

Embolization of a Large Uterine Fibroid

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CASE PRESENTATION

A 48-year-old woman presented to our institution with a history of uterine fibroid treated with high-intensity focused ultrasound.

MRI showed three fibroids, including a larger one with intramural measurements of 46 X 50 X 43 mm (Figure 1). Because of some anatomic complications from the last high-intensity focused ultrasound treatment, the patient was a candidate for uterine fibroid embolization.

PROCEDURE DESCRIPTION

From a right femoral approach, we catheterized the left uterine artery. Angiographic evaluation showed no abnormal patterns (Figure 2). Due to a clear vaginal artery, we chose not to intervene.

The right side evaluation, however, showed an abnormal pattern related to the larger fibroid (Figure 3). We chose a 0.021-inch, 2.4-F Direxion™ Torqueable Microcatheter with the capacity to inject large particles with a good overall flow rate, great control, and navigability. We used one 2-mL syringe of 500-µm Embozene™ Microspheres to embolize any feeding vessel of the fibroid.

FOLLOW-UP AND DISCUSSION

The treatment was successfully performed and the embolization was completed with good fibroid exclusion. Final angiography confirmed exclusion of the fibroid and preservation of tissue vascularization (Figure 4). ■

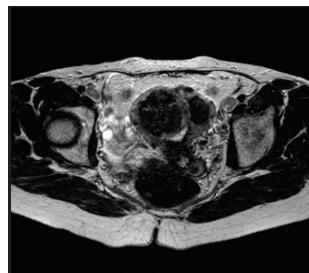


Figure 1.

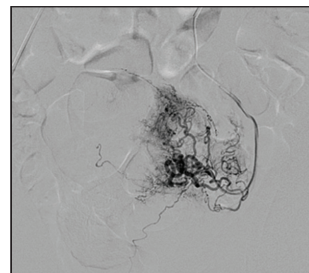


Figure 2.

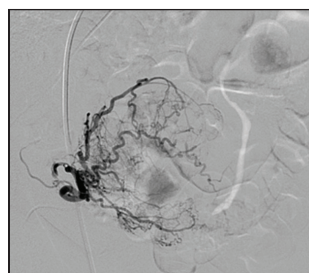


Figure 3.

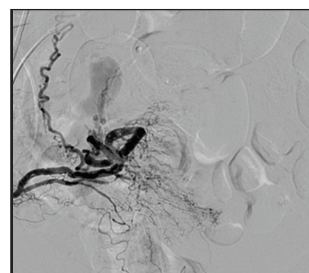


Figure 4.

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Direxion Direxion HI-Flo

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE

The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

CONTRAINDICATIONS

None known.

WARNINGS

- Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation.
- This Direxion Microcatheter family is not intended for use in the coronary vasculature or neurovasculature.
- The Direxion HI-FLO Microcatheter is not designed for the delivery of embolic coils.
- Use of excessive force to manipulate the microcatheter against resistance can cause a fracture in the nitinol shaft. Take care not to over-torque the microcatheter, and to relieve any tension before withdrawal by rotating the microcatheter in the opposite direction.

PRECAUTIONS

- This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.
- Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter.
- Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.

ADVERSE EVENTS

The Adverse Events include, but are not limited to: allergic reaction, death, embolism, hemorrhage/hematoma, infection, pseudoaneurysm, stroke, vascular thrombosis, vessel occlusion, vessel spasm, vessel trauma (dissection, perforation, rupture).

Embozene Microspheres

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INDICATIONS

Embozene Microspheres are indicated for the embolization of hyper-vascular tumors and arteriovenous malformations (AVMs).

CONTRAINDICATIONS

Embolization procedures shall not be performed if:

- Patient is unable to tolerate vascular occlusion procedures.
- Vascular anatomy precludes correct catheter placement or embolic injection.
- Presence or likely onset of vasospasm.
- Presence of a blood coagulation disorder that would prohibit arterial punctures.
- Presence of severe atheromatous disease that would preclude correct catheter placement.
- Presence of patent extra-to-intra-cranial anastomoses or shunts from the arterial to the venous circulation.
- Presence of collateral vessel pathways which could potentially endanger non-targeted tissue during an embolization procedure.
- Presence of any vasculature where Embozene Microspheres could pass directly into the central nervous system, central circulatory system or other nontarget territories.
- Patient has high-flow arteriovenous shunt with diameter greater than the selected Embozene Microspheres.
- Patient is pregnant.
- Patient has known allergies to barium sulfate, 3-aminopropyltriethoxysilane, polyphosphazene or IV radiopaque contrast agent.

WARNINGS

Vascular embolization is a high risk procedure. The procedure should be performed by specialized physicians trained in vascular embolization procedures. Complications can occur at any time during or after the procedure, and may include, but not limited to:

- Undesirable reflux or passage of Embozene Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds.
- Embolization of the wrong artery or migration of the microspheres to other parts of the body, which may necessitate further treatment.
- Hematoma, or bruising, at the incision site for arterial access.
- Arterial aneurysm at the incision site for arterial access.
- Deep vein thrombosis, or clotting of a deep vein in patient's leg(s).
- Thrombosis of the artery at the incision site for arterial access.
- Pulmonary embolization.
- Ischemia at an undesirable location.
- Capillary bed saturation and tissue damage.
- Ischemic stroke or ischemic infarction.
- Vessel or lesion rupture and hemorrhage.
- Neurological deficits including cranial nerve palsies.
- Vasospasm.
- Recanalization.
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Clot formation at the tip of the catheter and subsequent dislodgement.
- Allergic reaction.
- Risks of radiation from angiography and fluoroscopy used to visualize the blood vessels during embolization, which may include a radiation burn and risks to future fertility.
- Death.

Do not use Embozene Microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol or dimethyl sulfoxide (DMSO) at the same embolization site.

Do not use ionic contrast agent with this product. Ionic contrast agents could alter the microsphere characteristics resulting in microsphere deformation and procedure failure.

PRECAUTIONS

To maintain safety, the following precautions shall be considered:

- Safety and effectiveness of Embosphere Microspheres in the treatment of uterine fibroids has not been established
- Safety and effectiveness of Embosphere Microspheres for hepatic and renal embolization uses has not been established.
- The physician should carefully select the size and quantity Embosphere Microspheres according to the lesion to be treated based on the physician's education and training and currently available scientific evidence.
- Physicians must decide the most appropriate time to stop the infusion of Embosphere Microspheres. Typically the artery will accept fewer Embosphere Microspheres as the treatment progresses. Proximal slowing or termination of flow may indicate that the vessel or the target area is occluded by Embosphere Microspheres. Careful fluoroscopic monitoring is required.
- Microparticle embolization must be performed slowly. The injection speed and manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to embolization of other non-target healthy tissue or organs
- The color of the Embosphere Microspheres may be visible through the skin if injected into superficial arteries.
- If arteriovenous anastomoses, branch vessels which lead away from the targeted embolization area, or emergent vessels not evident prior to embolization are present, it can lead to non-targeted embolization and cause severe complications for the patient.
- Microspheres smaller than 100 μm can migrate to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller microspheres have a greater likelihood of causing unwanted ischemic injury. This should be considered prior to starting the embolization procedure. Possible consequences include, but are not limited to, paralysis, necrosis, swelling, abscess formation and more severe post-embolization syndrome.
- Ischemia of tissue adjacent to the targeted area may result from post-embolization swelling. Therefore, special care should be taken to avoid such ischemia of non-tolerant, non-targeted tissue such as the nervous system.
- Consider upsizing Embosphere Microspheres if angiographic appearance of embolization does not quickly appear during injection of the microspheres.
- If there are any symptoms of unwanted embolization during injection, consider stopping the procedure to evaluate the possibility of shunting. Such symptoms may include changes in patient vital signs, such as hypoxia or central nervous system changes.