Vascular plugs are associated with reduced fluoroscopy times compared to endovascular coils in proximal splenic artery embolization in trauma

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Abstract
Purpose: Proximal splenic artery embolization plays an important role in the treatment of hemodynamically stable blunt splenic trauma patients with medium- to high-grade injuries. Proximal splenic artery embolization is most often performed utilizing endovascular coils or vascular plugs. The objective of this study was to compare technical and clinical outcomes of proximal splenic artery embolization using either endovascular coils or vascular plugs in patients with traumatic splenic injuries.

Materials and methods: A single-institution retrospective review of all proximal splenic artery embolizations for trauma over a 5-year period was performed. Patients who underwent embolization using both endovascular coils and vascular plugs were excluded. Baseline characteristics, including patient age, sex, and grade of splenic injury, were recorded. Complication rates, rates of splenic salvage, and total fluoroscopy time were recorded and compared.

Results: A total of 26 patients were included in the analysis (17 males, 9 females, median age: 50 years). Of these, 15 patients were treated with vascular plugs (57.7%), while 11 patients (42.3%) were treated with endovascular coils. Mean grade of injury was 3.5 and 4.1 in the vascular plug and endovascular coils groups, respectively. There were no differences between the groups regarding these baseline characteristics. Splenic salvage was 100% in both groups. No major complications were identified in either group. Mean fluoroscopy time was significantly lower in the vascular plug group (14.5 versus 34.0 min; p < 0.0001).

Conclusion: Proximal splenic artery embolization for splenic trauma can be satisfactorily achieved with either vascular plugs or endovascular coils with no differences in splenic salvage or complication rates in this retrospective study. However, embolization utilizing vascular plugs had significantly reduced fluoroscopy times.

Keywords
Trauma, embolization, spleen, coils, endovascular plugs

Introduction
The spleen is the most commonly injured organ following blunt abdominal trauma, with roughly 40,000 splenic injuries occurring annually.¹ Spleenectomy is associated with numerous post-operative sequela, including hemorrhage, pancreatitis, gastric fistula formation, and potentially fatal infections, and is typically reserved only for patients who are unstable at the time of presentation or have failed attempts at non-operative management (NOM).²⁻⁵ Splenic preservation with NOM is preferred, when possible, and includes close monitoring,
splenic artery embolization (SAE), and splenorrhaphy. SAE has been shown to improve splenic salvage in patients selected for NOM and can be accomplished proximally (within the midportion of the splenic artery) or distally (selective catheterization of the bleeding vessel). Both methods are efficacious in preventing failure of NOM; however, proximal SAE (pSAE) has fewer minor complications, such as splenic infarction and abscess formation. The embolic agent used for pSAE is operator-dependent but typically performed using either endovascular coils (ECs) or vascular plugs (VPs). The purpose of pSAE is to decrease the systolic arterial pressure transferred to the splenic parenchyma while maintaining adequate blood flow through collaterals. Use of plugs and coils has previously been compared in pulmonary arteriovenous malformation, internal iliac artery embolization during endovascular aneurysm repair (EVAR), and varicose embolization during transjugular intrahepatic porto-systemic shunt (TIPS), but there is a paucity of such literature in the use of plugs versus coils in pSAE. A recently published pilot prospective randomized control trial of coils versus plugs for pSAE demonstrated both EC and VP result in excellent rates of splenic salvage with comparable technical success, complications, and mortality rates. While that study did measure primary technical success, it did not specifically evaluate intraoperative parameters, such as fluoroscopy time. Fluoroscopy time is an important technical endpoint since it can be used as a surrogate for procedure time and radiation exposure. As most pSAE is performed in the urgent or emergent setting, reducing procedural times is an important goal. Similarly, reducing radiation exposure to both the patient and interventional staff is part of best practices. Herein, the authors present a retrospective analysis comparing the use of EC and VP in pSAE, with a specific focus on fluoroscopy time.

**Materials and methods**

**Study design**

This is a retrospective single-center cohort study. Following local Institutional Review Board approval, the electronic medical record was queried for cases of SAE performed for splenic trauma in patients >15 years of age from 1 August 2010 to 31 July 2015. Exclusion criteria were cases of distal SAE, patients who necessitated concurrent procedures (e.g. renal artery embolization, inferior vena cava filter placement, or hepatic artery embolization), cases where both ECs and VPVs were deployed, and instances where fluoroscopy times were not recorded (Table 1). These exclusion criteria were chosen to reduce heterogeneity in the dataset as we examined the differences in plugs and coils for proximal embolization. Proximal versus distal embolization is performed based on operator preference. Our general institutional approach is to perform pSAE for blunt splenic trauma and to reserve distal embolization for penetrating trauma or large pseudoaneurysms. Calculations of power were not performed in the selection of sample size for this study, given that there was not a pre-determined primary endpoint. Charts were reviewed for a 6-month period following embolization. Charted variables, such as patient age, sex, and American Association for the Surgery of Trauma (AAST) grade of splenic injury, were recorded. Rates of splenic salvage were recorded and compared as were major complications according to the Society of Interventional Radiology (SIR) guidelines. Fluoroscopy times, which were used as a surrogate for procedure time and radiation exposure, were analyzed. Fluoroscopy equipment, including screen resolution, imaging protocol, and frames per second, was consistent across multiple fluoroscopy suites for all procedures. Eight operators participated in the procedures with experience ranging from 1 to 25 years. Radial artery access was not attempted. No technical failures were noted. Contrast volume was not recorded.

**Statistical analysis**

Categorical variables were analyzed using the chi-square test or Fisher’s exact test, when applicable. Continuous variables were analyzed using a two-tailed Student’s t-test. A p-value of less than or equal to 0.05 was defined as statistically significant.

**Embolic agents**

VP consisted of AMPLATZER™ (Abbott Laboratories, Chicago, IL) plugs which are a self-expanding, nitinol detachable embolic device. Use of EC was less standardized consisting of both detachable and non-detachable coils in both 0.18 in and 0.35 in sizes from multiple vendors. The decision to use plugs or coils was largely left to operator’s preference.

**pSAE procedure**

The groin is accessed under sonographic guidance; a 6-F vascular sheath is placed, and a 5-F diagnostic catheter is inserted to select the celiac artery. Digital subtraction angiography (DSA) is performed to evaluate the celiac artery. The splenic artery is one of the three main branches from the

| Exclusion reason                           | No. of cases excluded |
|-------------------------------------------|-----------------------|
| Combined proximal and distal embolization | 6                     |
| Other procedures done (e.g. renal angiogram) | 5                     |
| Both plugs and coils used                 | 5                     |
| Distal embolization only                   | 3                     |
| No embolization done                       | 2                     |
| Fluoroscopy time not recorded              | 2                     |
celiac trunk and provides blood supply to the pancreas and stomach as well. The first branch of the splenic artery is the dorsal pancreatic artery and the arteria pancreatica magna is a more distal branch (Figure 1). The ideal position of placement for the embolic agents is between these two branches. Post-embolization angiography of the celiac artery is performed to confirm placement (Figures 1 and 2). Regarding sizing of the VP and ECs, plugs are often sized ~50% larger than the target vessel, while coils typically need to be ~20% greater in diameter than the target vessel; although, this differs based on coil manufacturer and type.21

Results

A flow diagram showing patient characteristics and the type of intervention performed is demonstrated in Figure 3. During the 5-year review period, a total of 49 cases were identified. Of these, 23 cases were excluded from analysis either due to the presence of concurrent procedures, embolization with both coils and plugs, or incomplete charting of fluoroscopy times resulting in a total of 26 cases being included in the analysis. Of the initially identified 49 patients, 38 underwent pSAE alone. Of the remaining 26 cases, 15 patients were treated with VP, while 11 patients were treated with EC. The baseline characteristics of the treatment arms are outlined in Table 2. Mean grade of injury was 3.5 and 4.1 in the VP and ECs groups, respectively, (p > 0.5). Splenic salvage was achieved in every patient in the study. There were no failures in access of the femoral artery. There were no intra-procedural nor delayed complications. Mean fluoroscopy time for the two cohorts is presented in Table 3. Mean fluoroscopy time for the VP group was 15 min, and the mean fluoroscopy time for the EC group was 34 min (p < 0.0001).

Discussion

pSAE plays a pivotal role in the management of blunt splenic trauma patients. The current data are similar to that of a recently published randomized control trial comparing use of plugs and coils in pSAE that found the two embolic agents performed similarly with regard to the rates of splenic salvage and complications.18 In our analysis, plug embolization had the advantage of shorter fluoroscopy time which likely corresponds to shorter procedure time and lower radiation dose.22 Time to treatment is an important measure in trauma centers with a goal at many institutions for endovascular procedures to start within 30 min of initial consult. Time to hemostasis is also an important outcome measure, and it stands to reason that faster procedures would help in achieving that goal. Furthermore, many trauma patients are often young, and therefore radiosensitive.23 Measures to reduce radiation exposure should be taken in concordance with the ALARA principle, for the safety of both patients and interventional staff. Reducing procedure time may have other benefits that were not investigated in this study, such as decreased requirements for transfusion or vasopressors. Reduction of transfusions, in particular, would also allow care teams to be better stewards of often limited resources.

The current data are in line with other studies comparing VP and EC for embolization procedures. For instance, VPs were associated with reduced procedure and fluoroscopy times when used for embolization of the internal iliac arteries during EVAR.24,25 Similar findings were seen when comparing VP and EC for gonadal vein embolization in patients with pelvic congestion syndrome.26 In this study, clinical success rates were similar between the two groups, but VP embolization resulted in shorter fluoroscopy times and smaller radiation doses.26 One study of VP and EC for pulmonary arteriovenous malformation (pAVM) treatment did see a higher rate of recanalization with EC;27 although, this was not seen in this cohort.
Conversely, a pilot prospective study of EC and VP for pSAE found that EC likely had a higher rate of primary technical success than VP. One (2.6%) patient necessitated splenectomy after embolization which is consistent with previously published studies.\textsuperscript{11,20} This patient was treated with both EC and VP, thus was excluded from final analysis per pre-determined exclusion criteria. Certainly, more study in this regard is warranted. Longer fluoroscopy times associated with coil embolization may be due to several factors. First, anchoring and forming a stable coil pack within a high-flow vessel, such as the splenic artery, can be challenging. Second, multiple coils are typically needed to obtain stasis which could increase procedural time. Third, coils may be preferentially used in patients with difficult anatomy (i.e. celiac stenosis) or extremely tortuous splenic arteries where VPs may be difficult to place.

There are limitations to the study including the biases that occur with all retrospective cohort studies. Specifically, it is possible that coil embolization was chosen in cases of unfavorable anatomy which otherwise would have precluded plug placement, making the embolization in the coil group inherently more difficult. However, there is no definitive

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**Table 2.** Baseline patient characteristics of age, sex and laceration grade were analyzed.

|                | Plug (n = 15) | Coils (n = 11) | p-value |
|----------------|--------------|---------------|---------|
| Age            | 50.1         | 45.4          | 0.60    |
| Percent male   | 60 (9)       | 72.7 (8)      | 0.52    |
| Mean AAST laceration grade | 3.5 | 4.1 | 0.10 |

AAST: American Association for the Surgery of Trauma.

No statistically significant difference existed between the two groups in respect to these characteristics. p-values calculated using unpaired Student’s t-test.

Note, two laceration grades for plugs were unknown and one laceration grade for coils was unknown (CTs done at outside hospital, reports unavailable).

**Table 3.** Fluoroscopy time was 2.33 times lower in the plug group compared to the coil group.

|                | Plug       | Coils      |
|----------------|------------|------------|
| Mean fluoroscopy time (min) | 14.5 ± 8.2 | 34.0 ± 12.1 |

Patients who underwent plug embolization had significantly lower fluoroscopy times compared to patients undergoing coil embolization; p < 0.0001, calculated using unpaired two-tailed Student’s t-test.

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*Figure 3.* After identifying 49 patients who had undergone splenic angiogram for trauma, 23 were eliminated for various reasons (see Table 1). Of the remaining 26 patients, 15 underwent proximal embolization utilizing AMPLATZER VPs and 11 underwent proximal embolization using coils.
anatomical point at which either plugs or coils would be favored. It is our experience that operators make these clinical judgments without the use of actual measurements. Second, fluoroscopy time is only an indirect measurement for procedure time and an imperfect surrogate for radiation dose. Unfortunately, dose area product (DAP) and in-room procedure times were not recorded in the electronic medical record. Third, a wide variety of coils were used on patients in this study and with exclusion of newer generation coils, such as the POD® (Penumbra; Alameda, CA). Future prospective randomized controlled trials stratified on an intention to treat with VP or EC would be useful in elucidating potential differences between the two treatment methods to allow interventional radiologists to provide the most effective, prompt, and efficient care possible. Finally, though a cost analysis could be beneficial, one was not performed for several reasons. Given the wide variability in the cost of devices at different institutions, it was felt that a cost analysis of plugs versus coils at a single institution would have limited applicability to other operators. Any cost analysis of these two devices would have to include variables, such as room time, procedure time, and staffing costs among others. The data pertaining to these variables are not available due to the retrospective nature of the study.

Conclusion

In conclusion, pSAE is an important procedure to improve success for patients with high-grade splenic trauma selected for NOM. While both VP and EC appear to achieve high rates of splenic salvage, little is published to help the physician in selecting between these two embolic devices. This analysis shows that pSAE with VP was associated with significantly shorter fluoroscopy times, and by extension, likely shorter in-room procedure times and lower radiation exposure.

Declaration of conflicting interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: A.J.G. is a consultant and speaker for Boston Scientific, a speaker for Terumo, a consultant for Varian, and receives research support from Penumbra.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Institutional Review Board (IRB) of Yale University, Reference No. 1511016744.

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Informed consent

The requirement for informed consent was waived by the Institutional Review Board (IRB).

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