



A Novel Conformable Embolic for Selective Transarterial Embolization of Acute Hemorrhages: A Technical Note

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BACKGROUND

This publication summary describes a single center's early experience in using Obsidio Embolic for treating acute intra-abdominal hemorrhage, highlighting safety, technique, and effectiveness.

CASE 1

PRESENTATION: A 60-year-old female underwent bedside paracentesis and developed acute blood loss anemia, with CT demonstrating a left abdominal wall hematoma measuring approximately 10.3 × 6.3 cm with associated active extravasation. DSA demonstrated contrast extravasation of the left deep circumflex iliac artery.

TECHNIQUE: A total of 0.4 mL Obsidio Embolic was injected with a controlled manner via a 4 Fr Kumpe catheter, occluding a long segment of arteries measuring approximately 7.7 cm.

RESULT: Immediate cessation of flow was shown on the initial post-embolization angiogram and no procedural-related major complication occurred.

FOLLOW-UP: Patient was followed for up-to 6-month post embolization without re-bleeding.

CASE 2

PRESENTATION: A 46-year-old male presented with a stab wound to the right upper quadrant (Fig. 1) and CTA of the abdomen revealed contrast extravasation from segment IV, which was confirmed with angiography.

TECHNIQUE: Superselective embolization of segment 4 A branch was performed using 0.2 mL of Obsidio Embolic through a 2.8 Fr microcatheter.

RESULT: Post-embolization angiography showed successful cessation of bleeding with no evidence of residual extravasation and no procedural-related major complication occurred.

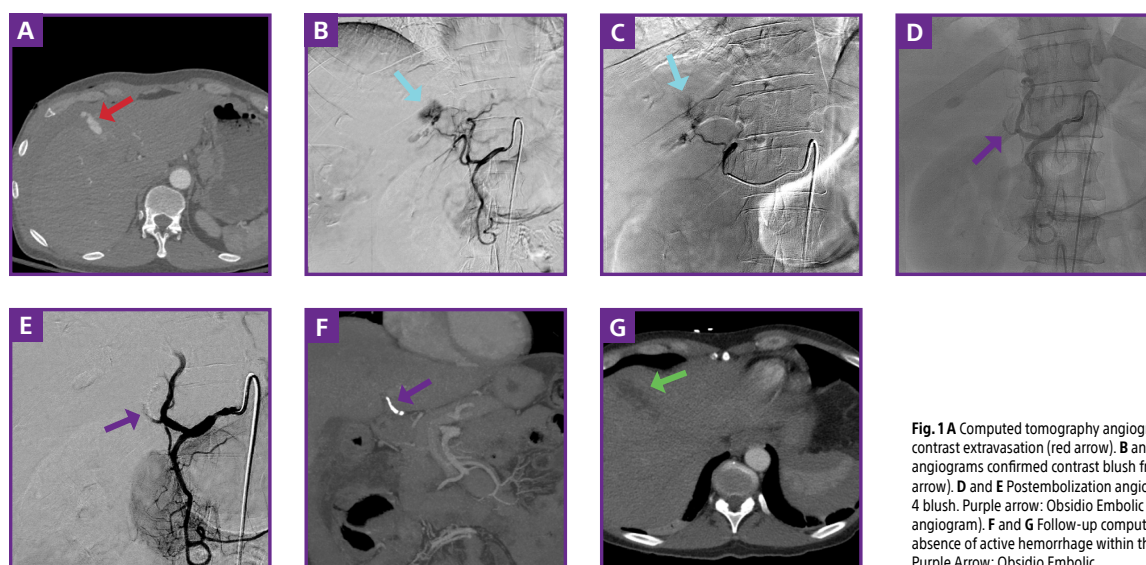


Fig. 1 A Computed tomography angiogram demonstrated segment 4 contrast extravasation (red arrow). B and C Celiac and proper hepatic artery angiograms confirmed contrast blush from the segment 4 hepatic artery (blue arrow). D and E Postembolization angiogram showed resolution of segment 4 blush. Purple arrow: Obsidio Embolic (D unsubtracted image; E subtracted angiogram). F and G Follow-up computed tomography demonstrated absence of active hemorrhage within the embolization bed (green arrow). Purple Arrow: Obsidio Embolic

CASE 3

PRESENTATION: A 48-year-old male presented with traumatic splenic artery pseudoaneurysm on CTA following motor-vehicle collision (Fig. 2), with catheter angiography revealing a 1.0 cm intraparenchymal pseudoaneurysm arising from a segmental branch of the superior aspect of the spleen.

TECHNIQUE: The culprit vessel was successfully embolized with 0.2 mL Obsidio Embolic via a microcatheter co-axial system.

RESULT: No procedural related major complication occurred and postoperative CT demonstrated resolution of pseudoaneurysm and wedge-shaped infarct of the treated angiosome.

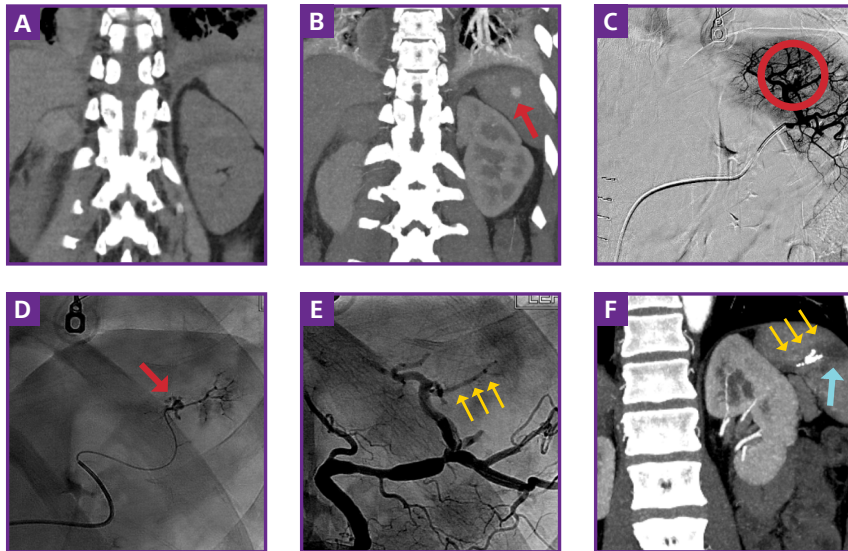


Fig. 2 A and B Contrast computed tomography demonstrated a traumatic splenic artery pseudoaneurysm (A pre-contrast image; B arterial phase maximum intensity projection) C and D Catheter angiography via the splenic artery (C) and segmental artery (D) demonstrate pseudoaneurysm (red circle and red arrow). E Post-embolization angiogram suggested successful occlusion of the culprit artery. Yellow arrow: Obsidio Embolic. F Follow-up computed tomography demonstrated splenic infarct in the embolization territory (blue arrow) of the embolized territory. Yellow arrow: Obsidio Embolic

DISCUSSION

- In all cases, 0.2-0.4 mL of Obsidio Embolic completely occluded the target vessel.
- Obsidio Embolic does not rely on intrinsic thrombosis for vascular occlusion, compared to metallic coils that rely on the patient's coagulation status.
- Obsidio Embolic formed a complete, impenetrable cast of the vessel on histology, suggesting suitability for patients on anticoagulation therapy or those with coagulopathy.
- Obsidio Embolic requires no preparation, a major difference with NBCA or EVOH-based liquid embolics.
- Because of its non-adhesive nature, Obsidio Embolic does not carry a risk of catheter entrapment, offering enhanced procedural flexibility and control.
- Compared to EVOH-based liquid embolics which require mixing and pre-loading with dimethylsulfoxide (DMSO), Obsidio Embolic can be injected directly through standard angiographic catheters with no known risk of polymerization within or degradation of the catheter.

OBSIDIO™ CONFORMABLE EMBOLIC

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE / INDICATIONS FOR USE: Obsidio Conformable Embolic is indicated for use in the embolization of: • Hypervascular tumors, • Blood vessels to occlude blood flow for controlling bleeding/hemorrhaging in the peripheral vasculature. **CONTRAINDICATIONS:** • Patients with a known hypersensitivity to porcine product • Patients intolerant to occlusion procedures • Vascular anatomy or blood flow that precludes catheter placement or embolic agent injection, such as: • Presence or likely onset of vasospasm • Presence of severe atheromatous disease • Presence of collateral vessel pathways potentially endangering non-target vascular territories during embolization • Presence of arteries supplying the lesion not large enough to accept the selected device • Vascular resistance peripheral to the feeding arteries precluding passage of the product • Arteriovenous shunts (i.e., where the blood does not pass through an arterial/capillary/venous transition but directly from an artery to a vein) • Presence of patent extra-to-intracranial anastomoses or shunts • Presence of end arteries leading directly to cranial nerves • Use in the pulmonary, coronary, and intracerebral vasculature • Use in any vasculature where the product could pass directly into the internal carotid artery, vertebral artery, intracranial vasculature **WARNINGS:** • Serious adverse events have been observed with use in the gastrointestinal tract. When Obsidio Embolic is aliquoted or pushed with saline, it may alter the performance of the device. This can lead to unintended ischemia or necrosis of tissue especially in anatomic structures with little vascular collateralization. • Serious adverse events have been observed with use in the gastrointestinal tract. Immediately post deployment of Obsidio Embolic, avoid forceful fluid injections in or near the Obsidio Embolic material which could alter Obsidio Embolic performance and may increase the risk of non-target embolization. • The physician should be sure to carefully select the amount of Obsidio Embolic used according to the size of the catheter appropriate for the target vessels at the desired level of occlusion in the vasculature. • Extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck. The physician should carefully weigh the potential benefits of using embolization against the risks and potential complications of this procedure, which may include blindness, hearing loss, loss of smell, paralysis and death. • Presence of air bubbles or voids within the Obsidio Embolic material may indicate a damaged product. If present, do not use syringe as patient injury may result. Replace with new Obsidio Embolic syringe. • As Obsidio Embolic syringe is being prepared for a wet-to-wet connection, the cohesivity of the product should be observed. If water or a water/tantalum suspension elutes from the syringe tip, the product should not be used, as this may indicate a damaged product that could result in patient injury. Replace with new Obsidio Embolic syringe **PRECAUTIONS:** Refer to Instructions for Use for all applicable information on Precautions. **POTENTIAL COMPLICATIONS:** Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following: • Paralysis resulting from non-targeted embolization • Ischemic injury from adjacent tissue edema • Undesirable reflux or passage of Obsidio Embolic into non-target arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds of systemic circulation or, pulmonary, or coronary circulations, resulting in non-target embolization • Pulmonary embolism and/or stroke due to arterial-venous shunting, for example from a patent foramen ovale • Ischemia at an undesirable location including ischemic stroke, ischemic infarction (including myocardial infarction), and tissue necrosis • Capillary bed occlusion and tissue damage, which may lead to abscess formation and sepsis • Vessel or lesion rupture and hemorrhage • Recanalization • Foreign body reactions necessitating medical intervention • Infection necessitating medical intervention • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgment, and nerve and/or circulatory injuries, which may result in leg injury) • Allergic reaction to medications (e.g., analgesics), contrast media or embolic material • Pain and/or rash, possibly delayed from the time of embolization • Death • Neurological deficits, including cranial nerve palsies/injury (e.g., blindness, hearing loss, loss of smell and/or paralysis) • Additional information is found in the Warnings section **97222344 B**

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Read the full study here:

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