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Peripheral uses of a Double Lumen Balloon Microcatheter: Onyx Embolization, Anchoring and other Techniques

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Abstract- *Purpose:* To evaluate the technical feasibility and safety of dual lumen balloon microcatheter Onyx embolization in peripheral interventions.

Material and methods: Between January 2013 and September 2014, seven patients underwent Onyx embolization through a double lumen balloon microcatheter. Onyx was injected as solely agent in three patients with chronic hemoptysis, two patients with life threatening organ bleeding and one with a rejected kidney graft. In one patient with a liver arterioportal fistula, a combination of coils and onyx was used through the same system. In addition to this technical implementation, we also describe three cases where an anchoring tecnhique were used in tortuous arterial anatomies in order to place micro and guide catheters in a stable position.

Results: All the Onyx embolizations were completed and well tolerated. During the Onyx embolization, no reflux was noted and inmediate forward flow was identified. Technical success was 100%. The clinical outcome of the patients was satisfactory with no (peri/postprocedural) complications.

Conclusion: Double-lumen balloon microcatheter Onyx embolization is feasible and safe in peripheral interventions, lowering the potential complications related to reflux or Onyx migration.

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I. Introduction

Ethylene vinyl alcohol copolymer, otherwise known as Onyx (ev3,Irvine, California) is a popular liquid widely used in neurointerventional procedures (1,2) and since 2012 distributed specifically for peripheral use (3,4).

In the present report we present our initial experience with transarterial Onyx injections through a coaxial dual-lumen balloon microcatheter (Ascent, Codman Neurovascular, Raynham, Massachusetts, USA). This compliant, Onyx-compatible balloon 2,3 Fr microcatheter has 2 lumens, one for balloon inflation and the other acting as a regular microcatheter for microwire insertion, infusion of liquid embolic agents, contrast medium or coils deployment. This microcatheter is compatible with 0.014" or smaller guidewires and there is a 0.017" inner diameter. The balloon increases the proximal resistance in the feeder, encouraging Onyx to penetrate more distally into the lesion (5).

Also, the anchoring technique basically consists on the inflation of a compliant ballon in a distal vessel in order to advance coaxially a larger catheter [6]. The Ascent microcatheter balloon came in handy in a critical scenario and was perfectly suitable for its perfomance.

Our objective was to assess the safety and feasibility of double lumen balloon microcatheters in peripheral embolizations.

II. Material and Methods

We retrospectively analyzed our database of all vascular peripheral interventional radiology procedures for cases in which Onyx was administered through the Ascent coaxial dual-lumen balloon microcatheter between January 2013 and September 2014. Our institutional review board approved this analysis and all the patients gave informed consent.

A group of seven separate embolization sessions were performed on seven patients by using this technique (Table). Three of these patients had hemoptysis secondary to lung infections, one had a bleeding renal angiomyolipoma, one patient suffered hypovolemic shock due to a liver mass biopsy, one patient was scheduled to undergo a HCC chemoembolization and a severe hepatoportal shunting was identified and finally, the last patient needed embolization of a kidney graft due to rejection.

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Table : Details of patients's pathology and procedures.

Pt. No.	Age(y)/Sex	Pathology	Indication	Amount of Onyx (ml)	Onyx injection duration	Technical procedure
1	48/F	Renal Angiomyolipoma	Spontaneous rupture	3	3 min	Onyx injection
2	79/M	Renal transplant	Rejection	6	5 min	Onyx injection
3	57/M	Tuberculosis	Hemoptysis	2	2 min	Onyx injection
4	60/M	Necrotizing pneumonia	Hemoptysis	2	2 min	Onyx injection Anchoring
5	80/M	Post-Biopsy hepatic bleeding	Hipovolemic shock	2	2 min	Onyx injection
6	61/M	Actynomycosis	Hemoptysis	2	1 min	Onyx injection Anchoring
7	62/M	Arterioportal fistula Hepatocellular carcinoma	Chemoembolization	0,6	6 sec	Onyx and coils embolization

Our criteria to choose this technique instead of conventional approaches were: difficult distal navigation due to proximal elongation, proximity to main non-target arteries and high flow fistula.

a) Procedure Technique

The procedure was carried out in the vascular angiography room under deep sedation or general anesthesia. In all cases, vascular access was established in the common femoral artery with a 6-Fr sheath. A 6Fr-guiding catheter and/or a 5 Fr diagnostic catheter (which is the minimum recommmended catheter size needed to accommodate the balloon microcatheter) was then positioned within afferent artery from which the pathology arose. Due to the diameter and tortusity of the afferent artery, we thought that the conventional Onyx (ethylene vinyl alcohol copolymer; ev3-covidien) embolization technique with a single microcatheter involved the risk of reflux into non target arteries as the creation of a 'plug' would be difficult and could cause retention of it. Thereafter, a compliant Ascent balloon 4x7 mm (Codman Neurovascular, Raynham, Massachusetts, USA), which is a dual lumen balloon, dimethly sulfoxide compatible, with a deadspace of 0.4 ml, was prepared with a mixture of 30% saline solution and 70% Visipaque 320 (GEHealthcare, Princeton, NewJersey).

The balloon microcatheter was then introduced into the guide catheter, and navigated over a 0.014-inch microwire (Traxcess, Terumo) into the arterial feeder vessel until its tip was as close as possible to the site of embolization. Pre and postinflation superselective runs were then performed through the balloon microcatheter, and changes in flow rate with balloon inflation were evaluated. Onyx18 was chosen as the embolic agent in six of the seven cases because the objetive was an embolization as distal as possible. Onyx34 was employed in a high flow hepatic arterioportal fistula considering that closure of the fistula point was our aim. The balloon was then deflated and the dead space of the balloon catheter (0.4 mL) was filled with dimethyl sulfoxide (DMSO). Injection of Onyx18 or 34 was then initiated in roder to fill the dead space during 1 minute. Then, the balloon was reinflated and Onyx injection was continued. The balloon was not deflated during the procedure, as reflux of Onyx can occur at any time following initial antegrade flow. The speed rate for injection of Onyx was much faster than with typical embolizations performed without balloon microcatheter considering that a safe plug is already performed. After Onyx injection, the balloon was deflated and withdrawn slowly under fluoroscopy.

Anchoring technique was performed in three of the procedures in order to ahieve a more stable position of the guiding catheter. First, the balloon was navigated beyond the tortuous anatomy over a 0.014-inch microwire with a distal J configuration. This microwire–microcatheter navigation through the tortuous segment creates significantly less stress on the vessel wall than a 0.035-inch wire. These smaller wires are far less likely to create any kind of traumatic injury or vasospasm, even in the setting of severe tortuosity or dysplasia. Next, when the balloon is inflated, it creates friction against the vessel wall distally, providing a distal anchor for the entire guiding catheter system. Advancing the guiding catheter system while applying gentle counter tension to the balloon catheter functions to add a distal 'pulling' force to the proximal 'pushing' force. The counter tension also functions to center the guiding catheter system within the parent artery, pulling it away from the outer curvature of the vessel and eliminating or diminishing the forces applied by the guiding catheter

system to the vessel wall. During this maneuver, no inner transitional catheter is used.

In one patient, case 7, additional coils embolization was performed so that a high flow fistula could be sealed without risk. The Ascent ballon was kept inflated and two 0,010" coils (Axium, Covidien) plus 0,06 ml of Onyx34 were introduced sequentially through the main lumen.

III. Representative Cases

a) Case 1

A 48-year-old female patient had a sudden rupture of a 6 cm-angiomyolipoma within her right kidney. A large retroperitoneal hematoma was identified in the contrast CT. In the emergent angiography we identified the vascularized tumor as well as the bleeding point. Due to reflux and non-target embolization risk a double lumen microcatheter was used for the Onyx embolization from the only arterial feeder vessel (Fig.1). After embolization, there was a complete devascularization of the vascular bed without non-target embolization.

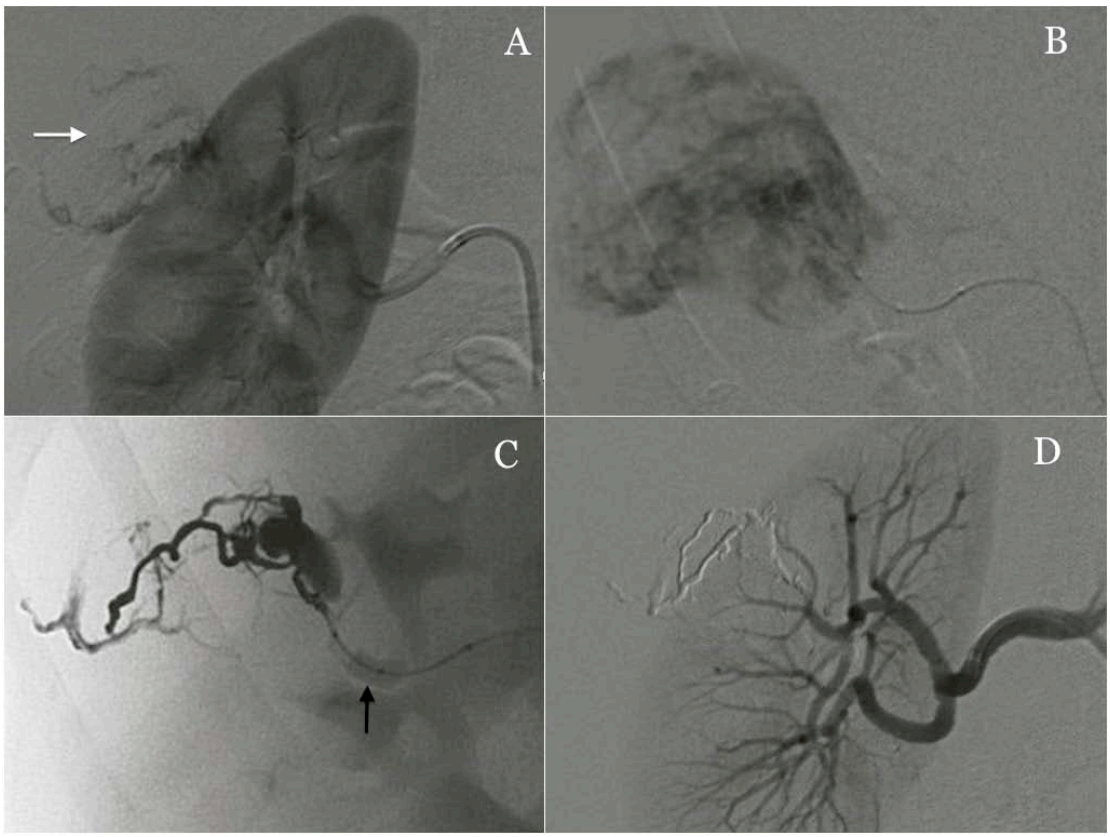

Figure 1 : A-D. Patient 1. A. Selective right renal artery angiogram demonstrates a vascularized round shaped renal tumor corresponding to a bleeding angiomyolipoma (arrow). B. Distal superselective injection through the Ascent microcatheter shows tumor vascularization. C Inflation of the ballon (black arrow) and Onyx progresion without reflux. D Final run showing normal renal vasculature and no tumor blush.

b) Case 2

A 79-year-old male patient had a rejection of a kidney graft transplanted 6 years before. Embolization was requested from nephrologists. Complete devascularization of the graft vascular bed was demanded and Onyx injection through a double lumen microcatheter was thought to associate good result. No reflux was noted and distal stuffing of the vessels was achieved (Fig.2). Additionally we embolized with a mixture of coils plus Onyx a superficial circumflex artery also involved in the graft arterial vascularization.

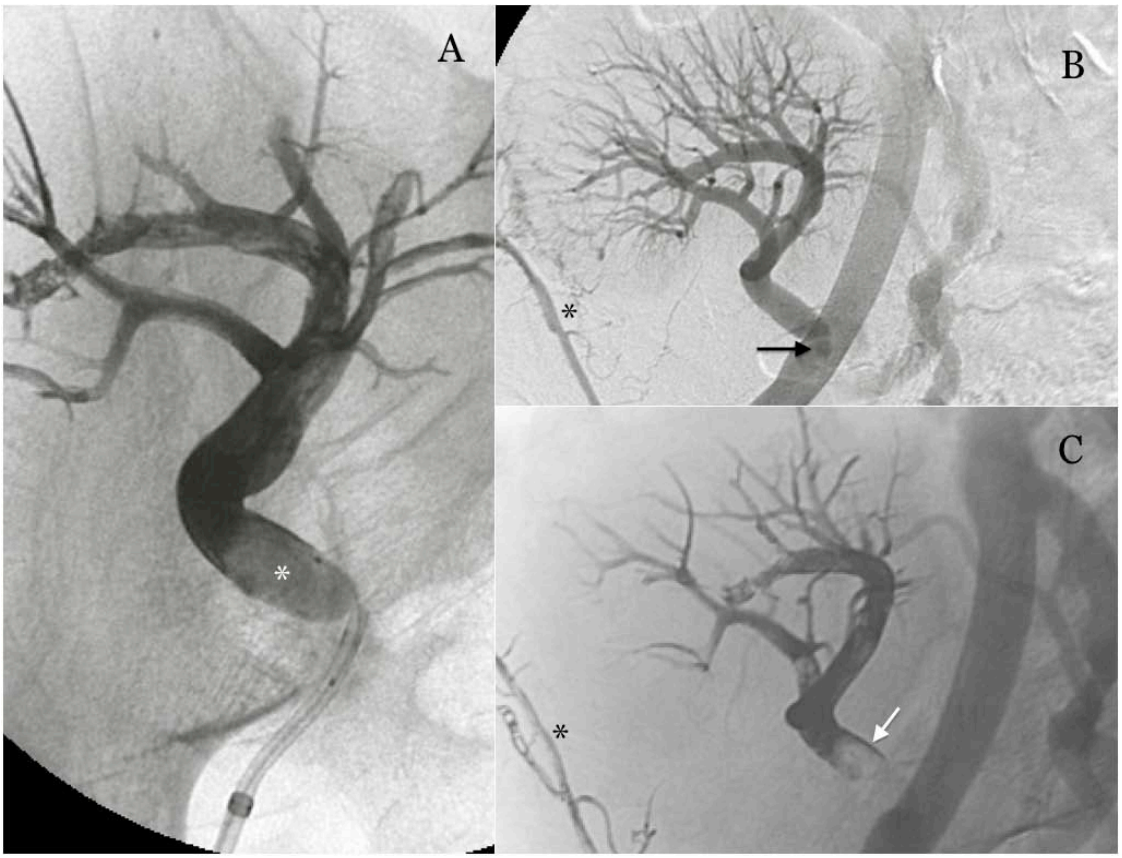

Figure 2 : Patient 2. A. Proximal Onyx injection through a double lumen balloon microcatheter during inflation (white asterisk) in a renal graft. Extreme distal reach of the liquid agent without reflux. B. The goal in the present case was to avoid reflux into external iliac artery (arrow) as well as distal embolization. Vascularization from cicumflex iliac artery is also seen (asterisk). C Withdrawal of the balloon microcatheter showing minimal reflux around the distal part of the balloon (arrow) and non-target embolization. Posteriously, we occluded the circumflex iliac artery as well (black asterisk)

c) Case 4

A 60-year-old male patient with an intense hemoptysis episode (1000 ml/24 h) was consulted to IR unit. Angio CT identifed an enlarged single right bronchial artery (4 mm) in addition to aneurysm like formations in the lower right lobe, findings in relation to necrotizing pneumonia.

In one hand, the Ascent ballon microcatheter was employed to help us to achieve a more stable position of the diagnostic catheter. For that reason, the dual lumen ballon catheter with the microwire were tracked into the bronchial artery, a gently inflation of the ballon allowed us to advance the diagnostic catheter over the system, achieving a more stable position (Fig.3).

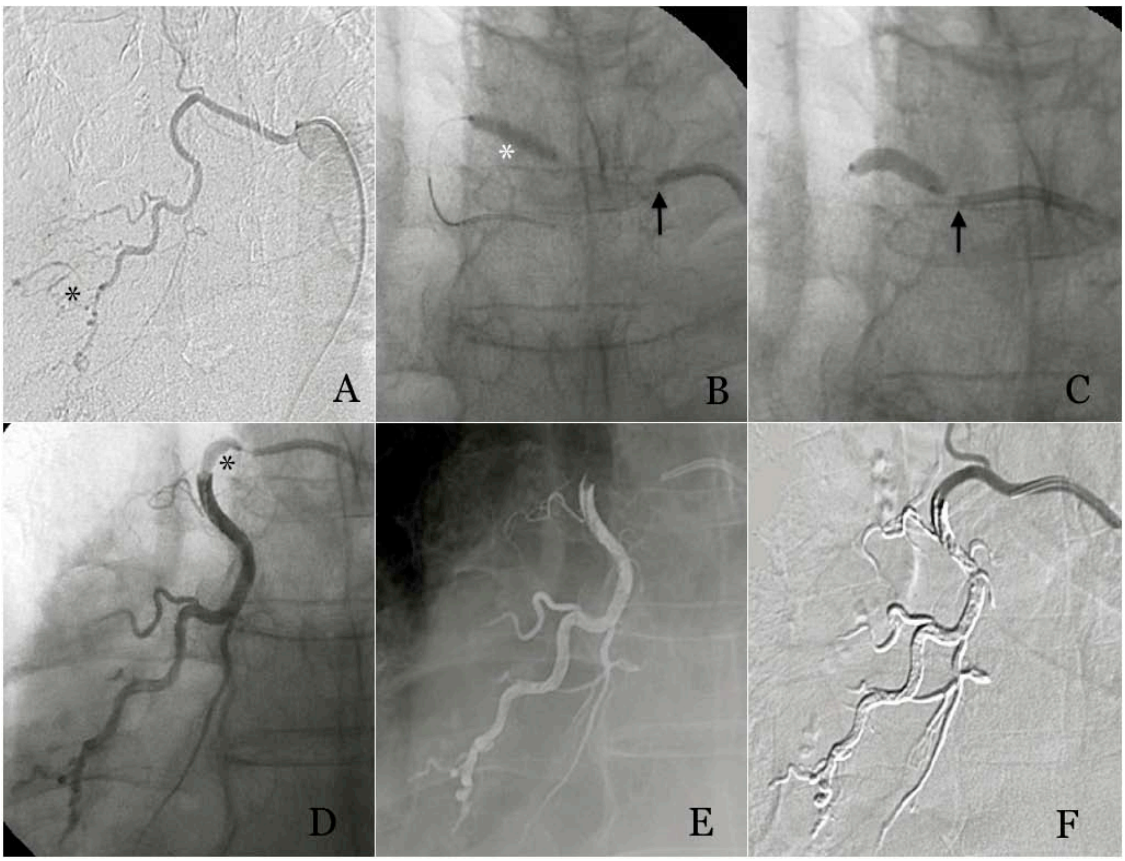

Figure 3 : A-F. Patient 4. A. DSA, selective injection from an enlarged right bronchial artery showing aneurysms-like formations in lower lobe (asterisk). B-C. Anchoring technique: Despite the passage of the glidewire to the artery not enough stability was achieved in the diagnostic catheter (arrow). Gentle inflation of the Ascent ballon (asterisk) in the bronchial artery allowed advancement of the 5Fr catheter over the system. D. Inflation of the ballon created a mechanical plug (asterisk) and Onyx injections was done sucessfully. E. After balloon deflation neither reflux nor adherence of Onyx to the catheter was noted. F. Final angiography showing complete occlusion of the artery and Onyx cast.

On the other hand, inflation of a proximal balloon created a 'mechanical plug', allowing for immediate forward flow of Onyx, reaching the more pathological vessels. No complications were noted.

d) Case 7

A 62-year-old male patient with a 6 cm right lobe hepatocellular carcinoma was scheduled to undergo a transarterial chemoembolization (TACE). During the initial angiography a high flow arterioportal fistula was identified and therfore the procedure was contraindicated. After multidisplinary discussion, an attempt to close the fistula and subsequent TACE was decided. For this purpose, the Ascent ballon was kept inflated in the arterial feeder and two 0,010" coils (Axium, Covidien) plus 0,6 ml of Onyx34 were introduced sequentially through its main lumen (Fig.4). In the final run no fistula was identified and the procedure was preformed as usually. No complications were noted and during a second TACE three months later the arterioportal fistula was still closed.

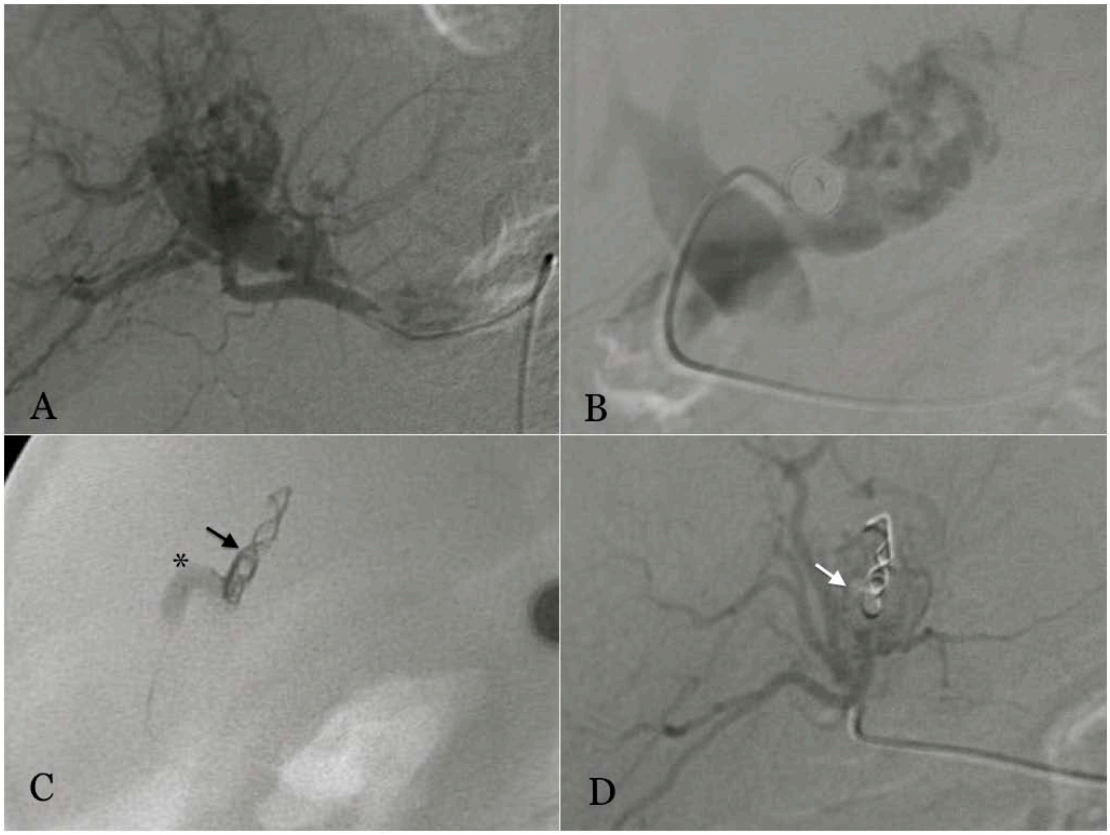

Figure 4 : A-D. Patient 7. A-B. Angiography identified a high-flow arterioportal fistula. A 3mm branch of the right hepatic artery was the single feeder. C-D. Inflation of the double lumen ballon (asterisk) at the fistula point, allows the combination of coils deployment (black arrow) and Onyx (white arrow) injection through the same lumen, decreasing the risk of Onyx migration.

IV. Discussion

Althought Ascent ballon was designed originally for ballon assisted coiling embolization of intracranial aneurysm; DMSO compatibility and Onyx injection through it have been described in the literature (5,7).

Inflation of a proximal balloon creates a 'plug', allowing for immediate forward flow of Onyx. Additionally, the balloon increases the proximal resistance in the feeder, encouraging Onyx to penetrate more distally into the lesion.

The drawbacks of Onyx embolization include the time needed to create a proximal plug that allows forward flow of the agent into the lesion (2) and proximal reflux of Onyx, which can compromise the normal vasculature and cause non-target embolizations and/or retention of the microcatheter. To obviate some of the risks associated with reflux of Onyx, the injection of Onyx through a dual-lumen balloon microcatheter has been described in the management of neurovacular procedures (7,8). In the present small series of embolizations performed by using this technique, there was immediate antegrade flow of Onyx into the pathologic vessel without the need for the initial formation of a plug. The inflated balloon essentially served as the plug, and embolization was achieved without catheter entrapment.

The present case series demonstrates the usefulness of the anchoring technique, a technique designed to allow the efficient and atraumatic positioning of a distal access-guiding catheter in patients with a tortuous anatomy. Hypercompliant balloon catheters can be reliably used to facilitate safe and rapid distal positioning of flexible guiding catheters beyond severe vascular tortuosity or in challenging arterial ostium (6).

Also, Onyx injections can be long, increasing the fluoroscopy times and radiation exposure. As seen in our series, because the use of the dual lumen balloon microcatheter precludes the need for creation of the Onyx plug, facilitates continuous Onyx injection, and there are no delays in microcatheter removal/extraction, the use of these devices may shorten the procedure times and, therefore, reduce radiation exposure.

There are several limitations to the present report. The present case series is small, and a much larger series of cases will be needed to fully document the safety of this technique, particularly in view of risks of vessel rupture during balloon inflation, arterio spasm, and balloon-induced intimal injury or thrombosis of arteries. Our results were also not compared with those in a control group of patients treated by using conventional embolization techniques. Finally, an

important potential limitation of this technique may be related to difficulties in navigating the balloon microcatheter to very small distal arterial feeder vessel.

V. Conclusion

Double lumen Ballon Onyx embolization is feasible and safe. The described embolizations techniques can be used in peripheral interventions for avoiding complications related to reflux or complex anatomies.

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