The Splenic Injury Outcomes Trial: An American Association For the Surgery of Trauma Multi-Institutional Study

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BACKGROUND

Approximately 39,000 adults are admitted with blunt splenic injury (BSI) to hospitals in the United States every year (1, 2). About 10% of these patients will be managed with urgent splenectomy (2-4). The remaining patients are managed using non-operative strategies that have developed over the last three decades (2, 5-13). This shift towards non-operative management (NOM) may have unintended consequences, such as delayed splenic rupture which is particularly worrisome in the outpatient setting (14-16). Other risks may result from strategies aimed at splenic preservation, mainly the use of angiography (ANGIO) and embolization (EMBO). Patients may experience exposure to radiation, invasive procedures, and increased costs as a result of guidelines and treatment algorithms aimed at splenic preservation (15, 17, 18).

There is wide debate in the literature regarding the optimal management algorithm for patients with BSI who do not need urgent operative intervention. Prior work studying various techniques aimed at splenic preservation are retrospective and primarily single center studies. (11-13, 19-25) Even the most recent guidelines published regarding the management of BSI are largely based on expert opinion and retrospective studies (26, 27). This lack of consensus extends to the American Association for the Surgery of Trauma (AAST), where a survey demonstrated variability in the optimal management of BSI (28). Examples of the variation in treatment recommendations include the use of ANGIO, serial computed tomography, serial ultrasonography, and prolonged bed-rest for management of BSI (11-13, 19-25, 29-31).

To begin to address the lack of prospective, multi-institutional data, we proposed a multi-center, prospective observational trial of patients with BSI. The aims of the trial were two-fold. The first aim was to ascertain the 180-day risk of delayed splenic rupture after 24 hours of NOM

of BSI. The second aim was to examine the role of angiography in the management of patients with BSI. Achieving the aims of this study are the first step in a continuum of research that is expected to lead to the development of management strategies that will result in subjecting adults with BSI to the least risk while preserving the most spleens.

METHODS

Participating centers

The AAST multi-institutional trials committee approved this study and participating centers were drawn from membership of the AAST. Eleven Level I trauma centers from across the United States participated. Principle investigators at each participating center were identified. Each participating center's institutional review board approved the study. Study related data were stored using the AAST online data collection service. To ensure that all centers utilized the same definitions for each data point, a standard data dictionary was developed and utilized throughout the study.

Study Population

Adult patients (≥ 18 years old) admitted to a participating center with a BSI managed for 24 hours without splenectomy were eligible for study enrollment. Patients who did not provide consent were excluded from the study. Other exclusion criteria included: 1) more than twenty-four hours from the time of injury to hospital admission; 2) a history of a previous splenic injury; 3) prior history of surgery involving the spleen; 4) a history of a significant bleeding disorder (eg. Factor VII deficiency, Factor VIII deficiency); 5) pregnant women (assessed by a urine pregnancy test); 6) or a history of any of the following: hereditary elliptocytosis; hereditary spherocytosis; sickle cell disease; thalassemia; Hodgkin's or non-Hodgkin'slymphoma; other

lymphomas; leukemia; polycythemia vera; myelofibrosis; metabolic storage diseases; amyloidosis; splenic vein thrombosis; cirrhosis; splenic cysts; sarcoidosis; or systemic lupus erythematosus.

Study Protocol

After enrollment and consent, demographic data, past medical history, past surgical history, and current medication usage were obtained. Detailed injury, physiologic and laboratory data were also recorded. Images and interpretations of the admission computed tomography (CT) exams of the abdomen were obtained. Patients were followed while in hospital and then as outpatients at 30, 90, and 180 days. Where possible, follow-up was performed face-to-face. If a face-to-face exam was not possible, a telephone follow-up was performed using a pre-defined standard script. The social security death index was utilized to determine if a patient had died after hospital discharge.

Initial spleen injury grading was obtained from the official radiology report from the admission CT using the AAST spleen injury grading scale. If a radiology report was not available or if the radiologist did not mention a AAST spleen injury score, the site PI graded the injury. Standard definitions were used to define splenic pseudoaneurysm (PSA) and splenic blush. A splenic PSA was defined as an abnormal accumulation of contrast contained within the parenchyma of the spleen. A splenic blush was defined as any extravasation of contrast outside the parenchyma of the spleen.

Spleen Related Interventions and Outcomes

The main outcome was splenectomy. However, detailed data regarding other spleen related interventions were also obtained. Spleen related interventions were defined as any use of ANGIO (with or without EMBO) or any operation on the spleen that did not result in

splenectomy. Indications for spleen related interventions were also recoded. Secondary outcomes of interest were hospital and intensive care unit length of stay and mortality.

Statistical Analysis

Bivariate analysis was performed to determine variables associated with splenectomy and the use of ANGIO and EMBO. Multivariable analysis was used to determine factors independently associated with splenectomy and angiography with embolization. Variables that had a $p<0.20$ or that were considered clinically significant were eligible for inclusion in multivariable models. A $p<0.05$ was considered significant. All risks are reported relative to a time-frame and rates are reported with person-time in the denominator. SAS 9.2 (SAS institute, Cary, NC) was used for all statistical analysis.

RESULTS

There were 1002 patients screened and 383 were consented and enrolled. Of those enrolled, 371 were discharged alive with a spleen. Follow-up was 95% at 30 days, 88% at 90 days and 87% at 180 days. The median age was 36 years (IQR 25-52) and 65.2% were male. The vast majority of patients were white and the median ISS was 22 (IQR 14 – 27). The AAST spleen injury grade was III - IV for 42.8% of patients. Splenic PSA were present in 8.4% of patients and splenic blushes were present on 12.9% of patients. ANGIO with EMBO was utilized in 18.7% of patients. Overall mortality was 1.04%, and no deaths were spleen related (Table 1).

The flow of patients through the study is outlined in Figure 1. Of the 383 patients, 70 underwent ANGIO at admission. Of those, 9 had no EMBO and one went on to splenectomy. One patient underwent a second ANGIO with EMBO. This patient did not require a

splenectomy. Sixty-one of the 70 patients that underwent ANGIO at admission had EMBO. Forty-eight had no further angiographic intervention and 2 required splenectomy. Thirteen patients underwent repeat ANGIO with 5 undergoing a second EMBO and 8 requiring no further EMBO. None of the 13 patients who underwent repeat ANGIO had a subsequent splenectomy. Of the 313 patients who had no ANGIO at the time of admission, 21 underwent ANGIO > 24 hours after admission. Ten of those had EMBO and there were no splenectomies. Eleven had no EMBO and three suffered a subsequent splenectomy. Of the 292 patients that were observed without ANGIO, seven required a splenectomy.

Of the 61 patients who underwent ANGIO and EMBO within 24 hours of admission, 51 (84%) had a primary indication that was the presence of a blush or PSA or both on initial CT scan. For 2 patients (3%) the primary indication was hemodynamic instability. In the remaining 8 patients (13%) the main indication was the appearance of the spleen on CT scan. Five of the 8 had a Grade III injury and 1 had a Grade IV injury. The remaining had Grade I and II injuries. Four of the eight had a repeat ANGIO and 1 had a repeat EMBO. There were no splenectomies in the 8 patients for whom the only indication for ANGIO and EMBO was the appearance of the spleen on CT scan. For the 9 patients who had ANGIO with no EMBO within the first 24 hours of admission, the primary indication for ANGIO was the presence of a blush or PSA or both in 8 patients. In 1 patient, the grade of the injury (Grade III) was the main indication. This patient went on to require an additional ANGIO and EMBO.

Overall, the risk of splenectomy while in hospital was 3.1%. The risk of outpatient splenectomy was 0.24% within 180 days. The overall splenectomy rate after 24 hours of NOM was 1.5 splenectomies per 1000 patient-days. The time course to splenectomy by injury grade is shown in Figure 2. The vast majority of splenectomies occurred within 10 days

of injury. There were no statistical differences based on grade of injury and time to splenectomy. Further, no grade I injuries required a splenectomy. Factors associated with splenectomy on bivariate analysis are shown in Table 1. Increasing age, injury severity score, spleen injury grade, admission contrast blush, and other solid organ injury all met criteria for inclusion in multivariable models. Only extravasation outside the spleen parenchyma at time of admission was associated with splenectomy (OR 3.6; 95% CI 1.4, 12.4;AUC=0.722;Hosmer and Lemeshow Goodness of Fit Test p=0.1626) after controlling for other factors. While not one of our primary outcome measures, ICU and total hospital LOS were significantly higher for those patients undergoing splenectomy.

In table 2, those who underwent ANGIO and EMBO are compared to those that did not. This analysis was done for all spleen injury grades and for BSI grades III – V. Considering all grades, the 180-day risk of splenectomy was 3.5% for those who did not undergo ANGIO with EMBO and 2.8% for those that did. The difference was not statistically significant. For grades III – V, the 180-day risk of splenectomy was 6.9% for patients who did not undergo ANGIO with EMBO and was 3.2% for those who did. There was no statistical difference between the groups. When we limited the analysis to patients with only Grades 4 and 5 injures the numbers were similar. There were 56 patients (50 Grade IV and 6 Grade V) spleen injuries. Of those, 34 underwent ANGIO with EMBO. Of those, 2 failed (6%). Of the 22 who did not have angioembolization, 3 required splenectomy (14%). Again, the difference was not statistically significant.

Because admission contrast blush was associated with splenectomy, we examined the use of ANGIO and EMBO in these patients. Of patients with an admission contrast blush (n=49), 17 (34.7%) did not have ANGIO and EMBO and 2 of those (11.8%) underwent splenectomy; 32

(65.3%) underwent ANGIO and EMBO and 2 of those (6.3%) required splenectomy. There was no statistical difference between those treated with ANGIO and EMBO and those not treated with ANGIO and EMBO.

DISCUSSION

This study represents the first attempt to collect multi-institutional, long-term prospective data for patients with BSI. The results shed light on two issues in the management of BSI. The first is the risk and timing of inpatient and outpatient splenectomy. After the first 24 hours, the risk of splenectomy is relatively rare and occurs in 3.1% of patients while in-hospital. In the outpatient setting the risk is even lower, 0.27% over 180-days. Overall, the vast majority of splenectomies occurred within 10 days of injury. Second, in this study, the benefit of ANGIO and EMBO in BSI are brought into question, highlighting the need for further multi-center trials.

Regarding the in-hospital risk of splenectomy after non-operative management for 24 hours, we observed a risk of 3.4%, which is consistent with this literature. Previously published retrospective studies estimate the in hospital risk of splenectomy after the first 24 hours range from 3% to 10% (2, 3, 30, 32). Turning to the outpatient setting, the literature is less clear. After hospital discharge, the risk for splenectomy is reported to range from 0.16% to 1.4% (2, 14, 16, 33, 34). In a large retrospective, multi-institutional study, Peitzman et al noted that 6 splenectomies, or 0.76% of their retrospective cohort, occurred after hospital discharge (2). A higher risk of splenectomy after discharge was found after in two studies that linked trauma registry data to state discharge databases. Of patients discharged alive after a BSI, 1.1% - 1.4% were readmitted and had a splenectomy (14, 16). Our prospectively collected data revealed an outpatient splenectomy risk of 0.27% over 180-days.

The timing of splenectomy was also important. In the current study, 70% of all splenectomies occurred within 7 days of injury. These data are consistent with a study using the National Trauma Data Bank that showed that 96.5% of splenectomies occur within 5 days of BSI (35). It is important to keep in mind that in the current study many of the patients were severely injured and had a long hospital length of stay increasing the chance that splenectomies would be observed while the patients were hospitalized.

Perhaps the most controversial question in the management of BSI revolves around ANGIO use to increase splenic salvage. Some advocate ANGIO for essentially all non-operatively managed high grade BSI (AAST Injury Grade III-IV) and for lower grade injuries (AAST Injury Grades I-II) that have evidence of active bleeding or parenchymal vascular lesions on admission CT scan (9, 12, 24). Not all authors are in agreement with this management recommendation. Harbrecht et al outlined the arguments against the use of ANGIO and EMBO in the setting of BSI. The authors demonstrated in retrospective studies that there has been a significant increase in the detection of minor BSI over time (3, 36). The authors argue that the success attributed to ANGIO with EMBO in studies using historical controls may be the result of time dependent increase in the detection of relatively minor BSI (which are less likely to bleed in the first place) as opposed to the effect of ANGIO and EMBO. Further, Peitzman et al argue that perhaps some patients for whom splenectomy was delayed may have been inappropriately triaged. After reviewing the charts of 80 patients in a multi-institutional, retrospective study, the authors found that 25% of patients with BSI that ultimately failed were hemodynamically unstable up until the time of either splenectomy or death (15).

The findings in the current study also provide a note of caution regarding the use of delayed ANGIO. There were 21 patients who underwent delayed ANGIO. Out of those, 10 had

an embolization and 11 had no embolization. Of the 11 who had no embolization, 3 had a splenectomy. Of the patients who required splenectomy, the indications for delayed angiography were transfusion of blood and hemodynamic instability. In no other patients who underwent delayed ANGIO was the indication for the delayed ANGIO hemodynamic instability or blood transfusion. Thus, in patients with spleen injuries who develop hemodynamic instability or who require blood transfusion, consideration should be given to proceeding directly to splenectomy and not obtaining ANGIO.

In the current study, ANGIO on admission was used in 18.3% and EMBO was performed on 87.1% of patients who had ANGIO. Taking all injury grades into account, there was no statistically significant difference for patients managed with ANGIO and EMBO compared to those managed without ANGIO and EMBO. The same was true for grades III – V BSI. Even when the highest risk patients in the study (those with a contrast blush on admission CT) were examined, ANGIO and EMBO was not associated with splenic salvage.

Lack of statistical significance for the use of ANGIO and EMBO in the management of BSI, particularly high grade BSI, is intriguing. One explanation is that the study may suffer from Type II error. To explore this possibility we performed a power analysis. This power analysis revealed that 906 patients with Grades III-V BSI would need to be randomized to either management with ANGIO and EMBO or watchful waiting for 80% power to detect a statistical difference at the 0.05 alpha level. In a non-randomized observational trial the number of patients needed to detect a difference at the same levels is higher. Despite an aggressive recruitment campaign and funding for this prospective study that required patient consent and long-term follow-up, we still fell below expected enrollment targets. We also had a low proportion of patients enrolled out of those who were screened. The low proportion of enrolled patients for

this study was due to variation in screening procedures at some study sites at the beginning of the study. Some sites reported all trauma patients admitted as "screened" even if they did not have a spleen injury. Some sites included patients who had a splenectomy within 24 hours as "screened". With standardization and education regarding screening and enrollment, the screen to enroll numbers were more in line with what was expected. These challenges offer lessons regarding resource allocation for future prospective studies in this patient population.

There are also public health implications of a weaker than expected effect of ANGIO and EMBO. Based on national estimates, 39,000 people will suffer a BSI every year (1, 2). Of those, 10% will have splenectomy within 24 hours of admission leaving 35,100 patients with BSI managed non-operatively for at least 24 hours(37). Based on data from the current study for all injury grades, 8340 patients would have at least 1 ANGIO and of those 552 would have splenectomy. Of the 26,760 who would never get an ANGIO, 639 patients would require a splenectomy. The difference is only 87 potentially saved spleens. Similar calculations for the estimated 15,030 patients who would be expected to have grade III – V BSI reveal that only 274 spleens would potentially be saved. Though three times as many spleens would be saved, it is possible that the high resource utilization for ANGIO and EMBO is not justified for such a limited number of saved spleens. Resource utilization versus patient outcomes is an area of debate and it is likely that only large-scale, patient-centered, randomized controlled trials will help resolve these issues.

The results, while provocative, need to be viewed in light of this study's limitations. The definitions used to define splenic blushes and PSA may be inconsistent with previously published studies in the literature. This could limit the ability to compare this study to previous works as well as limit generalizability of this study. However, due to the lack of a clear

consensus definition during the design of this study, the authors decided on the definition outlined in the methods section of the manuscript. The definition used in this study was applied consistently to all CT scans. Also, there was no protocol for the management of patients with BSI and there was considerable variation in the types of patients for whom ANGIO and EMBO was utilized. This limits our ability to make management recommendations. There were limited data available regarding the amount and timing of blood transfusions, thus we are unable to comment on blood transfusion in the setting of BSI. Further, because the study focused on patients managed non-operatively for the first 24 hours, we do not have information regarding patients who had splenectomy in the first 24 hours.. It is well known that there is significant variation in the use of early splenectomy as well as ANGIO (37, 38). A center with a liberal splenectomy policy on admission may enroll a different type of patient compared to a center with a more restrictive splenectomy policy on admission. This could influence the results of the analysis, particularly in reference to ANGIO and EMBO. Further, the observed mortality in this study was low given the severity of injuries. This could be a result of selection bias to exclude patients who were likely to die. It is also possible that the 24-hour cutoff for study inclusion may have also contributed to the low mortality by excluding patients who died early.

Despite good follow-up for the study, well above 80% for all time points, patients who followed up could have been somehow different compared to those who did not and this could bias the results. We also looked to see if the lost to follow-up population was examined to evaluate if they were significantly different than the study population. We found no statistical differences.

Resource utilization, complications, and cost are very important issues when trying to determine which treatment is optimal for patients with BSI. Intensive care unit length of stay,

hospital length of stay, operating room costs, transfusion requirements, and the costs of ANGIO and EMBO are all important to consider. There is also the potential for complications from splenectomy such as subphrenic abscess, pancreatic tail injury, bleeding from short gastrics, enterotomy or fistula from bowel injury, adhesive bowel obstructions, and ventral hernias, to name a few. Complications from ANGIO and EMBO such as arterial injury, splenic abscess, and splenic infarction should also be considered. In this study, there is minimal information regarding complications of ANGIO, EMBO, or splenectomy, so, we cannot comment on the risks or costs associated with any of these procedures.

Despite these limitations, there are important conclusions to be drawn from the data for patients with BSI managed non-operatively during the first 24 hours. After the initial 24 hours, no additional interventions are warranted for patients with Grade I injuries as long as there are no concerning features on admission CT such as a splenic blush or a subcapsular hematoma. For grade II – V BSI, observation is indicated for 10 – 14 days as this is the time of greatest risk of splenectomy. Observation could occur in hospital or as an outpatient with explicit instructions for signs and symptoms of bleeding. Further, patients with grades III – V BSI may benefit from ANGIO, but the effect may be small. Watchful waiting is also a viable strategy for these patients. Ultimately, a randomized study is needed to definitively make recommendations regarding ANGIO use and BSI. Any such study would require at least 450 patients per group and a large multi-center trial is necessary to accrue these numbers. The AAST is well positioned to carry out such a trial and this is the next step in the development of management strategies that will result in subjecting adults with BSI to the least risk while preserving the most spleens.

Author Contributions:

Study Design: Zarzaur, Coimbra, Kozar

Data Collection: Zarzaur, Kozar, Myers, Claridge, Scalea, Neideen, Maung, Alarcon, Corcos, Kerwin, Coimbra

Data Analysis and Interpretation: Zarzaur

Drafting of Manuscript: Zarzaur

Critical Revisions: All authors

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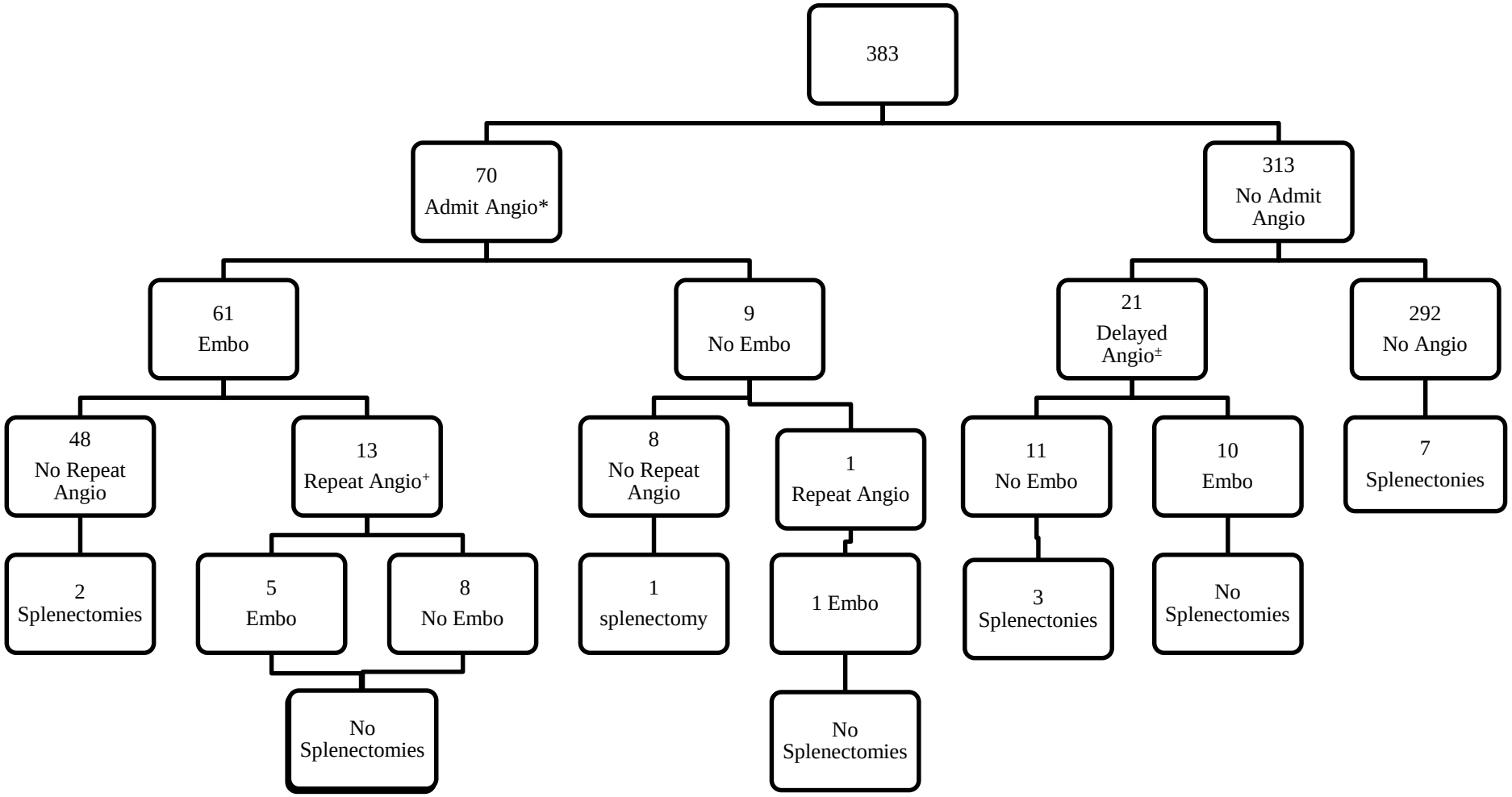
Table 1. Characteristics of patients with blunt splenic injury who did or did not undergo splenectomy within 180-days

Variable	Entire Cohort	Splenectomy		*p*-value
		No	Yes	
	n=383	n=370	n= 13	
Age (years)	36(25, 52)	35 (25, 52)	47 (40, 56)	0.1217
Male (%)	65.3	64.9	76.9	0.5552
Body Mass Index (kg/m^2)	26.7 (23.2, 31.6)	26.8 (23, 2, 316)	25.1(23.3, 32.3)	0.9099
Injury Severity Score	22 (14, 27)	22 (14, 27)	22(21,26)	0.167
Admit Systolic Blood Pressure < 90 mnHg (%)	5.5	5.5	8.3	0.5007
Admit Hematocrit (g/dl)	39 (35, 42)	39 (35, 42)	41(32,42)	0.7891
Admit International Normalized Ratio (IU)	1.04 (1.00, 1.12)	1.00 (1.00, 1.12)	1.00 (0.95, 1.05)	0.2992
Spleen Injury Grade (%)				0.0502
1-2	57.2	58.1	41.9	
3-5	42.8	30.8	69.2	
Admit Pseudoaneurysm (%)	8.4	8.5	8.3	0.9889
Admit Blush (%)	12.9	12.2	33.3	0.0548
Other Solid Organ Injury (%)	28.5	27.8	46.2	0.2072
Hollow iscus Injury (%)	4.2	4.1	7.7	0.431
Angiography with Embolization (%)	18.7	3.5	2.8	0.7485
Intensive Care Length Of Stay (days)	3 (1, 6)	3 (1, 6)	6 (3, 13)	0.0278
Hospital Length Of Stay (days)	6 (3, 11)	6 (3, 10)	12 (6, 15)	0.0304
Mortality (%)	1.04	1.1	0	0.7063

Table 2. Risk of splenectomy with and without angiography with embolization

	All Grades		
	No Angiography and Embolization (n=311)	Angiography and Embolization (n=72)	p-value
Splenectomy	3.5%	2.8%	1.0
	Grade 3 - 5		
	No Angiography and Embolization (n=102)	Angiography and Embolization (n=62)	p-value
Splenectomy	6.9%	3.2%	0.4851

Figure 1: Flow Chart of Patient Outcomes



* Indications for admit angiography: 30 Pseudoaneurysm, 37 blush, 5 unstable, 2 drop in hematocrit, 2 transfusion of blood, 13 others

+Indications for repeat angiography: 2 Pseudoaneurysm , 3 unstable, 7 follow-up angiography

± Indications for delayed angiography: 4 Pseudoaneurysm , 2 unstable, 4 drop in hematocrit, 2 transfusion of blood, 5 follow-up angiography

Note: Indications may not add up to the total due to either missing information or due to the fact that patients could have more than one indication.

Figure 2. Time course to splenectomy by injury grade