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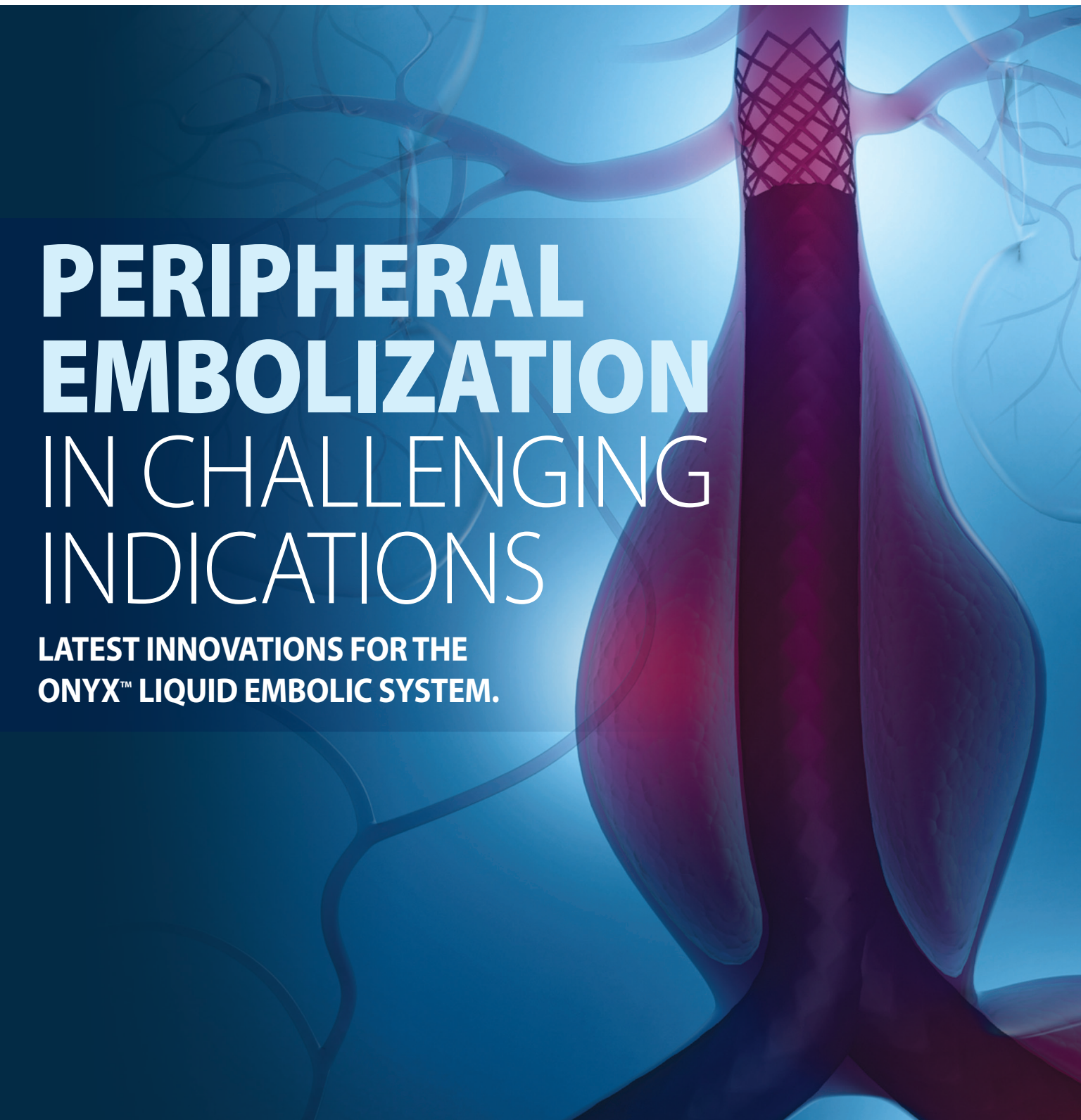

PERIPHERAL EMBOLIZATION IN CHALLENGING INDICATIONS

LATEST INNOVATIONS FOR THE ONYX™ LIQUID EMBOLIC SYSTEM.

PERIPHERAL EMBOLIZATION IN CHALLENGING INDICATIONS

LATEST INNOVATIONS FOR THE ONYX™ LIQUID EMBOLIC SYSTEM.

A look at the published and presented data from studies of the Onyx™ liquid embolic system.

A Brief Discussion of the Midterm Results Using Onyx™ Liquid Embolic System in Treating Persistent Type II Endoleaks After EVAR

By Michel Bosiers, MD; Arne Schwindt, MD; Konstantinos P. Donas, MD, PhD; Giovanni Torsello, MD, PhD

STUDY OVERVIEW

We retrospectively reviewed our prospectively maintained database in search of patients who, until December 2011, had persistent type II endoleaks, with growth of their aneurysm diameter of > 5 mm and were treated with Onyx™ liquid embolic system.

RESULTS

Our mid-term results in 10 patients with 13 type II endoleaks resulted in technical success in nine patients (12 out of 13 endoleaks [92%]). In one patient, a strong angulated orifice of the iliolumbar artery led to a rupture of the internal iliac artery, which required us to abort the procedure and instead place a covered stent in the internal iliac artery. In the remaining nine patients, treatment with Onyx™ liquid embolic system succeeded very well.

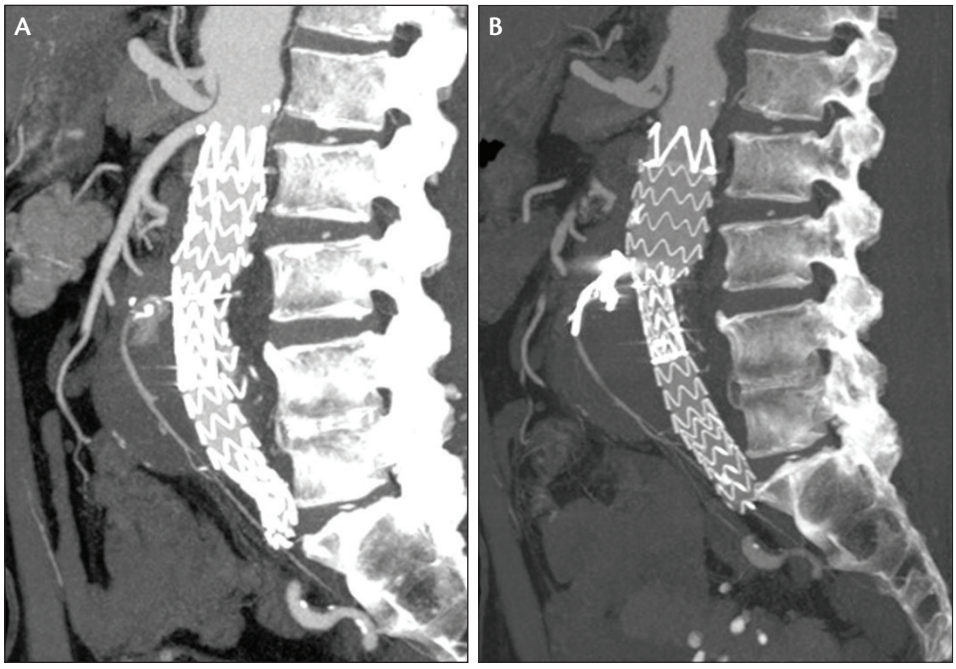

Figure 1. Pre CT (A). Post-CT after Onyx™ liquid embolic system (B).

There were two patients in whom we had to perform a staged procedure due to unconnected type II endoleaks.

During the follow-up period of 3 to 31 months, we observed that all patients with successful embolization remained stable or exhibited shrinkage of their aneurysms.

In one patient there was extravasation of the Onyx™ liquid embolic system out of the aneurysm sac into the inferior vena cava, which required retrieval with a GooseNeck™ snare maneuver.

CONCLUSIONS

We also looked at patients with type II endoleaks we had treated previously with mainly coil embolization or open conversion. We saw that in the coil embolization group, we had to perform reinterventions because they did not remain stable or did not exhibit shrinkage. We can conclude that embolization with Onyx™ liquid embolic system is a feasible and safe procedure, as well as being more efficient compared to coil embolization alone. In our institution, we use Onyx™ liquid embolic system as our standard treatment for type II endoleaks. ■

Ethylene-Vinyl Alcohol Copolymer (Onyx™ Liquid Embolic System) to Seal Type 1 Endoleak: A New Technique

By Olof Henrikson, MD; Håkan Roos, MD; Mårten Falkenberg, PhD

A single-center experience in treating six patients with large aortic aneurysms and remaining type 1 endoleaks during or after EVAR.

PURPOSE

The aim of this study was to investigate whether the liquid embolic agent Onyx™ liquid embolic system, an ethylene vinyl alcohol copolymer, can be used to seal type 1 endoleaks during endovascular aneurysm repair (EVAR).

Patients:

We used Onyx™ liquid embolic system to treat six patients with type I endoleak. These patients had contraindications to open repair and large aortic aneurysms; the mean diameter was 83 mm (range, 70-93). The mean age was 77 years (range, 62-88), and all patients were men. We used Medtronic's Endurant stent graft in the abdominal cases and Valiant in the thoracic case.

In four patients, Onyx™ liquid embolic system was used to seal a remaining type 1 endoleak after endovascular repair of infrarenal aortic aneurysms using the chimney technique. Balloon-expanded covered stents were used for all chimneys (Advanta V12, Atrium), and additional lining with flexible self-expanding stents was done in some cases to improve adaptation to vessel anatomy. Two procedures were primary EVAR, and two were reinterventions with proximal extensions. All cases treated using the chimney technique had a short infrarenal sealing zone of < 1 cm and severe juxtarenal angulations. They were not considered candidates for open repair due to comorbidities, and they were not considered candidates for fenestrated EVAR due to neck angulations and production times.

Technique:

Patients in this series had disadvantageous anatomy at sealing zones, and we therefore planned for possible Onyx™ liquid embolic system embolization. The decision to use Onyx™ liquid embolic system was taken only in cases of persistent type 1 endoleak despite repeated balloon dilation of the stent grafts in the sealing zone. In one patient

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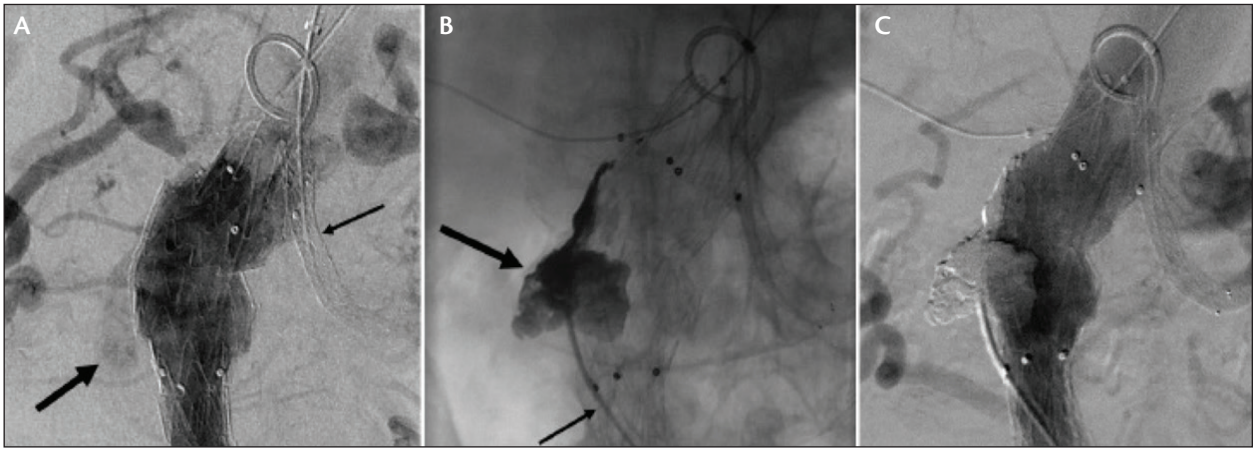


Figure 1. Subtraction angiogram with left oblique projection of the proximal neck during EVAR of an infrarenal abdominal aortic aneurysm using the chimney technique. Thin arrow shows the chimney stent to the left renal artery. Thick arrow shows a type 1 endoleak. Proximal neck angulation is indicated by the bent configuration of the deployed aortic stent graft (A). Onyx™ liquid embolic system (thick arrow) is injected through a catheter from the groin (thin arrow). The catheter was initially used for angiography during positioning of the stent grafts, and it was left outside the stent graft in case of a remaining type 1 endoleak. The catheter was exchanged over a starter guidewire to a selective Berenstein cathteter, through which a microcatheter was advanced into the area of the leak (B). Completion angiogram with no remaining endoleak (C).

Selective Arterial Embolization With Ethylene-Vinyl Alcohol Copolymer for Control of Massive Lower Gastrointestinal Bleeding: Feasibility and Initial Experience

By Jose Urbano, MD, PhD; et al

PURPOSE

To evaluate the safety, efficacy, and clinical outcomes of superselective embolization using ethylene-vinyl alcohol copolymer (Onyx™ liquid embolic system) as the primary treatment for acute and massive lower gastrointestinal bleeding (LGIB).

MATERIALS AND METHODS

Between January 2008 and October 2013, all patients with focal massive LGIB who were treated by embolization were retrospectively analyzed. Onyx™ liquid embolic system was chosen as the embolic agent in all cases in an intention-to-treat fashion. Embolization was indicated in 31 consecutive patients (mean age, 80 y ± 11.1). Multidetector computed tomography and digital subtraction angiography were performed in all patients.

CLINICAL OUTCOME

By intention-to-treat, the clinical success of embolization with the Onyx™ liquid embolic system for LGIB was 96.7%. Immediate and long-term control of bleeding was obtained in 100% of the patients who could undergo embolization, stabilizing the level of hemoglobin in the blood and alleviating rectal bleeding or melena. None of the patients who underwent embolization required any other invasive treatment for bleeding control during the follow-up period. The 30-day re-bleeding rate was 10% (three cases); the bleeding was minimal and self-limited in all cases.

LONG-TERM OUTCOMES

The mean follow-up time was 23.7 months (range, 1-71 months). Two patients died during follow-up at 4 months after the embolization; both of these patients did not have additional episodes of LGIB. The remaining patients were alive at the conclusion of the study. One patient with rectal neoplasia received neoadjuvant chemotherapy and radiation therapy, and an oncologic surgical resection was performed 3 months after the embolization. None of the patients exhibited clinical intestinal subocclusion or obstruction during the follow-up period.

DISCUSSION

In the present study, embolization of massive LGIB using Onyx™ liquid embolic system 18 LES could be applied in 30 of 31 patients. The technical success rate was 93.5% (29 of 31 cases). Immediate and long-term control of LGIB was obtained in 100% of the patients who could undergo embolization, with no major complications or procedure-related deaths.

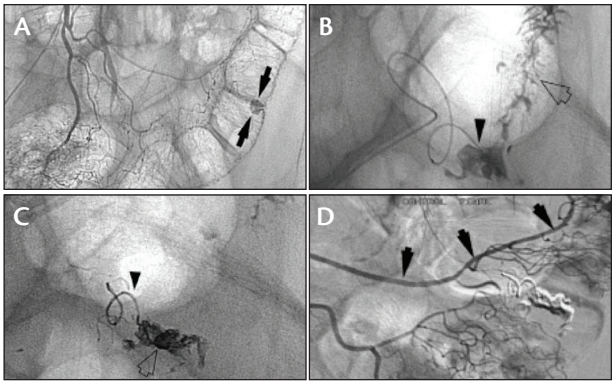


Figure 1. Angiography of the inferior mesenteric artery reveals active bleeding from a diverticulum in the left colon (arrows) (A). Microcatheter tips at the bleeding site (arrowhead) and contrast extravasation toward the colonic lumen (arrow) (B). Mold of Onyx™ liquid embolic system filling the vasa recta responsible for the bleeding (arrow) and Onyx extravasation through the bleeding site toward the intestinal lumen (arrowhead) (C). Final control angiography shows untouched marginal artery (arrows) (D).

Although microcoils are the most frequent embolic agent utilized for embolization of LGIB, Onyx™ liquid embolic system is a very good alternative. Onyx™ liquid embolic system produces a plug in the eroded artery and simultaneously blocks the primary site of the bleeding. The slow real-time injection under fluoroscopic guidance provides greater control over the distribution of the embolization agent, avoiding nontargeted embolization. Because this product is nonadhesive, the microcatheter is not entrapped. Coagulopathy is a negative predictive factor for survival, bleeding control, and rebleeding in patients with LGIB. Onyx™ liquid embolic system has the remarkable advantage of acting independently of any underlying coagulopathy or low platelet count.

Compared to cyanoacrylates, the main concern is the uncontrolled release, which is associated with a high risk of distal migration and nontargeted embolization, as well as the risk of causing severe intestinal ischemia. Risk related to microcatheter entrapment is also a major concern. ■

Reprinted from JVIR, Vol. 25, No. 6, Urbano J, Cabrera M, Franco A, Alonso-Burgos A. Selective arterial embolization with ethylene-vinyl alcohol copolymer for control of massive lower gastrointestinal bleeding: feasibility and initial experience, Pages No. 839-846, Copyright 2014, with permission from Elsevier.

Reduction of CT Beam Hardening Artifacts of Ethylene-Vinyl Alcohol Copolymer by Variation of the Tantalum Content

By Marcus Treitl, MD

INTRODUCTION

As Onyx™ was initially approved for embolization of intracranial pathologies, its high tantalum content (TC) ensured fluoroscopic contrast despite the high x-ray absorption of the braincase. Tantalum, however, causes relevant beam hardening artifacts in CT examinations that might limit diagnostic information of any follow-up imaging. We developed an aortic phantom to simulate treatment and follow-up imaging of endoleaks, and assessed the diagnostic performance of Onyx™ liquid embolic system formulations with different, reduced TCs in order to determine a tantalum dosage that interferes less with diagnostic CT imaging, but still enables fluoroscopic visualization during embolization.

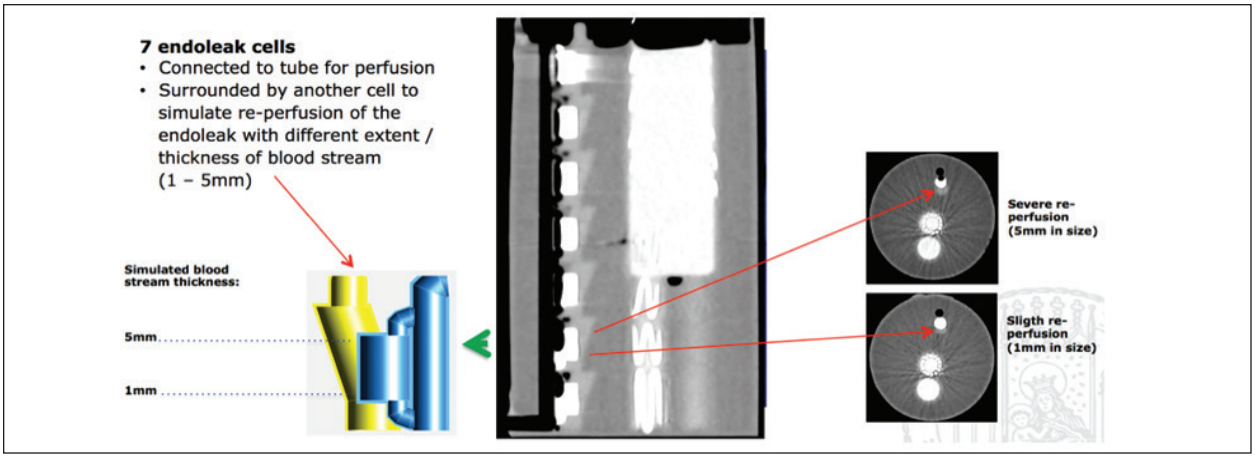


Figure 1. Phantom to simulate treatment and re-treatment of endoleaks after aortic stent grafting. A stent graft is placed in a central tube, surrounded by simulated thrombus, as it can be found in an aneurysm sac. Two tube systems with small cavities simulate the endoleak and the reperfusion of the endoleak with different severity.

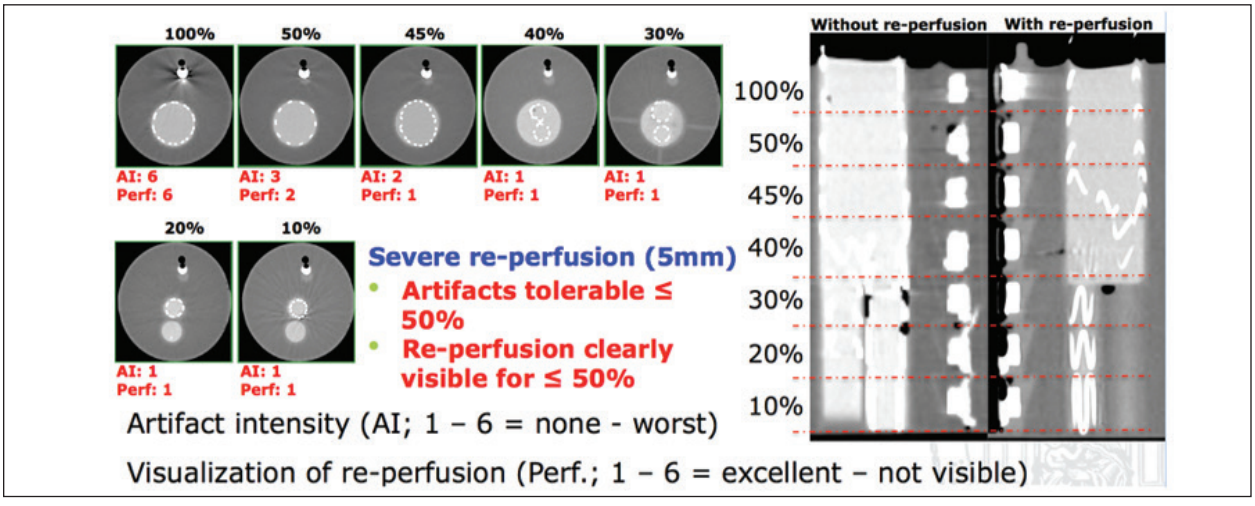


Figure 2. Artifact intensity and visualization of reperfusion after treatment of the simulated endoleaks with Onyx™ liquid embolic system with decreased tantalum content.

METHODS

Onyx™ liquid embolic system specimens of different TC (10%-50% and 100%) were injected in an aortic phantom bearing a stent graft and endoleak cavities with simulated reperfusion of different strength (1-mm and 5-mm wide rim of contrast surrounding a simulated endoleak, standing for slight and severe reperfusion) (Figure 1). Fluoroscopic visibility of the Onyx™ liquid embolic system specimens was analyzed. In addition, six radiologists analyzed endoleak visibility and artifact intensity of Onyx™ liquid embolic system in CT scans.

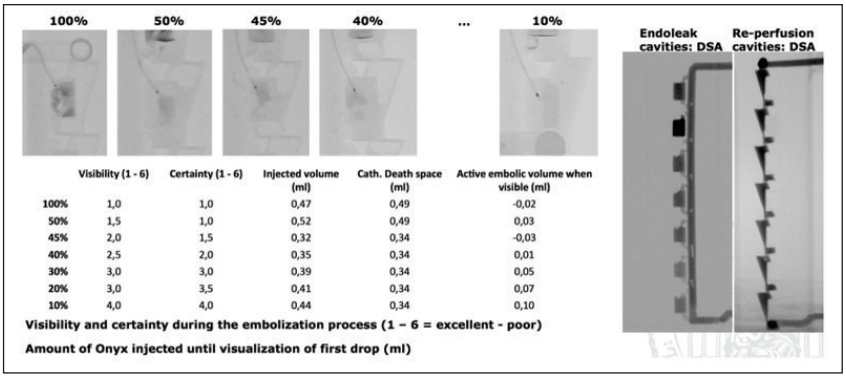


Figure 3. Fluoroscopic visualization of Onyx™ liquid embolic system with decreased tantalum content. The visualization of the first drop decreased, and the active embolic volumes increased consecutively, reaching intolerable volumes with a tantalum content of 30% and less of the original product.

RESULTS

Reduction of TC significantly decreased CT-artifact intensity of Onyx™ liquid embolic system and increased visibility of endoleak reperfusion ($P < .000$) (Figure 2). It also significantly decreased fluoroscopic visibility of Onyx™ liquid embolic system ($R \geq 0.883$; $P \leq .01$) and increased the active embolic volumes prior to visualization ($\Delta \geq 40$ µL) (Figure 3). Onyx™ liquid embolic system specimens with a TC of 45% to 50% exhibited reasonable visibility, a low active embolic volume, and a tolerable CT-artifact intensity.

CONCLUSIONS

Our data suggest a reduction of the TC of Onyx™ liquid embolic system to 45% to 50% of the original to interfere less with diagnostic imaging in follow-up CT examinations, but still allowing for fluoroscopic visualization. This may improve diagnostic accuracy of follow-up CT examinations and provides safe fluoroscopic control of the embolization process. ■

Presented at the 2012 RSNA annual meeting in Chicago, Illinois.

(Continued from page 4)

with a chronic type B dissection, these measures had been taken during previous procedures, and Onyx™ liquid embolic system embolization was therefore decided in advance. In this patient, we initiated the treatment with microcoils in the proximal neck to further improve the seal.

In four cases, a standard angiographic catheter from the groin was left outside the aortic stent graft, crossing the sealing zone. If a type 1 endoleak was found, the angiographic catheter was changed to a selective Berenstein catheter. This was then used as a guide for a microcatheter into the leaking neck. In two cases, selective angiographic catheters and microcatheters were navigated into the proximal neck from a brachial approach after stent graft placement and dilation.

Onyx™ liquid embolic system was injected through a microcatheter (Progreat™, Terumo™, Tokyo, Japan). We used the recommended technique, priming the microcatheter with 0.27 mL DMSO. DMSO is the solvent in Onyx™ liquid embolic system and will prevent Onyx™ liquid embolic system from hardening in the catheter. We then started with just a minimal amount of Onyx™ liquid embolic system injected out of the catheter, letting it begin to harden during a few minutes. A slow injection with several pauses was done, filling the leakage space in the neck. Using this technique, the Onyx™ liquid embolic system usually spreads out in different directions, filling the neck around the stent graft.

Follow-up:

- The type 1 endoleak was successfully sealed by Onyx™ liquid embolic system in all six patients.
- This was demonstrated by a computed tomography (CT) scan before discharge or after 1 month.
- There were no perioperative complications and no distal embolization of Onyx™ liquid embolic system.
- The follow-up time was 3 to 18 months.
- Six patients had no endoleak and decreasing aneurysm diameter on follow-up CT scan.

Alternative Treatment:

- Balloon-expandable stents.

CONCLUSION

This early experience with Onyx™ liquid embolic system as a bailout solution for treating type 1 endoleak after complicated EVAR is encouraging.

Onyx™ liquid embolic system offers a new treatment option in these difficult situations and may prove to be a good complement to conventional methods, such as stent graft extensions and balloon-expandable stents.

More reported cases and longer follow-up are necessary to evaluate this new technique. ■

Henrikson O, Roos H, Falkenberg M. Vascular. Vol. 19; No. 2; pp. 77–81, copyright © 2011 by SAGE Publications. Reprinted by Permission of SAGE.

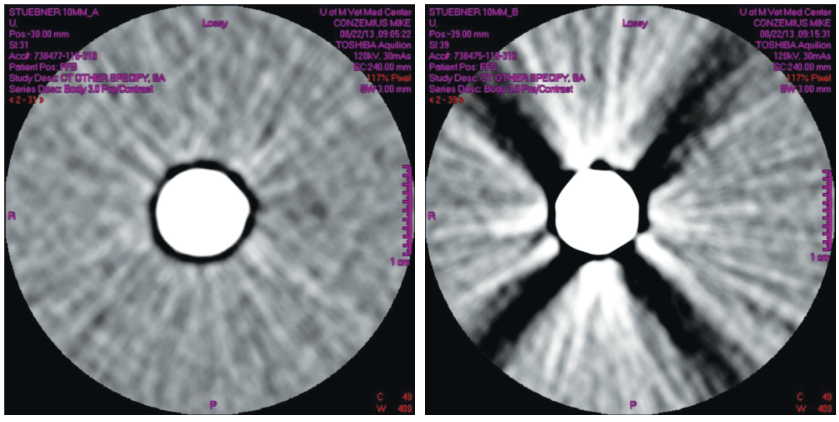
NEW Formulation
Onyx™ 34 liquid embolic system

The advantage of time.
The power of control.

The **Onyx™ liquid embolic system** is an EVOH co-polymer designed to provide complete filling and distal penetration[1].

Less streak artifacts on CT with good visibility during injection[3]

CT VALIDATION[2]
New generation Onyx™ 34L liquid embolic system, 10 mm vessel



NEW Formulation of Onyx™ 34L liquid embolic system

Current Formulation of Onyx™ 34 liquid embolic system

Now with a 6 ml and 1.5 ml vial

The Onyx™ liquid embolic agent allows for:

- A slow controlled injection and delivery method
- The ability to start and stop injections (Note: pauses in Onyx™ injection should not exceed 2 minutes)
- Cohesive deposition and delivery
- Excellent visibility[2]
- Control angiography during embolic injection
- Excellent surgical handling characteristics[2]
- Less tantalum compared to current version of Onyx™ 34 liquid embolic system[3]
- Less streak artifacts on CT with a good visibility during injection[3]

1 'Embolization of a bleeding gastroduodenal artery with Onyx™ Liquid Embolic System', Femin Urtasun, M.D., Department of Radiology, Hospital de Navarra, Pamplona, Spain.'Treatment of type-2 endoleak after EVAR by using direct percutaneous puncture of the aneurysm sac and injection of Onyx™', Prof. Peter M. Pattynama, M.D., PhD, Interventional Radiology Service, Department of Radiology, Erasmus University Medical Center Rotterdam, Netherlands. 'Treatment of pseudo aneurysm by embolising the feeding arteries with Onyx™', Femin Urtasun, M.D., Department of Radiology, Hospital de Navarra, Pamplona, Spain.

2 'Preoperative Embolization of Intracranial Arteriovenous Malformations with Onyx™', Neurosurgery Vol 61; 2: 251 Weber et al. (2007).

3 CT artifact Validation in vitro using a water phantom tank to simulate body tissue and synthetic vessel Document TR_NV 11300 RevA 2013-08-20. All images property of Covidien.

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