



## **OBSIDIO™** Conformable Embolic | PUBLICATION SUMMARY

### **Early Experience Using Tantalum-Loaded Nanocomposite Hydrogel Conformable Embolic for Upper Gastrointestinal Bleeding: Open-Sandwich Technique**

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#### **STUDY BACKGROUND & METHODOLOGY**

- Upper gastrointestinal bleeds (UGIBs) resulting from peptic ulcers, gastric malignancies, and vascular abnormalities are associated with high mortality
- In UGIBs treated by embolization, the gastroduodenal artery (GDA) is the most common target vessel
- This retrospective study reports results from 10 consecutive gastroduodenal artery embolization (GDA) procedures performed using Obsidio Embolic
- Data was included for consecutive patients at the institution from January 2023 to June 2024
- Patients were followed at 4 weeks and 6 months post-embolization

#### **PROCEDURAL & TECHNIQUE DETAILS**

- The majority of cases in this study were performed using an open-sandwich technique, a technique adapted from the established sandwich technique
- In the described open sandwich technique, retrograde sources of blood flow, namely the right gastroepiploic artery (RGEA) are embolized distal to the extravasation site using a single coil prior to Obsidio Embolic delivery
- Following distal coiling, the Obsidio Embolic was injected continuously while withdrawing the microcatheter to near the origin, allowing it to embolize past the proximal branches of the GDA
- Finally, the microcatheter is removed and confirmatory angiography is performed through the base catheter
- 24-48 hours after the procedure, CTA was performed to assess occlusion and non-target embolization

#### **RESULTS**

- Patient cohort included 8 males and 2 females with a mean age of 67.3 years
- Duodenal/gastric ulcers were the most common cause of bleeding (6/10)
- Of the embolization procedures, 6 were performed empirically and 4 were for active extravasation
- 6/10 patients were hemodynamically unstable at time of embolization
- Mean hemoglobin levels increased 1.47 g/dL ( $p = 0.0001$ ) 24 h post-embolization
- **100% Technical success** (10/10), defined as complete stasis on angiography, was achieved
- **80% Clinical success** (8/10), defined as absence of rebleeding for 30 days, with the 2 rebleeds resulting from collateral or other feeding vessels
  - One GDA was not occluded past the SPDA which later bled
  - One patient developed a rebleed due to collateral flow from the pancreaticoduodenal arcade (inadequate distal placement of coil)
- **No significant adverse events** were observed

## DISCUSSION

- This study demonstrates high technical and clinical success using the “open sandwich” technique for GDA embolization with Obsidio Embolic
- This technique may eliminate the need for a terminal or proximal coil, streamlining the procedure and potentially lowering the risk of ischemic complications and additional bleeding after embolization.
- Other technical considerations include injection speed and catheter size, with slower injections and smaller catheters resulting in more distal travel of Obsidio Embolic
- GDA embolization using a single coil and Obsidio Embolic may provide time and cost-efficiency advantages compared to coil embolization alone

## CONCLUSION

- In this initial experience, GDA embolization with Obsidio Embolic had high rates of technical success and long-lasting treatment effectiveness
- Obsidio Embolic can be effectively combined with coils to achieve desired embolization outcomes

Read the full study here: <https://doi.org/10.3390/jcm14072345>

### 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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