

ArtVentive endoluminal occlusion system for proximal splenic artery embolization

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ABSTRACT

We aimed to discuss and evaluate the technical success and efficacy of the ArtVentive endoluminal occlusion system (EOS) device for splenic embolization. A retrospective review was undertaken for all patients in whom the EOS device was deployed for the purpose of splenic embolization. Data was collected by a search of splenic artery embolization procedures in the hospital computer database. Data was reviewed for all patients in whom an EOS plug was deployed. Patient demographics, technical aspects of the procedure and follow-up at one month were reviewed. We review the technical success and efficacy of this occlusion device. Six patients underwent splenic embolization with the EOS plug. There were 5 male and 1 female patients; age range was 24–88 years. Five 8 mm and one 5 mm EOS plugs were deployed for the occlusion of the splenic artery. The technical success rate was 100% occurring in all 6 splenic arteries. One patient underwent a second angiogram and subsequent splenectomy for persistent splenic hemorrhage. One patient had a subsequent splenectomy for bacteremia with the spleen as the suspected source. This early data supports the efficacy of the EOS plug for the embolization of the proximal splenic artery.

The spleen is a frequently injured organ in blunt abdominal injuries. Splenic embolization has a central role in the non-operative management of high-grade blunt traumatic splenic injuries (1). This can be performed using various different embolization materials, including coils, gelfoam, endovascular plugs, amongst others.

The EOS device is an endovascular plug which has been successfully used for vascular and for ureteral embolization (2–4). A single case report has been published using the device for splenic embolization (5). The purpose of this study is to report our initial experience, efficacy and safety outcomes for acute occlusion in the arterial system, specifically for the occlusion of the proximal splenic artery for the purpose of splenic embolization. This is the first case series describing the use and outcomes of the EOS device in this setting.

Technique

Approval for this study was obtained from the local Human Research and Ethics Committee as per our hospital guidelines. A retrospective review was undertaken for all patients in whom the EOS device was deployed for the purpose of splenic embolization, identified by a search of the hospital computer database. All patients in whom an EOS plug was utilized or attempted to be utilized for the embolization of the splenic artery were included. Patient demographics, technical aspects of the procedure, including safety, technical success, efficacy and outcome at 30 days were recorded and anonymized.

Device characteristics

The endoluminal occlusion system (EOS; ArtVentive) device was developed for the endovascular occlusion of both arteries and veins. There are three device sizes: the 5 mm EOS for a 3–5 mm vessel, 8 mm EOS for a 4.5–8 mm vessel, and 11 mm EOS or a 7.5–11 mm vessel. A 6 F guiding catheter or sheath is required for the 5 mm or 8 mm EOS Plugs. The plug is comprised of a polytetrafluoroethylene membrane with a self-expanding nitinol scaffold, which is deployed by removing the clip on the handle of the delivery system and flushing with

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dilute contrast. The final length depends on the diameter of the target vessel. The 5 mm EOS plug is 9–11 mm in length, and the 8 mm EOS is 17–21 mm, depending on expansion within the vessel.

Procedure

A femoral puncture using a Seldinger technique and selective catheterization of the splenic artery was performed in all patients. Splenic arteriogram was performed using hand injection via a 5 F C2 catheter (Cook Medical). The 5 F diagnostic catheter was exchanged for the 6 F EOS device guiding catheter with inner dilator *in situ*. The wire and inner dilator were removed. Then the EOS plug was deployed under imaging guidance, using 2 mL contrast diluted with 8 mL normal saline and the detachment mechanism. The EOS plug was deployed in the main splenic artery proximal to the hilum in all cases in keeping with our departmental protocol for high grade splenic trauma (Fig. 1). No adjuvant embolic agents were employed in the splenic artery. A post deployment angiography was performed in the proximal splenic artery.

Patients

Six patients underwent splenic embolization with an EOS device at this level 1 trauma center (Table). Indications for embolization included high AAST grade (IV–V) splenic injury or those with active bleeding (6). There were 5 male and 1 female patients, age range was 24–88 years. One 5 mm and five 8 mm EOS devices were deployed for the occlusion of the splenic artery.

The technical success rate was 100%, with immediate occlusion occurring in all 6 splenic arteries, as evidenced by post deployment angiography performed in the proximal splenic artery. No intraprocedural complications occurred.

In postprocedural outcomes, two patients (33%) had a subsequent splenectomy. Patient A was treated for a grade IV splenic

injury with known pseudoaneurysms (Table). The decision was made to perform a proximal embolization rather than tandem (proximal and distal) embolization. There was immediate technically successful occlusion of the splenic artery at the point of deployment (Fig. 1b). However, 6 days later, a routine CT angiogram was performed for follow-up of the patient's aortic injury, which had occurred at the time of initial trauma. This demonstrated persistent occlusion of the main splenic artery; however, there was persistent arterial enhancement of the splenic pseudoaneurysms (Fig. 2a). A catheter angiogram confirmed the main splenic artery remained occluded from the EOS plug, but demonstrated persistent vascular supply to the spleen and filling of the pseudoaneurysms from an early branch of the splenic artery and multiple collateral arteries. The splenic artery was embolized with coils proximal to the position of the plug across the origin of the early splenic

branch, as was a second collateral artery (Fig. 2b). However, given the multiplicity of feeding collateral vessels and persistent flow within the splenic pseudoaneurysms, the decision was taken to proceed to splenectomy due to risk of bleeding from the large pseudoaneurysms. Subsequent 30 day follow-up was uneventful, with no clinical complications.

A second patient (patient B) also had successful occlusion of the splenic artery by the EOS device at the time of deployment; however, also went on to splenectomy 10 days post embolization for *Enterobacter cloacae* complex and *Serratia marcescens* bacteremia, with suspicion of a splenic source. No splenic imaging was performed between initial angiography at embolization and subsequent splenectomy. No evidence of abscess was seen at pathologic evaluation. The patient was managed with intravenous and subsequently oral antibiotics, and subsequent 30 day follow-up was uneventful.



Figure 1. a, b. Angiogram (a) demonstrates high grade splenic injury in Patient A, and subsequent angiogram (b) demonstrates successful occlusion of the splenic artery after EOS plug (arrow) deployment.



Figure 2. a, b. CT angiogram (a) performed 6 days post embolization in Patient A demonstrated persistent occlusion of the main splenic artery, seen with minimal artifact from the EOS plug (black arrow); however, there was arterial enhancement of the splenic pseudoaneurysms (white arrow). Repeat angiography (b) in Patient A confirmed main splenic artery occlusion by the EOS plug (black arrow). Vascular supply to the spleen and filling of the pseudoaneurysms (white arrow) persisted despite coil embolization of the left gastric and splenic artery proximal to the EOS plug (across the origin of the early splenic branch). Splenectomy was subsequently performed.

Main points

- This report provides early evidence that the EOS device produced rapid and effective occlusion of the splenic artery.
- The delivery system and plug tracked easily through the splenic artery in these cases.
- Robust evidence including a prospective study is warranted to compare the EOS device with other embolization systems.

Table. Patient characteristics and outcome summary

Patient	Age (years)	Gender	Etiology	AAST Grade	EOS size (mm)	Technical success	Fluoroscopy time (min:s)	Gy/cm ²	30-day follow-up
A	37	F	Trauma (MVA)	4	8	Yes	9:42 ^a	34.89 ^a	Splenectomy - pseudoaneurysm
B	78	M	Trauma (fall)	4	8	Yes	7:48	96.2156	Splenectomy - infection
C	41	M	Post gastrectomy	1 (active bleed)	8	Yes	6:18	132.0	Uneventful
D	88	M	Trauma (fall)	4	8	Yes	19:00 ^b	203.56 ^b	Uneventful
E	29	M	Trauma (MVA)	5	5	Yes	20:34 ^c	120.92 ^c	Uneventful
F	24	M	Trauma (MVA)	4	8	Yes	07:48	28.61	Uneventful

AAST, The American Association for the Surgery of Trauma; EOS, endoluminal occlusion system; F, female; M, male; MVA, motor vehicle accident.

^aDiagnostic pelvic angiogram also performed at the time of splenic embolization.

^bSelective hepatic arterial embolization also performed at the time of splenic embolization.

^cTraumatic left renal fistula selective embolization also performed at the time of splenic embolization.



Figure 3. Angiography in Patient F demonstrates a tortuous splenic artery and post-traumatic injury of the inferior pole of the spleen. The EOS plug was deployed (arrow) proximal to the splenic hilum, navigating the tortuous vessel without difficulty.

The remaining 4 patients (patients C–F) underwent uneventful clinical follow-up, with no clinical evidence of bleeding or visceral infarction at 30 day follow-up for all 4 patients. No postprocedural imaging is routinely performed at our institution in patients with an uneventful clinical postprocedural course.

Discussion

The EOS device was successful in occluding the main splenic artery in all patients in this case series. Two patients in this series (33%) had subsequent splenectomy. Splenic infection and abscess are severe but rare complications of embolization (1). The use of proximal rather than distal splenic arterial embolization in the setting of blunt trauma is considered to be faster, with a lower rate of splenic infection or abscess and

lower failure rate of non-operative management (1). In one case, a repeat angiogram was performed. While this was a failure of embolization, we consider this not to be an early failure of the device, as the splenic artery remained occluded on CT and angiographic imaging (Fig. 2). Perfusion via collaterals is expected to occur, with the benefit of retaining some splenic immune function (7). Although a 33% splenectomy rate is higher than expected, all angiograms showed technical success and this disparity is likely to be exaggerated by the small numbers in this retrospective study.

In our series, we noted that the EOS guide catheter tracked easily over the wire and the EOS plug tracked easily within the guide catheter, even in the presence of tortuous vessels (Fig. 3). Difficulty in tortuous splenic arteries has been cited as a potential factor limiting the utility of other plugs (8). The EOS device was safely deployed in all cases. Although there is a learning curve necessary for the deployment of the EOS device, no complications occurred during these initial cases and the learning curve is anecdotally relatively easy to overcome.

There are some reported benefits with the use of plugs for the embolization of the splenic artery as compared with coils, including a trend towards reduced time to occlusion, fluoroscopy time and radiation with the use of endovascular plugs (8). A robust comparison between common embolization materials and the EOS plug is warranted. The cost of the device at our institution is US \$1079.51 for the EOS plug and US \$ 239.44 for the guide catheter which we used in these cases. Other relevant benefits

of the EOS plug include the minimal artifact on follow-up CT imaging (Fig. 2a).

While our initial results indicate that the EOS plug is safe and effective for the proximal embolization of the splenic artery, there are limitations to this study, including the retrospective nature, and that the cases in which the operator chose to use the EOS device were non-consecutive and thus open to selection bias. Potential limitations of the device include possible difficulty of placing the delivery system in very long tortuous arteries and inability to perform selective embolization. Bias including choosing the device for less tortuous splenic arteries, although not deliberate by the operators, may have occurred in this study. Further prospective evaluation of this device compared with other techniques is warranted.

Conclusion

This initial report shows that the EOS device produced rapid and effective occlusion of the splenic artery in all cases. The delivery system and plug tracked easily through the splenic artery in these cases. Robust evidence including a prospective study is warranted to compare the EOS device with other embolization systems.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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