontarget embolization (such as gastrointestinal or skin ulceration). In the 9 patients whom the SIS could not be successfully deployed, follow-up ranged from 0.8 to 9.5 months (mean 5.9). None of these patients reported symptoms suggestive for nontarget embolization. One case in this group of technical failures had to be cancelled because an accessory left gastric artery could not be embolized; thus, 90Y radioembolization was contraindicated.

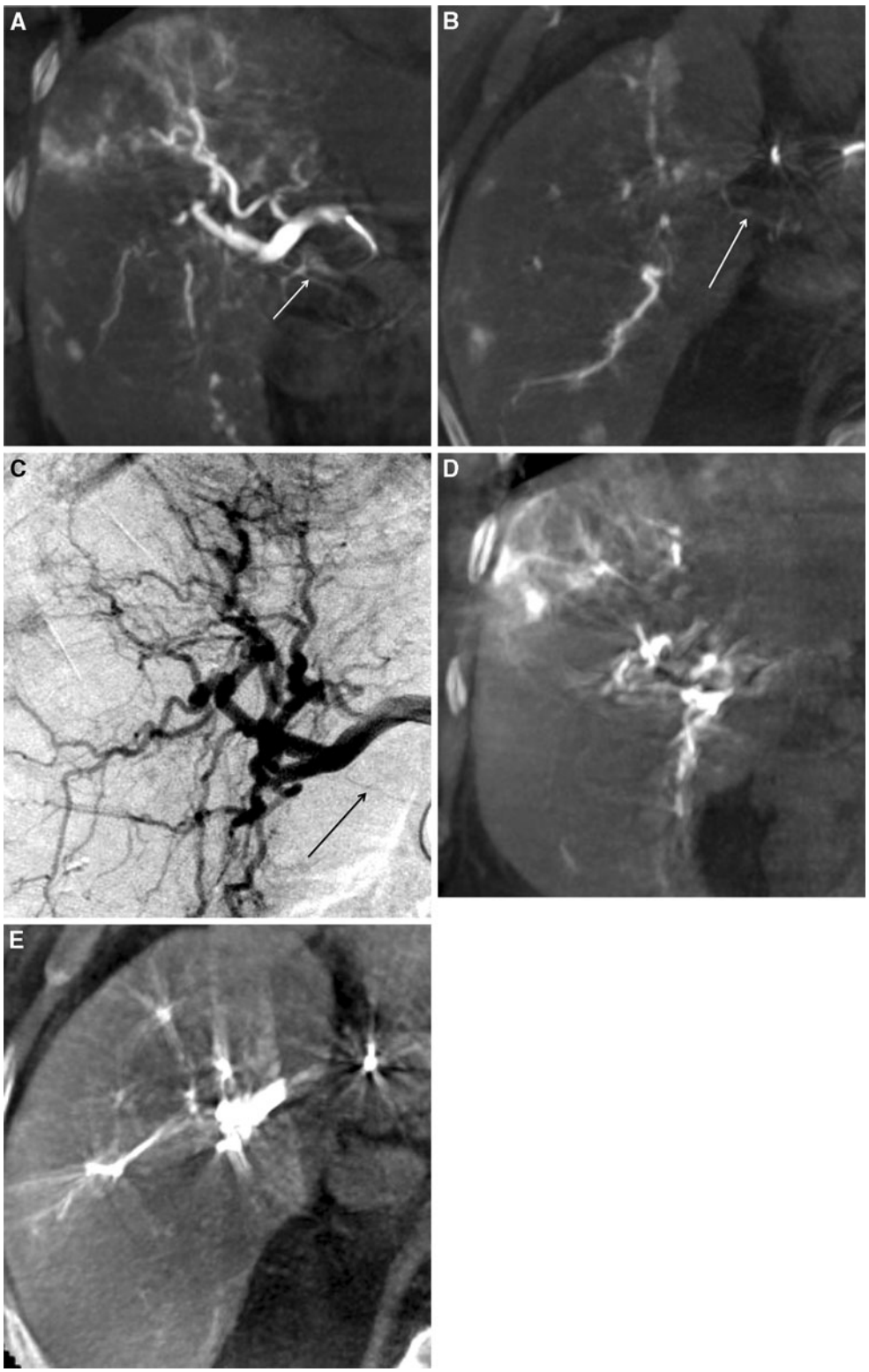
Discussion

In the splenic artery, temporary proximal occlusion by balloon catheters has been documented to result in a decrease of blood pressure by a mean of 42 mm Hg in the distal splenic arterial bed, thus causing reversal of blood flow in nonsplenic arteries to prevent nontarget particle embolization [11]. In the hepatic arteries, investigators have described use of temporary occlusion balloons to cause hepatoenteric arteries in the treatment distribution within the liver to reverse and flow hepatopedaly to protect nontargeted structures during chemoembolization or ^{90}Y radioembolization [13, 14]. The SIS, with its expandable tip microcatheter, similarly causes a blood pressure decrease in the antegrade or downstream vascular compartment.

It is noteworthy that the SIS operates in a fundamentally different fashion than an occlusion balloon in that it permits antegrade blood flow. The expandable tip has been observed fluoroscopically and angiographically to have three states: antegrade systolic flow (tip is collapsed significantly), antegrade diastole flow (tip is collapsed only slightly), and arrested retrograde flow (tip is fully sealed to the vessel wall).

The blood pressure decrease was significant at all anatomic locations (common hepatic artery *vs*, lobar *vs*. segmental hepatic arteries), and across the full range of vessel diameters from 2.3 to 6.6 mm, and was significantly greater for arteries <4 mm compared with those ≥4 mm. Although this device was designed primarily to prevent retrograde reflux of embolic agents into upstream nontarget arteries, relative antegrade protection is likely provided by the nature of its causing blood pressure decrease downstream, at least at rest and probably under conditions of low-velocity injections (e.g., <0.5 ml/s) and low embolic load. In short, the expanded SIS tip effectively creates two separate vascular compartments: the vascular territory downstream from the tip and the rest of the body. Haydar et al. made a case for the safety of Y^{90} radioembolization without coil embolization provided that blood flow in the gastroduodenal artery is predictably hepatopedal [15]. Because the blood pressure is

Fig. 2 An 82-year-old woman with multifocal hepatocellular carcinoma undergoing ^{90}Y radioembolization of the right lobe of the liver with glass microspheres. **A** Postcontrast cone beam CT in coronal format showing epicholedochal artery (*white arrow*). **B** Corresponding postcontrast cone beam CT in axial format showing epicholedochal artery (*white arrow*). **C** Corresponding contrast enhanced digital subtraction angiography in axial format showing epicholedochal artery (*black arrow*). It was technically not feasible to catheterize the epicholedochal artery. The SIS was deployed in the right hepatic artery upstream from the epicholedochal artery. Blood pressure (mm Hg) taken by way of the Surefire microcatheter with the tip closed was 101/50 (mean 65) and with the tip expanded was 68/43 (mean 50). The decrease in blood pressure in the right hepatic lobe was 33/7 (mean 15). **D** Postcontrast cone beam CT in coronal format after deployment of Surefire device showing that no enhancement of previously seen epicholedochal artery. **E** Postcontrast cone beam CT in axial format after deployment of Surefire device showing no enhancement of previously seen epicholedochal artery. ^{90}Y radioembolization was performed by way of the SIS despite patency of this hepatoenteric artery. During 6-month clinical follow-up, she experienced no symptoms of gastrointestinal ulceration ▶



reliably and significantly decreased in the antegrade compartment, blood vessels that bridge between this compartment and anywhere else in the body should have blood flow directed into this compartment.

The standard practice for protecting nontarget vascular beds during transarterial cytotoxic therapy has been permanent and potentially expensive coil embolization. Catheterization to perform coil embolization is not always

possible, especially if the hepatoenteric vessels are small caliber and/or have hostile anatomy, such as is often the case with supraduodenal, right gastric, and falciform arteries. In addition, coil embolization of the gastroduodenal artery has been shown to cause recruitment of supraduodenal arteries in approximately 35 % of patients [16]. The option of achieving both retrograde and antegrade protection from nontarget delivery of agent and altering blood flow characteristics limited to the duration of the embolization procedure appears to be a desirable feature.

There is at least one important caveat regarding use of this device to effect temporary blood flow redistribution during embolization. The expanded tip prevents retrograde reflux of blood, contrast, or emboli. Stasis of blood flow and/or some reflux during conventional straight tip–catheter embolization is an important fluoroscopic visual clue for the operator to stop, at least temporarily. Because the SIS eliminates reflux, the angiographic end point of embolization could be different because the tip creates a separate antegrade vascular compartment. Because blood flow reversal is not possible, it is feasible to over embolize the downstream territory. In the case report on temporary balloon occlusion of the splenic artery, it was noted that during the course of small-particle embolization of the splenic parenchyma, the resistance in the splenic artery bed increased and the differential between systemic blood pressure and distal splenic arterial blood pressure became significantly less, and thus the degree of protection by flow reversal likely was less [11].

There are several limitations to this report. It is a relatively small, retrospective, single-institution study. Nevertheless, after expansion of the SIS tip, a clinically significant distal blood pressure decrease occurred in every patient, every procedure, and every hepatic arterial location. This work examined only the effect on distal blood pressure and did not directly prove alterations in downstream hemodynamics and blood flow direction. Just as water, when under the influence of a gravitational field, consistently flows downhill, fluids should consistently flow from a compartment with greater pressure to one with lower pressure, provided a conduit is available. Indirect evidence was illustrated in Fig. 2. Although clinical follow-up detected no cases of nontarget embolization in the patients who had successful deployment of the SIS, neither were cases of nontarget embolization found in the group of similar patients with high-risk vascular anatomy but in whom the SIS device was not able to be delivered to the targeted hepatic artery. Because reported rates of gastrointestinal ulceration after ^{90}Y radioembolization generally range between 1 and 8 %, a much larger cohort of patients likely would be necessary to evaluate actual clinical benefit. This study focused only on the blood pressure decreases before embolization and did not address the effects of embolization on blood pressure changes as portions of the distal vascular bed become occluded. This latter topic is significantly more complicated and is the subject of a separate, ongoing evaluation. This study dealt only with blood pressure alterations caused by the SIS tip expansion and did not address other clinical outcomes, such as tumor response and safety.

One difficulty we experienced was being able to deliver the requisite 4.8F straight guide catheter to the targeted hepatic artery. We found that this was primarily due to a sharp angle between the infrarenal abdominal aorta and the celiac artery or superior mesenteric artery [12]. An angle $<45°$ as depicted on sagittal reconstructed view of contrast enhanced CT or magnetic resonance imaging scans was highly predictive of failure. A second-generation device has just been released in which a 3F microcatheter with a constrainable Surefire SIS tip can be advanced over an angled microguidewire coaxially through a 5F shaped angiographic catheter with an inner diameter of at least 0.054 inches. Potentially, technical advances such as this may significantly decrease the technical failure rate.

Given the high likelihood of blood flowing into the downstream hepatic compartment from hepatoenteric branches with hepatopedal blood flow, and inflow from adjacent hepatic compartments, the distribution of embolic agents may be altered, especially in the peripheral zone of the downstream hepatic compartment [17]. The distribution patterns of embolic materials cannot be assumed and are a topic worthy of future investigation.

In summary, the SIS, with a temporary expandable-tip microcatheter, reliably causes significant decrease in blood pressure in the downstream or distal vascular compartment when the tip is expanded. This device has the potential of not only providing protection from retrograde reflux of embolic agent into nontarget arteries but also antegrade protection by causing hepatopedal blood flow in hepatoenteric arteries, at least under conditions of relatively low degrees of embolization.

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Conflict of interest S. C. Rose has a potential conflicts of interest in having been a speaker for this company and potentially developing a patent for the SIS device. J. Chomas is a stockholder and CEO of Surefire Medical.

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