Narrative Review Article

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The Onyx Liquid Embolic System: Another Chance in the Management of Peripheral Bleeding

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Ethylene vinyl alcohol or Onyx copolymer (Medtronic) is an embolization agent increasingly used in peripheral interventional radiology. The Onyx Liquid Embolic System (LES) offers a liquid, non-adhesive, non-absorbable, injectable and permanent embolic agent with an indication for neuro-interventional procedures. Due to its physical properties, Onyx has more embolic predictability than other currently available liquid agents and seems to have good potential in endovascular bleeding management, especially for patients with coagulopathies or anti-coagulation therapy. The aim of this brief review is to analyze the advantages of Onyx in the emergency setting on the basis of evidence in the current literature.

Keywords: *Embolization; Hemorrhage; Endovascular; Onyx*

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INTRODUCTION

The use of the Onyx Liquid Embolic System (LES) is increasing. Onyx is a peripheral embolic agent that has been described for different indications [1]. In recent years, it has been used increasingly as a bleeding control embolization agent. The aim of this paper is briefly to discuss the role of Onyx in the management of peripheral bleeding according to the current literature. We will not discuss here the usage of Onyx for aortic intervention.

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General Technical Aspects of Onyx and How to Use It

The Onyx LES consists of an elastic polymer comprising an ethylene-vinyl alcohol copolymer (EVOH), dissolved in dimethyl sulfoxide (DMSO), and provided with x-ray radiopacity by adding micronized tantalum powder [1]. Onyx is available in two different viscosities: Onyx 18 (with 6% EVOH) and Onyx 34 (with 8% EVOH), and in two different formulations (1.5 ml and 6 ml). Onyx is a liquid, non-adhesive, non-absorbable, injectable and permanent embolic agent. Owing to its non-adhesive physical property, it is easy to deliver due to a low risk of sticking to a microcatheter tip. Its viscosity helps to achieve a correct delivery, although a risk of distal embolization is still present [1]. Potential advantages of Onyx are that it has high vascular penetration and that a small quantity of the agent is enough to obtain hemostasis [2,3].

Moreover, with other embolization agents, such as particles or cyanoacrylate, free flow is necessary, but Onyx works equally well with or without flow, which is an advantage when vasospasm is present. Onyx is known to have only a weak inflammatory effect on the endothelium, and its action is independent of underlying coagulopathies or low platelet count. By forming a cast of the vessel (Figure 1), the development of a blood clot is less important than with other embolic agents, indeed it was

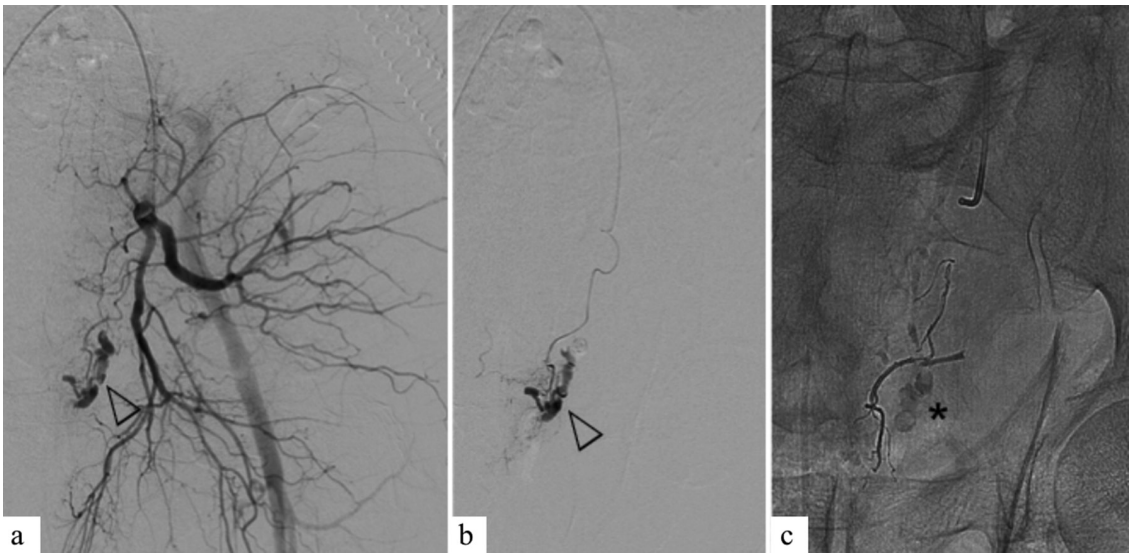

Figure 1 A multi-trauma patient with (**a**) active pelvic bleeding (arrowhead), (**b**) successfully catheterized (arrowhead), (**c**) and embolized with Onyx (asterisk).

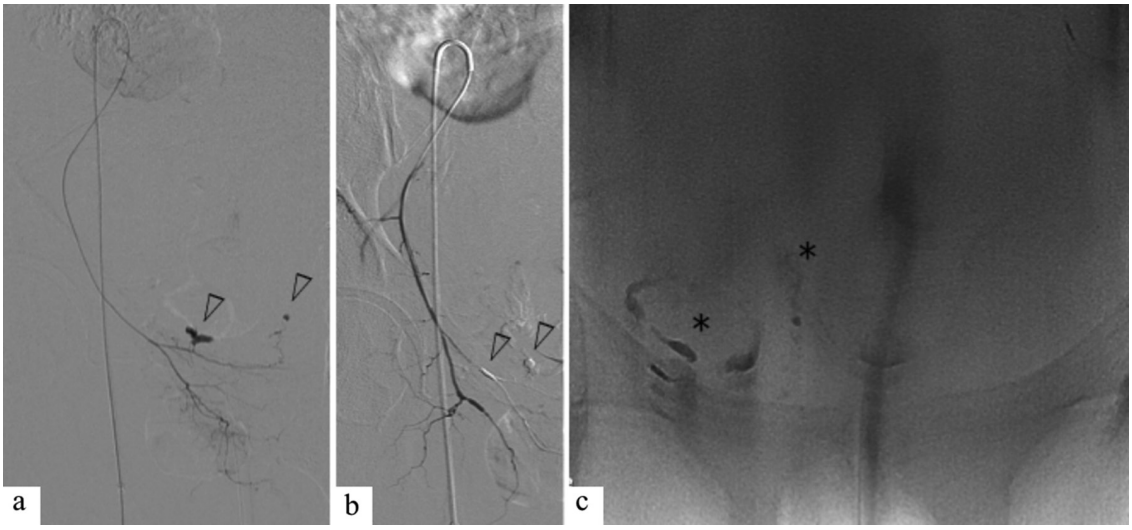

Figure 2 Traumatic bleeding in an uncoagulated patient (**a**) originating from a branch of the hypogastric artery (arrowhead), (**b**) successfully embolized with Onyx (arrowhead). (**c**) A single shot confirms the presence of Onyx (asterisk).

used with success in such settings (Figures 2 and 3) [2–5]. Controlled and slow injection is possible, permitting a relatively low risk of non-target embolization compared with the use of cyanoacrylate or particles which require a quicker injection and an indirect visualization of the embolizing material path, respectively [6]. A known drawback of Onyx lies in the artifacts seen after embolization on computed tomography (CT) images, but magnetic resonance (MR) shows fewer artifacts than is the case for coils [2–4]. No artifacts are observed on ultrasound examinations.

The manufacturer recommends placing the ready-to-use vials of Onyx on a mixer, shaking them for at least 20 minutes until a homogenous solution is created with the tantalum powder. DMSO-compatible devices (microcatheters, syringes, etc.) must be used as recommended by the manufacturer (Table 1). The microcatheter should be positioned as close as possible to the target vessel/bleeding, even though embolization can be performed when the microcatheter tip is far away from the target area due to high downstream penetration [1,7].

Before use, the microcatheter must be flushed with saline solution and then with DMSO, which prevents copolymerization within the microcatheter activated by contact with an ionic solution such as blood

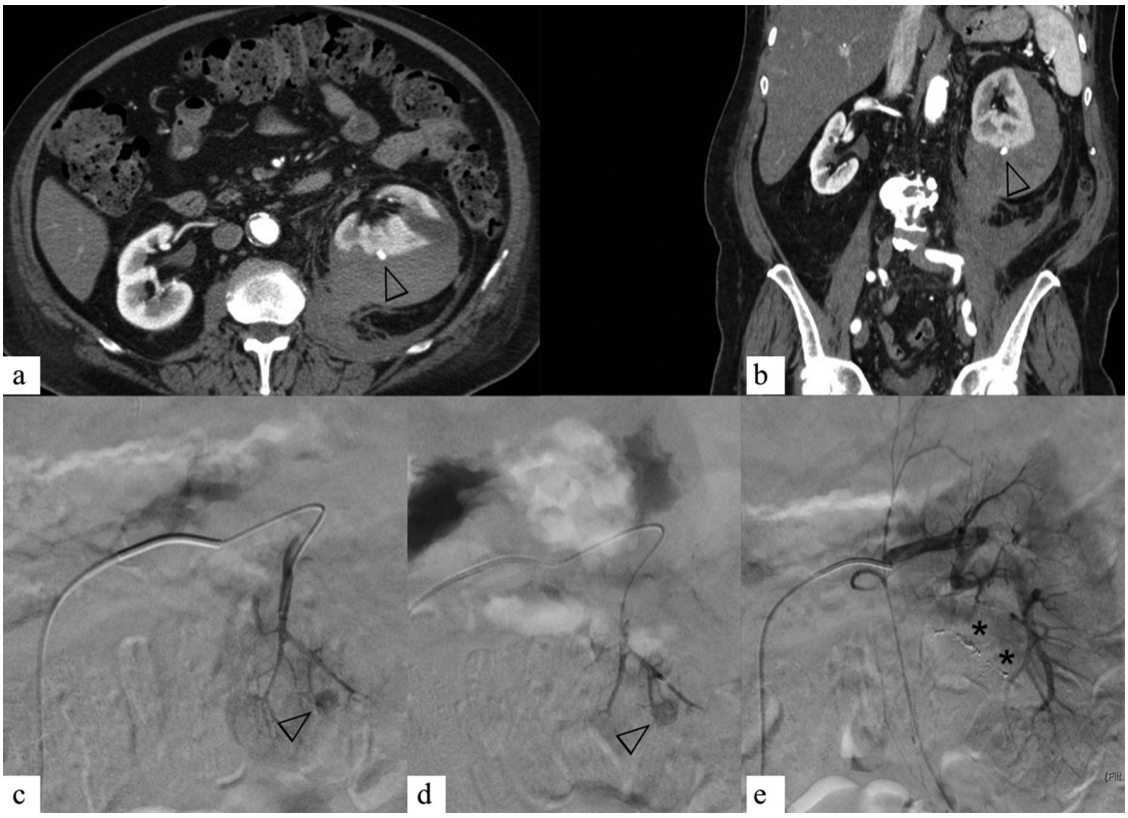

Figure 3 (**a**, **b**) Axial and coronal MPR CT images showing active spontaneous bleeding in an uncoagulated patient originating from a small pseudoaneurysm located between interlobular and arcuate renal arteries (arrowhead). (**c**, **d**) The same bleeding is clearly shown after superselective catheterization using a 2.8F DMSO-compatible coaxial microcatheter system (arrowhead; Progreat, Terumo Interventional Systems). (**e**) After successful embolization, a single shot confirms the presence of Onyx (asterisk).

or saline solution. Once the microcatheter dead space is filled with DMSO, Onyx must be injected very slowly and carefully with constant pressure under fluoroscopic guidance. Indeed, a quick injection of Onyx, leading to a fast displacement of DMSO in the bloodstream with local high concentrations of the solvent, can lead to strong pain. This is why the presence of an anesthesiologist could be useful to both stabilize the patient, when necessary, and manage the possible development of pain. Pain is due to DMSO angiotoxicity caused by endothelial irritation which potentially leads to the development of endothelial necrosis and the inflammatory response of the artery wall. However, a slow injection showed no untoward endothelial effects [1,4,8]. Onyx, after its solidification, typically forms a plug, which is fundamental in preventing the backflow of the embolic agent, with a lower risk of non-target embolization. Onyx solidification takes about five minutes, achieving a foam-like consistency [1,7]. The day after the procedure, the patient may complain about a garlic-like smell; this is due to the DMSO and should disappear within two days [1]. The required shaking time (20 minutes) may limit the use of Onyx in emergency settings. However, a well-coordinated procedure and promptly available Onyx embolization-related material can certainly be used in emergency procedures, such as with trauma patients (Figure 2) [1]. It is advisable to start shaking the Onyx as soon as it is suspected that it might be necessary during the preparation of the patient at arrival in the angiographic suite. If vials are not used, they can be returned to storage [4]. Specific training in the use of Onyx is required since it might migrate, and experienced hands are demanded during injection [4].

Since 2005, Onyx has been approved by the Food and Drugs Administration (FDA) for the treatment of brain arteriovenous malformations (AVMs), and since 2007 for the treatment of intracranial, saccular, sidewall aneurysms with a wide neck (≥4 mm) or with a dome-to-neck ratio <2, which are aneurysms that are not easily managed by surgical treatment [9]. Although Onyx is approved just for brain procedures, it has also been used both in the extracranial central nervous system (e.g., spinal cord) and in peripheral vascular, and even non-vascular (e.g., bile leakage) locations [4,10,11]. There are now several papers about peripheral applications of Onyx that demonstrate its safe and effective use [2–4,6,10–12].

Table 1 Known catheters approved for Onyx usage. In addition to these, there are now new catheters, e.g., Tokai microcatheters, that are compatible with DMSO and Onyx.

Catheter Name	*Manufacturer*	*Total Length (cm)*	*Proximal/Distal Diameter (F)*	*Dead Space Volume (ml)*
Rebar 14	Medtronic	153	2.4/1.9	0.49
Rebar 18	Medtronic	153	2.7/2.4	0.49
Rebar 27	Medtronic	130	2.8/2.8	0.49
Echelon 10	Medtronic	150	21/1.7	0.34
Echelon 14	Medtronic	150	2.4/1.9	0.34
Apollo	Medtronic	165 165	2.7/1.5	0.23
Progreat	Terumo	110;130;150	2.9/2.4	0.48;0.53;0.58
Progreat	Terumo	110;130	2.9/2.7	0.57;0.64
Progreat	Terumo	110;130;150	3.0/2.8	0.61;0.68;0.75
Renegade	Boston Scientific	105;130;150	3.0/2.4	Not specified
Renegade HI-FLO	Boston Scientific	105;130;150	3.0/2.8	Not specified
Direxion	Boston Scientific	105;130;155	–/2.4	0.40;0.46;0.56
Direxion HI-FLO	Boston Scientific	105;130;155	–/2.8	0.55;0.64;0.73

Other Embolization Agents Used in Bleeders Differ from Onyx

There are several agents used for embolization without universally accepted guidelines for the choice of which to use, which depends heavily on the operator's experience and confidence level. The efficacy of particles (e.g., PVA), coils and gelfoam is highly dependent on the patient's coagulation status, and the rate of clinical failure after embolization is high when the patient has a coagulopathy, for example, in a trauma setting [13–16]. N-butyl-2-cyanoacrylate (NBCA), which is a glue, has a high hemostasis effect with a low recurrent bleeding rate, but control of vascular glue penetration can be difficult and requires considerable experience [17].

One of the advantages of Onyx over NBCA or PVA particles is that Onyx permits a controlled injection capable of reducing the risk of non-target embolization and allowing stop-and-restart administration, whereas the quick polymerization of NBCA requires faster administration to reduce the risk of microcatheter gluing. Another advantage of Onyx compared with PVA particles is that Onyx is radiopaque and can, therefore, be seen at fluoroscopy, whereas a reflux of PVA particles can potentially be missed [14]. As with PVA particles, pure NBCA can be mixed with iodized-oil. However, the more oil is added, the longer will be the polymerization time, giving a higher risk of non-target embolization since the mixture can be washed away with the blood flow before it polymerizes [18,19]. The major disadvantage of Onyx over the other embolization agents is a higher cost compared to both PVA particles and NBCA and this cost is not always justifiable because, according to the clinical situation, the same results can be achieved by other embolic agents. However, an ideal embolic agent should have rapid and effective embolization potential so that it can reach and fill the distal vasculature targeted for embolization, be easy to prepare and use, have a high radiopacity, be well controllable during administration, and be biocompatible and cost-effective [20]. Onyx meets some of these major criteria well.

Published Series with use of Onyx for Peripheral Bleedings (Table 2)

The much-appreciated results of Onyx usage in the embolization of intracranial aneurysms [22–24] and AVMs have encouraged Onyx interventions also in a peripheral setting (Table 2) [2,4,5,15,16,21,25–31]. So far, there are only a few series of publications on Onyx embolization in peripheral bleeding, and most studies have a small sample size. These series are heterogeneous since the patients have presented different types of bleeding (e.g., as a consequence of trauma, or gastrointestinal (GI), uterine, AVM bleeding, etc.).

The first paper about the use of Onyx in peripheral bleedings was published in 2002 by Cantasdemir et al. [27]. It reported on the embolization of deep femoral artery branch pseudoaneurysms in three patients with massive hemorrhage, two for a penetrating injury, and one at the site of a fixation pin (an iatrogenic injury). In all cases, a successful closure of the pseudoaneurysm was obtained without re-bleeding during the follow-up period [27]. GI bleedings are very common and can have many causes, such as angiodysplasia, ulcers, tumors, diverticulas, varices, pancreatitis, etc.; however, their management is usually endoscopic, sometimes requiring an endovascular procedure [32].

A rare, but tricky and potentially life-threatening, condition is an arterio-enteric fistula; in this setting, the treatment of a saccular aneurysm of the right internal iliac artery was successfully treated with a combination of coils and Onyx [2]. Two series, published by

Table 2 Published series where Onyx was used for urgent bleeding control.

Study	*n° Patients*	*n° Lesions*	*Bleeding Site*	*Mean Follow-Up Time*	*Outcome*
Barral et al. 2017 [25]	12	16	uterus	29	1 technical failure
Bommart et al. 2012 [26]	15	28	lung in patients with hemoptysis	43.5 d	2 recurrences
Cantasdemir et al. 2002 [27]	3	3	thigh	4.3 mo	No recurrence
Ierardi et al. 2015 [4]	15	15	multiple	minimum f.u. time 4 mo	No recurrence
Khalil et al. 2010 [28]	15	15	lung in patients with hemoptysis	9.7 mo	1 technical failure
Khalil et al. 2012 [29]	12	12	lung in patients with hemoptysis	6.4 mo	2 recurrences, 1 technical failure
Klamroth et al. 2009 [5]	7	8	joints	16 mo	3 recurrences
Lenhart et al. 2010 [21]	16	16	GI	13.1 mo	No recurrence
Müller-Wille et al. 2012 [15]	13	13	multiple	27 d	1 erectile dysfunction possibly related to embolization, no recurrence
Regine et al. 2015 [16]	26	26	multiple	6 mo	No recurrence
Thulasidasan et al. 2016 [30]	7	10	angiomyolipoma of the kidney	284.2 d	1 retreatment (for new feeding vessels)
Urbano et al. 2014 [31]	31	31	GI	23.7 mo	4 recurrences, 2 technical failures
Vanninen et al. 2007 [2]	4	4	multiple	2.7 mo	No recurrence

**List of major case series; isolated case reports not included. GI: gastrointestinal.*

Lenhart et al. and Urbano et al. [21,31], investigated the potential role of Onyx, alone or combined with coils, in the treatment of GI bleeding in an emergency setting. For a retrospective double-center study, Lenhart et al. enrolled 15 patients (16 procedures in total, with one patient being treated on two of the sites) with GI tract acute arterial bleeding, untreatable solely by endoscopy, and therefore treated with trans-catheter arterial embolization. All patients were treated with Onyx only, except for two who received a combination of Onyx and coils. In combination with Onyx, coils are often used to prevent excessive distal migration of the embolic agent. The technical success rate was 100% with angiographic demonstration of bleeding cessation. Neither procedure-related complications, such as non-target embolization and signs and symptoms of bowel ischemia, nor re-bleeding during follow-up were registered [21].

A slightly different experience was reported by Urbano, who used Onyx, both alone and with coils, for the treatment of GI bleeding. In their cohort, 31 patients were retrospectively enrolled, and super-selective embolization was performed in 30 vessels. One patient underwent surgical resection due to severe atherosclerosis and failure of super-selective catheterization of the target vessel. One technical failure was registered due to reflux of Onyx in a marginal artery, without signs of intestinal ischemia during the follow-up period [31].

Klamroth et al. used Onyx in seven patients, six with hemophilia A and one with hemophilia B. All had elbow or knee bleedings that were not responsive to the administration of concentrated coagulation factors (fVIII/fIX). Eight joints were treated, each presenting two/three bleeding sites, all successfully embolized [5].

The ability to embolize regardless of the patient's coagulation status was the key to choosing Onyx for the management of hemoptysis by Khalil et al. Two re-bleedings (16.6%) were registered and attributed to an infection [29]. The Khalil team's experience of hemoptysis management with vascular embolization procedures includes not only pulmonary artery embolization but also the treatment of systemic vessels, such as the bronchial artery, inferior diaphragmatic artery and left internal thoracic artery [28,29]. The team identified two major groups of indications requiring the use of Onyx: anatomical and relapses of the previously occluded artery (e.g., re-bleeding). The anatomical indications for the use of Onyx were as follows: false aneurysms of a systemic artery, opacification of the bronchial artery causing bleeding through small anastomosis, unstable catheter position, spasm or dissection of the bronchial artery, and complete and definitive occlusion of the so-called dangerous artery, the embolization of which can be risky [28].

A paper on a more homogenous group was published by Bommart et al., who described a series of patients, including some affected by hemoptysis due to bronchial artery bleeding. Similar results to those obtained by Khalil and colleagues were achieved, with two failures out of 28 procedures [26].

Barral et al. studied the feasibility and effectiveness of Onyx as a single embolic agent for the treatment of uterine bleedings in both stable and unstable patients.

They enrolled 12 patients with uterine bleeding due to AVMs. Nine of the 12 were hemodynamically stable, and three hemodynamically unstable. Eight single procedures and four double embolizations were performed according to the size of the AVMs. In the patients undergoing a double procedure, the second was performed 15–21 days after the first to avoid uterine necrosis. Clinical success was defined as the absence of recurrent uterine bleeding within a month of the procedure. Neither uterine necrosis nor off-target embolization and other types of complications were registered [25].

Some good results have been reported on the employment of Onyx for the treatment of patients with renal bleeding angiomyolipomas (AMLs), or for other patients at high risk of bleeding. In a recent study, Thulasidasan et al. [30] treated AMLs >4 cm in diameter or bleeding AMLs of any size and obtained successful hemostasis and a statistically significant reduction in maximum lesion diameter. It is interesting to note that no statistically significant difference in glomerular filtration rate was observed. This is of basic importance because patients with tuberous sclerosis are at high risk of developing new AMLs, and therefore have an elevated risk of further kidney injuries. According to this study, to reduce recurrences, embolization should be selective but not as distal as possible in each case. Indeed, the closure of the proximal feeding vessels may prevent further regrowth.

The most common complication observed in some series was pain. However, it was short-lasting, successfully managed with analgesic drugs, and prevented by a reduction in the DMSO injection rate [2–4]. A rare, but tricky, situation was experienced by Vanninen and Manninen, who had a patient with an iatrogenic pseudoaneurysm of a side branch of the second lumbar artery as a consequence of a renal biopsy for sarcoidosis, rheumatoid arthritis, and suspected nephropathy. Although it was an urgent situation, as the patient developed hypotension, the pseudoaneurysm was successfully treated with the deployment of Onyx, and he recovered uneventfully [2].

DISCUSSION

Onyx has been used successfully to stop acute peripheral bleedings in several series. On the basis of our literature review, the properties of Onyx make it a useful and safe embolic agent, since some situations require a controlled injection and an opportunity to reach the most distal, thin, bleeding vessels. GI bleeding seems to respond particularly well to the embolizing properties of Onyx [4,15,16,21,31].

We agree with Khalil and colleagues that an unstable catheter might speak for the use of Onyx, since difficult catheterization of an artery prevents safe and effective coil deployment, and the use of NBCA or PVA particles may be risky in terms of non-target embolization. Moreover, the occlusion of a vital artery is a good indication for choosing Onyx since controlled injection allows the operator to check constantly where the embolic material is and, unlike NBCA, to interrupt the injection in case of undesired embolization without the risk of catheter gluing (thereby permitting injection restart at any time).

The need for embolization of bleeding AMLs (or AMLs at high risk of bleeding) is also an indication for Onyx use. Indeed, in these cases, very careful deployment of the embolic agent is required to be more selective, thereby preserving kidney function in both healthy patients with isolated AMLs and patients with tuberous sclerosis at high risk of further kidney injuries.

However, AML treatment not only requires selectivity but also embolization of the proximal feeding artery from its origin so as to prevent future regrowth. Here, the importance of Onyx features since the agent can enter the most distal vessels, and also embolize the feeding vessel from its origin, thanks to backflow during the controlled injection. No other embolic agent has this property [30].

In addition, Onyx's hemostasis power, which is not influenced by the patient's coagulation status, makes it helpful in the primary control of bleeding as well as in the prevention of re-bleeding in patients with coagulation disorders (Figure 3) [5].

It should be noted that the re-bleeding rate is often overestimated since new bleeding episodes are registered sometimes although they are not at the site of the embolization. This was the case in the series by Urbano and colleagues, in which four minor recurrences, over the 30 procedures performed effectively, were registered, but just one had occurred on the site of the previous embolization. This means that the re-bleeding rate requires careful analysis [31].

One of the most common drawbacks of Onyx use is pain. In our experience, patients with muscle hematomas experience more pain after DMSO injection than others with parenchymal bleeding [4]. The injection rate of the solvent may be responsible for the onset of pain, and we have corrected the rate during operation, resulting in symptom improvement [4]. Morphine i.v. significantly reduces patient discomfort, but it must be used very carefully, especially in patients with hemoptysis, as its central antitussive action reduces airway reflex, which can be life-saving in this case [28,29].

Nevertheless, as shown in Table 2, all the papers included in this review demonstrate high efficacy and a low complication rate. One severe complication registered was that of erectile dysfunction in a patient who had had a car accident and showed bleeding from the internal pudendal artery treated with Onyx embolization. However, this is not really a complication of the embolic agent but of the procedure itself. The embolization necessary to stop the bleeding was responsible for disruption of the blood flow within the dorsal and the deep artery of the penis, the latter supplying the corpus cavernosum. Probably, the same problem would have been registered using any other embolic agent.

Unfortunately, given the uncommon use of Onyx in peripheral applications, only case reports and small case series appear in the published literature. No multi-institutional studies, prospective studies, or randomized controlled studies are available. Accordingly, the use of Onyx copolymer in peripheral embolization cannot yet be standardized. Therefore, more liberal use of Onyx in academic institutions is recommended.

CONCLUSIONS

Onyx seems to be a potentially useful, safe and effective tool in the management of peripheral bleeding. Onyx use should now be increased in academic institutions within a non-industry funded blinded comparative multicenter randomized controlled trial with cost analysis in order to extend its use in peripheral bleeding from off-label employment to standard clinical practice.

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