Sniper®
Balloon Occlusion Microcatheter

Principles Quick Guide

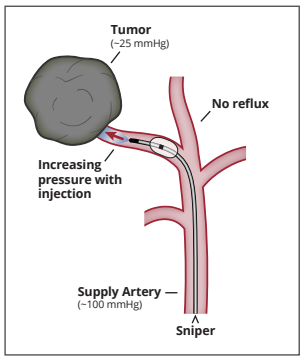
Pressure-Directed Embolization

Balloon occlusion is based on a well-established physical property of fluid dynamics, whereby liquids always flow from high pressure to low pressure environments. Balloon occlusion of a supply artery produces pressure mediated hemodynamic changes that increase therapeutic agent delivery into targeted tumors, prostates or fibroids with antegrade and retrograde non-target embolization protection.[1,2] This technique is called **Pressure-Directed Embolization**. There are two methods to achieve pressure-directed embolization: **Selective** and **Nonselective Delivery**.

Selective Delivery

Placement
- Sniper's tip is advanced to a distal location where the embolization target isolated.

Mechanism
- When the balloon is inflated and the supply artery is occluded, an isolated embolization target area is created.
- As embolization progresses, pressure increases in the target area beyond systemic circulation. This causes a greater degree of microvascular embolic penetration into the tumor, prostate or anatomical target.
- Embolic agents are injected into this target area past the point of stasis.
- The Sniper's balloon prevents retrograde flow (reflux) from traveling to non-target locations.[1,2]

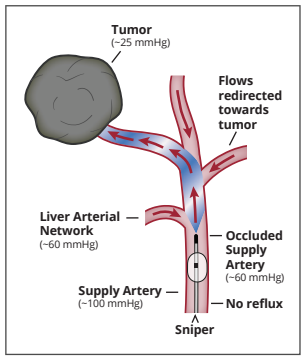


Infusion and Endpoint
- Embolic agents are injected until the endpoint is achieved. The embolization endpoint is observation of embolic reflux around the Sniper balloon or the Sniper balloon "pushing back" in the vessel or observation of contrast in the portal vein.

Nonselective Delivery

Placement
- Sniper's tip is advanced to a proximal location where branch arteries are evident between the microcatheter's tip and embolization target.

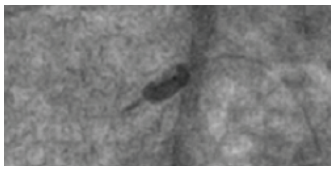
Mechanism
- When the balloon is inflated and the supply artery is occluded, an area is created downstream from the tip of the microcatheter at a lower pressure than the systemic circulation.
- This causes the blood flow to slow down and redistribute flow from adjacent arterial networks into this lower pressure vascular compartment and ultimately into the lowest pressure tumor, prostate, or fibroid.[1,2]

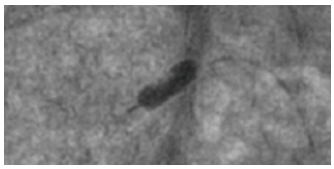


Infusion and Endpoint
- Embolic agents are injected slowly to maintain low pressure. The embolization endpoint is achieved with observation of contrast stasis in the distal arteries.

Principles

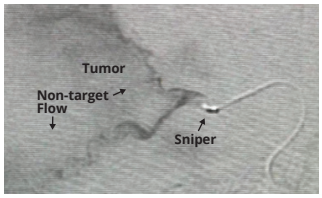
1 Ensure Complete Occlusion
- To achieve complete vessel occlusion, the balloon must be inflated about 0.5 mm larger than the vessel diameter. This can be visualized by the balloon sides flattening and the balloon length elongating.
- The balloon may be over-inflated to ensure complete occlusion. The balloon material is extremely compliant and will elongate in the vessel instead of dilating the vessel.
- It is not recommended to inflate the balloon where it elongates past the tip of the catheter.


Balloon Size in 3.5 mm vessel at Occlusion[3]

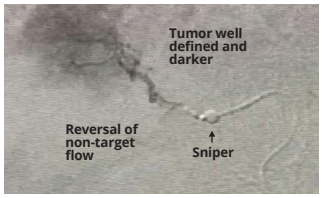

Balloon Size in 3.5 mm vessel when Over-inflated[3]

2 Inject Contrast and Embolic Agent Slowly
- Slow injection is required to maintain a low pressure environment. Rapid injection will increase pressure and overwhelm the protective pressure gradient.
- Suggested injection rates are the following:
  - **Contrast injection rate**
    - Between 0.5 to 1.0 mL/second
  - **Embolic injection rate**
    - About 1.0 mL/minute with intermittent pause between injections
  - **Y-90 TheraSphere Infusion**
    - 0.3 mL/second consistently without pause.[4] Note: After Therasphere infusion, a minimum of 3 syringe flushes (60 mL total) are recommended.[5]
  - **Y-90 SIR-Sphere Infusion**
    - 1.0 mL/minute with intermittent flushing between small aliquots of SIR-Spheres. Note: Avoid completely filling the 'A' line with SIR-Spheres.[6]

3 Confirm Preferential Flow
- Take an angiogram with the balloon deflated.
- Take another angiogram with the balloon inflated.
- Confirm flow has redistributed and is preferentially flowing towards your target location and away from non-target areas.



Sniper Balloon Deflated[7]



Sniper Balloon Inflated[7]

EMBOLX

4 Check Vessel Size

Liver

What

- When the target's supply artery's diameter is smaller than the diameter(s) of the surrounding branch arteries, flow may not be preferentially redirected into the tumor target.[9]
- For flow redistribution to occur, the target's feeder artery diameter must be equal to or larger than branch artery(s) between the Sniper tip and target location.

Why

- Liquids always flow from high pressure to low pressure.
- As the artery diameter increases, pressure decreases. As the artery diameter decreases, pressure increases.
- Even though the tumor target is the lowest pressure in the system, pressure in a small diameter feeder artery will be greater than the pressure in larger branch arteries.

Identify

- Under angiography, identify the feeder artery and branch artery(s) to confirm that the feeder artery is larger than the surrounding branch artery(s). With balloon inflated, assess contrast flow to non-target locations.
- **Liver tumor case example:** Feeder arteries into tumors T1 and T2 are small in diameter (3 mm) relative to the branch artery (5 mm) into the liver arterial network N2. At location A, balloon is inflated. Contrast infusion results in contrast flow preferentially to network N2.

Prostate

What

- Prostatic arterty embolization with anastomosis to pudendal artery.
- In majority of cases with anastomosis to other organs, balloon occlusion will redirect flow and anastomosis will disappear. In rare cases, the anastomosis will not disappear.

Why

- Even though the prostate target is the lowest pressure in the system, pressure in the small diameter supply arteries will be greater than the pressure in larger diameter branch arteries or anastomosis.

Identify

- Under angiography, confirm that supply artery(s) to the prostate are larger than the surrounding branch artery(s) or anastomosis. With balloon inflated, assess contrast flow to non-target locations.
- **Left prostate case example:** At location A, balloon is inflated. While contrast infusion results in some opacity of prostate gland, contrast flows preferentially through large diameter artery anastomosis to pudendal artery. Flow redistribution to prostate is not achieved when balloon is inflated.

5 Treating Tumors with Multiple Supply Vessels

What

- When a tumor has multiple supply arteries either in the same or adjacent liver segments, flow may not be preferentially redirected into the tumor target.[1]
- A tumor with more than one supply artery that originates from adjacent liver segments, is called a **watershed tumor**.

Why

- A tumor with multiple supply arteries may have high systemic blood flowing through the tumor and into the low pressure area created by balloon occlusion.

Identify

- If the tumor is visible during angiography with the balloon deflated and the tumor (or portions thereof) disappears during angiography when the balloon is inflated, the tumor may have more than one supply artery.
- **Watershed tumor case example:** Location A, balloon inflated. Contrast infusion results in contrast flow into branch artery and liver arterial network. Tumor is not visualized.

Possible Solutions To Achieve Favorable Flow Redistribution

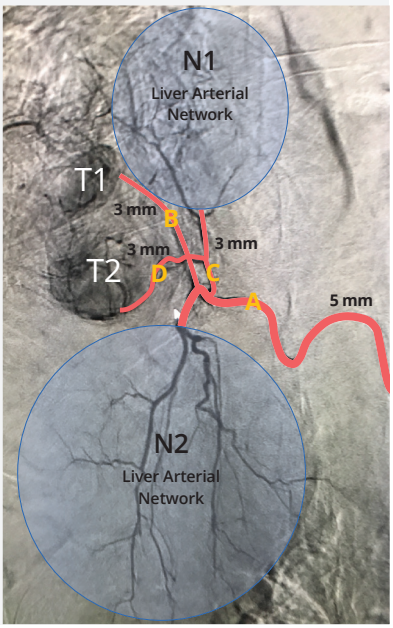
Liver Tumor Case Example[7]

1. Location B, balloon inflated. Contrast infusion results in preferential contrast flow to tumor T1. Use selective delivery to embolize.

2. Location C, balloon inflated. Contrast infusion results in preferential contrast flow to tumor T2. Network N1 flow redistributed to tumor T2. Use nonselective delivery to embolize. It is also possible to use selective delivery if network N1 can be sacrificed.

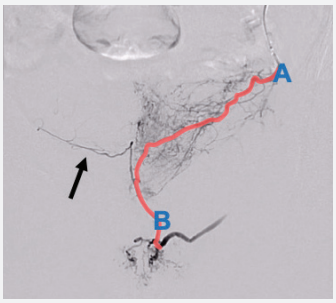
3. Location D, balloon inflated. Contrast infusion results in preferential contrast flow to tumor T2. Use selective delivery to embolize.

4. Occlude network N2 supply with coil or temporarily with additional Sniper[8]. Once network N2 supply is occluded, proximal contrast infusion at location A results in contrast flow preferentially to both tumors T1 and T2. Use nonselective delivery to embolize. It is also possible to use selective delivery if network N1 can be sacraficed.

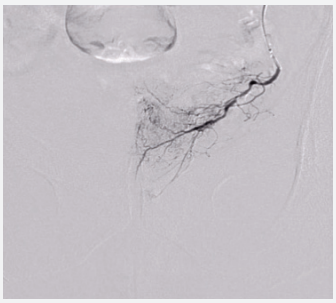


Possible Solutions To Achieve Favorable Flow Redistribution

Left Prostate Case Example[7]



Large diameter anastomosis

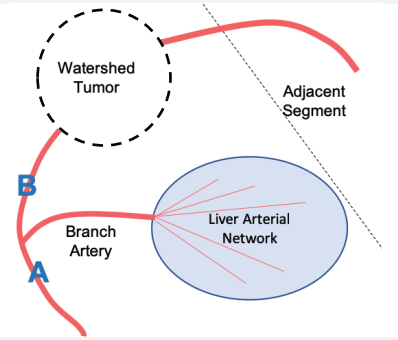


Post anastomosis coiling

- Occlude branch artery(s) or anastomosis (location B in case example) with coil. Embolize with balloon inflated from a proximal position (location A in case example) using nonselective or selective delivery. Flow redistribution will occur (note non-target flow at black arrow is now eliminated).

Possible Solutions To Achieve Favorable Flow Redistribution

Watershed Tumor Case Example[7]



- Advance to a distal position (location B in case example) and use selective delivery to embolize.
- Occlude branch artery with coil or temporarily with an additional Sniper[8]. Embolize from a proximal position (location A in case example) using selective delivery.
- As a final solution, embolize with the balloon down.

1. Rose S, Narsinh K, Isaacson A, Fischman A, Golzarian J. The Beauty and Bane of Pressure-Directed Embolotherapy: Hemodynamic Principles and Preliminary Clinical Evidence. AJR (2019) 212.
2. Rose S, Halstead G, Narsinh K. Pressure-Directed Embolization of Hepatic Arteries in a Porcine Model Using a Temporary Occlusion Balloon Microcatheter: Proof of Concept. Cardiovasc Intervent Radiol (2017) 40: 1769.
3. Fluoroscopy images from Embolx Animal Study, Nov 16, 2018.

4. BTG International Ltd., case proctor, 11/7/2018.
5. TheraSphere™ Y-90 Glass Microspheres IFU, 990252.SPE.
6. SIR-Spheres® Microspheres IFU, PI-EC-12.
7. Embolx Sniper cases, data on file.
8. Kouri B. Interventional Oncology: Optimizing Transarterial Therapies for the Treatment of Hepatic Malignancy. Techniques in Vascular & Interventional Radiology (2018) 21: 205-222.
9. Irie T, Kuramochi M, Takahashi N. Dense Accumulation of Lipiodol Emulsion in Hepatocellular Carcinoma Nodules during Selective Balloon-occluded Transarterial Chemoembolization: Measurement of Balloon-occluded Arterial Stump Pressure. Cardiovasc Intervent Radiol (2013) 36: 706-713.

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