Wake Forest[™] School of Medicine

Improving the Management of Blunt Splenic Injury: A Single Institution's Experience

Background

Non-operative management of hemodynamically stable blunt splenic injury (BSI) is suggested by the Eastern Association for the Surgery of Trauma as appropriate therapy regardless of age, splenic injury grade, and associated injuries. However, this management protocol is not supported by any randomized controlled trials, which has produced some therapeutic controversy. As a result, the National Trauma Institute (principal investigator - Zarzaur, University of Tennessee at Memphis) is sponsoring a prospective study on the outcomes of non-operative management of BSI, despite the fact that little splenic artery embolotherapy (SAE) optimization information is available and standardization of SAE is virtually non-existent.

Introduction

Splenic artery embolotherapy may play an important role in the nonoperative management of BSI; however, the details of how, where, and when this treatment should be employed remain controversial (Smith, 2006). This issue came to the forefront at our institution when the trauma surgeons opted for splenectomy rather than SAE due to the perceived high failure rate for SAE in BSI patients with splenic injury grades 3 to 5.

In response, our IR section undertook a series of projects to evaluate the actual failure rate of non-operative management (both local and national) and to initiate quality improvement programs.

This review found the following systematic problems with the nonoperative management of BSI:

Local:

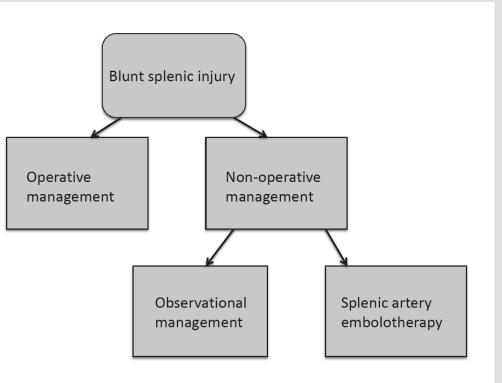
- No IR outcomes review of BSI patients treated with SAE.
- No standardization of SAE technique (proximal vs. distal).
- Our trauma surgeons at their morbidity and mortality conferences added observational management failures to SAE failures.

National:

- The American Association for the Surgery of Trauma Organ Injury Grading Scale (1994 revision) is a surgical grading scale, not necessarily applicable to currently available computed tomography.
- Poor standardization of treatment nomenclature.
- Inadequate information on the optimal embolotherapy technique (proximal vs. distal).
- Inadequate data on the hemodynamic changes in the distal splenic artery after proximal embolotherapy.
- Inadequate information on the short and long term outcomes of SAE.
- No information on the non-operative management of BSI for isolated splenic injury vs. splenic injury in multi-trauma.

Quality Improvement Steps 1. Nomenclature

It became obvious, early in this process, that nomenclature is a problem. Many of the series in the literature include SAE with observational as a type of non-operative management, while in other series, SAE is analyzed separately. To prevent confusion, we have defined the terms nonoperative management, observational management, and SAE as follows:



2. Literature Review

Overwhelming Post-splenectomy Infection (OPSI):

According to a meta-analysis by Bisharat et al, the risk of OPSI in posttrauma splenectomy patients is 3.2%, with a mortality of 1.4% (at a mean follow-up of only 4 years). Additionally, vaccines do not prevent all postsplenectomy infection risk.

The CDC provides the following information:

- Neisseria meningitidis: 20% of patients needed a second vaccination to achieve adequate antibody levels.
- after 3 years.
- Influenza: need yearly vaccinations.
- Vaccinations may be ineffective if patients develop significant comorbidities, such as cirrhosis, diabetes, or chronic kidney disease.

The Risk of Surgery:

Prior to 2008, the risk of splenectomy/splenorrhaphy in the trauma literature was assumed to be negligible. None of the previously published series evaluating the outcomes of BSI non-operative management included surgery outcomes. However, Kaseje and colleagues (2008) and Wei and colleagues (2008) found that the risk of post-splenic surgery complications is 8.7% and 36%, respectively (including delayed bleeding, pancreatitis, and abscess).

- Hemophilus influenza: 12% did not maintain adequate antibody titers

Immunologic Function of the Spleen after Proximal SAE:

Another important mode of failure is functional asplenia. Although any splenic function is better than none, this is a reasonable question.

- Tominaga and colleagues (2009) found that the immunologic profile (IgM, IgG, C3 comlement, completent factor B, helper T cells (CD3, CD4), supressor T-dells (CD8), and complete blood counts) of BSI patients treated with main splenic artery embolotherapy is similar to controls.
- Romero-Torres (1998) found that despite the ligation of the splenic and left gastric arteries (at a treatment of pre-sinusoidal portal hypertension due to splenic vein thrombosis), the spleen was viable with the major blood supply coming from the right gastroepiploic artery.
- Dormagen and colleagues (2008) found that the resistance index of the distal splenic artery after proximal SAE was 0.39 immediately after treatment and returned to 0.52 at 10 months post-treatment. This is compared to the resistance index of healthy volunteers (0.57).

3. BSI at Wake Forest from 2004-2005

An internal retrospective review found that 243 adult patients were admitted for BSI during 2004-2005. Initial therapy was surgery (93, 38.3%), observational management (125, 51.4%), and embolotherapy (25, 10.3%). (Requarth, unpublished data)

For the surgery group, the complication/post-operative event rate is:

- 40% re-exploration of the abdomen
- 2% left upper quadrant abscess
- 5% delayed hemorrhage.

For the embolotherapy group, the complication/event rate is:

- 12% delayed hemorrhage (not statistically different from surgery)
- 33% delayed hemorrhage distal SAE only

4. Monthly Meeting with Surgeons

Interventional Radiology faculty and fellows began attending the monthly trauma multidisciplinary conferences in 2007. At these meetings, we were able to participate in discussions of management issues regarding trauma patients, develop relationships with our referring surgeons, and provide our expertise in collaboration with the surgeons to develop protocols for the management of acute trauma patients.

5. Meta-Analysis

We then performed a meta-analysis of outcomes for BSI published between 1995 and 2009 (Requarth et al. J Trauma 2011;71:898-903). Less than 10% of the outcome data were reported with their respective splenic injury grade, but for those that were, the failure rate of observational management increases with splenic injury grade (20%, 44%, and 83% for grade 3, 4, and 5 injuries, respectively, Figure 2).

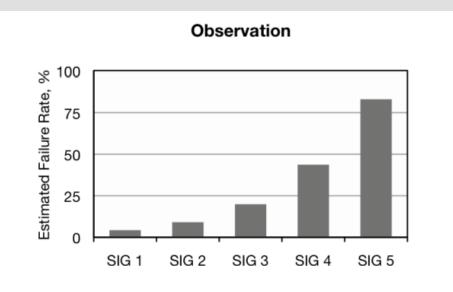


Figure 2: Random effects estimate of failure of observational management of blunt splenic injury (BSI) by splenic injury grade (SIG). The average estimated failure rate is 17.4% (95% CI 10.8-26.9). Only 12.3% of blunt splenic injury patients have SIG 4 and 5 injuries, and their high rate of failure has been lost in the overall averages.

The failure rate of SAE is 18%, 17%, and 25%, respectively, for grades 3-5 injuries (Figure 3). Overall, the failure rate of SAE does not change significantly with severity of splenic injury. Importantly, the failure rate of SAE is significantly less than observation for grades 4 and 5.

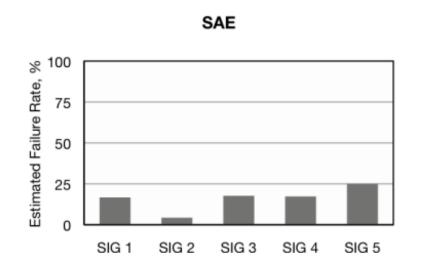


Figure 3: Random effects estimate of failure of splenic artery embolotherapy (SAE) by splenic injury grade (SIG). The overall estimated rate of failure is 15.7% (95% CI 10.4-23.2) and is not statistically different (P=0.413) across the SIG cohorts.

Proximal embolotherapy alone in patients with active extravasation on contrast enhanced CT has a high failure rate and is a unique subgroup with very poor results as can be seen in Figure 4 (Duchesne, 2008).

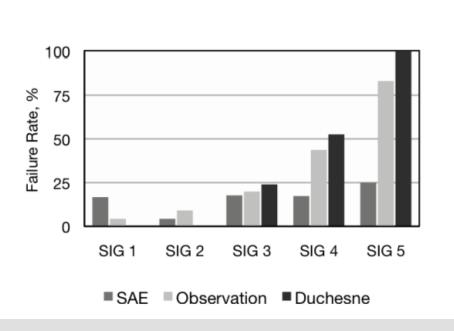


Figure 4: Estimate of failure by splenic injury grade (SIG) for splenic artery embolotherapy (SAE), observational management, and proximal SAE only in patients with active extravasation (Duchesne).

Kurt A. Schoppe, MD, Daniel C. Brown, MD, and Jay A. Requarth, MD, FACS Department of Radiology, Wake Forest School of Medicine, Winston-Salem, NC

6. Mechanism of Delayed Hemorrhage

Our next step was to determine why the failure rate of SAE remains a relatively constant 16% across all grades of blunt splenic injury.

What about pressure in the distal splenic artery?

Rupture of splenic parenchymal pseudoaneurysms is considered the likely etiology of delayed splenic hemorrhage after SAE. Assuming that splenic parenchymal pseudoaneurysms are spherical, the risk of rupture can be modeled mathematically with the Law of Laplace, where σ = wall tension, P = pressure, R = radius, and h = wall thickness.

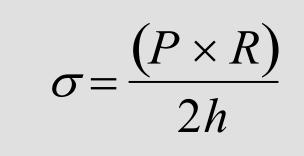




Figure 5: Image of two pseudoaneurysms; the larger is much more likely to upture.

The radius and wall thickness of the pseudoaneurysm cannot be altered; thus, wall tension is directly proportional to distal splenic artery pressure. Theoretically, a reduced pressure in the distal splenic artery will reduce the wall tension of a pseudoaneurysm, which will be clinically manifested as a decrease in the delayed hemorrhage rate.

Splenic hilar collaterals:

The distal splenic artery "stump" pressure is determined during transient proximal splenic artery occlusion using an embolectomy balloon. Preliminary analysis showed that the hemodynamic changes caused by proximal splenic artery occlusion is variable (Requarth. J Trauma 2010; 69: 1423-1426).

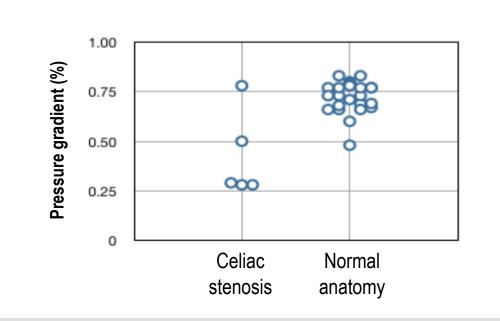


Figure 6: Pressure gradients from the aorta to the distal splenic artery after proximal splenic artery balloon occlusion in patients with celiac artery stenosis and normal anatomy. (Requarth, et al. Unpublished data presented at the American Association for the Surgery of Trauma 2011 Meeting).

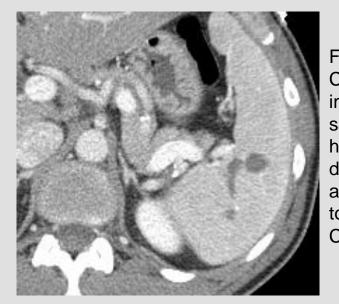
Further analysis of the aorta-splenic artery stump systolic pressure gradient in the normal celiac artery is approximately 75%; whereas, the gradient in celiac artery stenosis can be a little as 28% (Figure 6). We assume that the lack of pressure drop in patients with celiac artery stenosis is due to pre-existing robust collaterals to the splenic hilum.

Blunt splenic injury is a diffuse injury:

Blunt splenic injury is rarely focal, as demonstrated in Figure 7. Thus, distal embolotherapy only will treat the dominant lesion, but will leave the remaining spleen vulnerable to delayed hemorrhage.



Contrast enhanced CT underestimates vascular injuries: Once we began to perform angiography on all grade 3-5 injuries (even without a contrast blush on CT) we were impressed by the poor correlation of CT to angiography findings. Even with delayed imaging, many vascular injuries are missed on CT angiography, as in Figure 8.



7. Designing a Novel BSI Protocol

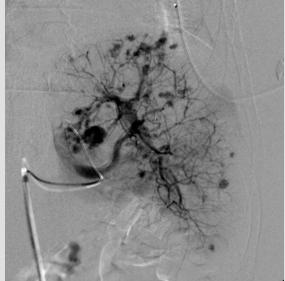
Therapeutic decisions for blunt splenic injury patients were based on multiple factors agreed upon by the interventional radiologists and trauma surgeons.

The following statements are (probably) accepted at many trauma centers:

- Unstable patients need to go to the operating room.
- Stable patients have the option of non-operative or surgical management (splenectomy or splenorrhaphy).
- There are short and long-term risks associated with splenectomy (5% post-op bleeding, 2% abscess, 5% OPSI).
- Immunologically, any spleen is likely to be better than no spleen.
- The distal splenic artery is defined as the trabecular artery beyond the short gastric confluence with the trabecular arteries.
- The target for proximal splenic artery embolotherapy is between the dorsal pancreatic artery and the arteria pancreatica magna.
- Vascular injury, as denoted by a blush on contrast enhanced CT, requires embolotherapy regardless of splenic injury grade.
- Large pseudoaneurysms and active extravasation require distal embolotherapy, which will result in a focal infarction.

Figure 7: Image of explanted spleen showing the diffuse nature of BSI

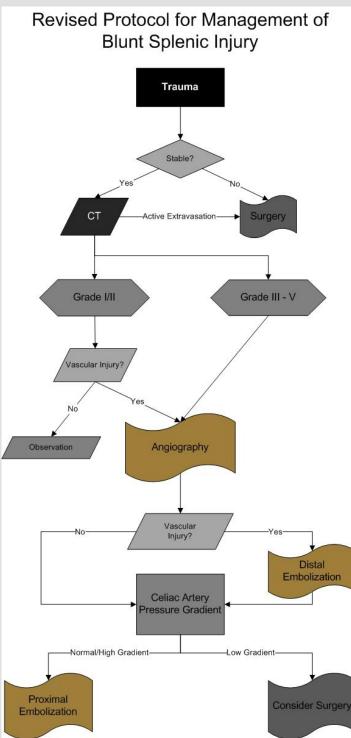
igures 8A and B: CT and angiographic mages form the ame patient highlighting both the diffuse nature of BSI and lack of sensitivity o vascular injuries by



The following statements are either not nationally accepted or may be novel in the treatment of BSI:

- Observational management of grade 4 and 5 injuries is associated with a very high rate of failure, 44% and 83%, respectively.
- Vascular injury is possible (and even likely) in grades 3-5, even without a blush on contrast enhanced CT.
- Grade 3-5 BSI should be treated with proximal embolotherapy to reduce the splenic perfusion pressure to allow for splenic healing.
- After proximal SAE, the pressure in the distal splenic artery stump is highly variable and may depend on the celiac artery anatomy. Preexisting robust collaterals to the splenic hilum may render proximal SAE ineffective.
- Patients with inadequate splenic artery stump pressure drop should be sent back for surgical management.

Putting it all together:



8. Preliminary Data from Protocol

Since institution of our revised BSI management protocol, patients have been unofficially randomized to on-protocol and off-protocol treatment based on the referring surgeon and treating interventional radiologist.

Those treated "on protocol" (n=25) have had a 0% delayed bleeding rate; whereas, the patients treated "off-protocol" (n=14) have a 28.6% delayed bleeding rate (P=0.0122).

Where to go from here?

The retrospective data, meta-analysis, and new protocol were presented to the North Carolina Committee on Trauma in October, 2010. The committee unanimously suggested creation of a non-operative management of BSI registry (<u>https://redcap.tsi.wfubmc.edu</u>)

This registry is designed to compare the outcomes of surgery vs. observation vs. embolotherapy by splenic injury grade and abbreviated injury scores. The distal splenic artery stump pressure can also be entered if obtained (not necessary for inclusion).

This study is also an active (unfunded) multi-institutional study with the Eastern Association for the Surgery of Trauma (principle investigator – Requarth, Wake Forest University). We are actively seeking additional participants.

Conclusions

We demonstrate an internal quality improvement project that improved patient care, expanded basic science knowledge, improved a radiologic product, fostered collaboration between surgery and radiology, and increased referrals to the section of interventional radiology (Figure 9).

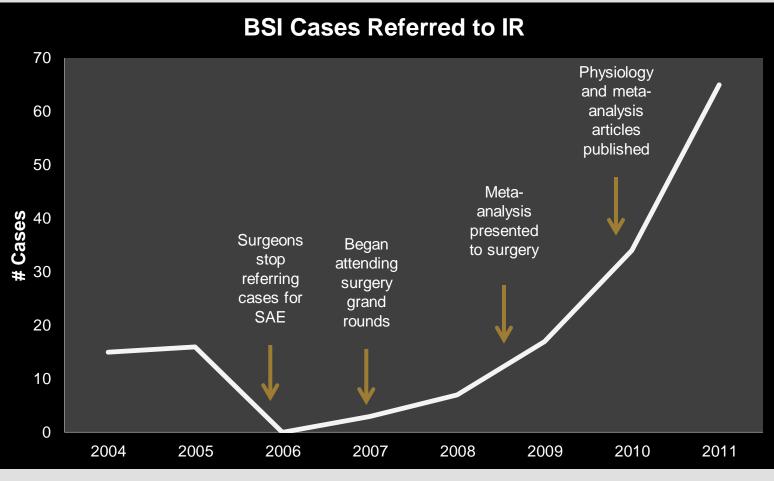


Figure 9:

The BSI referral rate to interventional radiology. The rate for 2011 is an estimate based on the referrals submitted by the RSNA abstract deadline.

Important lessons include:

- 1. Surgical treatment of BSI has inherent risks.
- 2. Interventional radiology departments should participate in surgical morbidity and mortality conferences as part of internal QA and take a co-leadership role in BSI treatment decision making.
- 3. Our data suggests that patients with celiac stenosis are less likely to develop a significant pressure gradient after proximal embolization, which is presumably due to pre-existing collaterals to the splenic hilum.
- 4. The newly developed BSI treatment protocol is significantly more likely to yield successful index treatment than non-protocol therapy.