Pelvic Angioembolization

A Prospective Multi-Institutional Study

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Brief Summary

Introduction: The treatment of hemorrhage from pelvic fractures poses a significant challenge for trauma surgeons. Embolization has become the standard of care to treat pelvic fracture-associated hemorrhage and is indicated in approximately 3-10% of pelvic fractures.[1,2] However, pelvic angiography only identifies arterial sources of bleeding. The best treatment for pelvic fracture-associated hemorrhage is still not resolved in two specific clinical scenarios. The first scenario is in the presence of a negative angiogram either due to intermittent or non-arterial hemorrhage. Arterial embolization, in theory, can be done to treat pelvic venous bleeding by decreasing the arterial pressure head; however, there is limited data in the literature to support this theory. The second scenario is in angiograms that are positive for arterial hemorrhage; controversy exists as to when nonselective embolization (NSE) vs. selective embolization (SE) is appropriate.

Study Design: Prospective, Multi-Institutional Study

Aim: To determine if embolization of patients without an identified arterial source of bleeding, negative angiogram, would aid in hemorrhage control. When the angiogram is positive, to determine which level of embolization, nonselective or selective, is superior?

Methods: All blunt trauma patients undergoing angiography for pelvic fracture associated hemorrhage will be eligible for the study. Demographic, physiologic, operative, and post-operative data will be collected including blood product resuscitation, classification and management of pelvic fracture, associated injuries, angiographic details, complications, outcomes and overall injury burden. The study population will be stratified based on presence of arterial hemorrhage on initial angiogram (positive or negative angiogram) and then further stratified based on performance of embolization. NSE will be defined as embolization of the main internal iliac artery, either unilaterally or bilaterally and SE as any embolization distal to the main internal iliac artery. Bivariable and multivariable analyses will be performed to determine differences in

pelvic hemorrhage as measured by transfusion necessity and quantity of products required, complications and to identify independent risk factors for outcome variables. A power analysis was performed based off of thromboembolic complication difference in selective vs non selective embolization and then again with blood transfusion requirement difference in embolized vs not embolized for those who have no evidence of arterial bleeding on angiogram (IE the two questions we are trying to answer).

For the first a total of 285 subjects will be required to test a difference in proportions of 0.10 (0.03 for selective and 0.13 for non-selective) with 80% power at 0.05 significance level. Assuming we observe a similar selective to non-selective subjects ratio (1:2), the selective group will require 95 subjects and the non-selective group will require 190 subjects.

For the negative angio pts a total of 150 transfused negative angio subjects will be required to test a difference in 3.5 PRBC units (STD = 7.35) between embolized vs. no intervention. However, we had 67 with negative angiogram (on the retrospective study) out of 194 patients of which 78% received a PRBC transfusion within 24 h. For prospective study will need to get a total of 550 patients to get 150 with negative angio and transfusion.

Goal enrollment is 550 patients.

Background and Significance

The treatment of hemorrhage from blunt trauma-associated pelvic fractures poses a significant challenge for trauma surgeons. This type of hemorrhage has a reported mortality of 8.8-35.5% in hemodynamically unstable patients.[1,3] The treatment of pelvic fracture-associated hemorrhage by embolization has become the standard of care and is indicated in approximately 3-10% of pelvic fractures.[1,2] However, pelvic angiography only identifies arterial sources of hemorrhage while, 85% of pelvic fracture-associated bleeding originates from the venous circulation and bone.[4]

The best treatment for pelvic fracture-associated hemorrhage is still not resolved in two specific clinical scenarios. The first scenario is in the presence of a negative angiogram. The angiogram in this case may be negative due to either the intermittent nature of the hemorrhage or because the bleeding source is venous. Arterial embolization, in theory, can be done to treat pelvic venous bleeding by decreasing the arterial pressure head; however, there is limited data in the literature that support this theory. The second scenario is in angiograms that are positive for arterial hemorrhage; there is controversy as to when nonselective embolization (NSE) vs selective embolization (SE) is appropriate.

Embolization of the internal iliac arteries is not without risk. Potential complications of nonselective internal iliac embolization are as follows: gluteal necrosis, wound complications, claudication, neuropathy, poor fracture healing and impotence. The frequencies of these complications range from 3.3% to 66% .[5-14] While these complications are referenced in the literature as due to pelvic embolization, controversy does exist as to whether they are in fact a result of the initial injury.

Rational

Utilization of angiographic techniques to control pelvic hemorrhage in the blunt trauma patient with pelvic fractures is widely accepted as standard of care. When the angiogram is negative, whether or not to perform a non-selective embolization of the main internal iliac arteries is unclear. We recently performed a multicenter retrospective study which showed that in the bleeding patient, non-selective embolization does in fact decrease hemorrhage as measured by blood transfusion requirements (7.5 units PRBCs vs. 4.0, p=0.05). However, the sample size was small with only sixty-seven patients having a negative angiogram. [15]

Should the angiogram identify a bleeding artery, the decision to embolize is more straightforward. Where to embolize, non- selective embolization vs. selective embolization, is not well defined. In our recent retrospective study, we found that non-selective embolization was associated with more complications including significantly

increased thromboembolic events (12.0% vs. 0%, p=0.01).[15] We were unable to clearly differentiate whether this difference was directly attributable to the embolization or to a difference in fracture pattern between the groups.

The findings of our retrospective study are theoretically explained by non-selective embolization decreasing the arterial pressure head across the pelvic vasculature and therefore decreasing venous hemorrhage. The decreased venous flow slows bleeding but potentially at the cost of increasing thromboembolic events. These preliminary findings have provided the basis for the current prospective observational multi-institutional trial designed to further investigate the use of embolization in patients with negative angiogram and to ascertain whether the observed complications are truly associated with non-selective embolization.

Description

We propose a multicenter prospective observational study to investigate the use of embolization in patients with negative angiogram and to ascertain the optimal level of treatment when the angiogram is positive; non-selective vs. selective embolization. We will divide patients into groups based on positive or negative angiogram. Within each group we will compare those embolized and level of embolization.

Patient Selection:

All blunt trauma patients undergoing angiography for pelvic fracture associated hemorrhage will be eligible for the study. Pregnant and pediatric patients < 18 yrs will be excluded. Patients undergoing angiography greater than 24 hours from arrival will be excluded. Patients will be stratified based on outcome of initial angiography (positive vs. negative angiogram). Patients will be further stratified based on angiographic management (embolization or no intervention).

Study variables:

The following variables will be abstracted for the study:

Demographics and physiologic data: age, sex, mechanism of injury, associated injuries, ISS, pelvic AIS, procedures performed, initial SBP and HR, use of pelvic binding, DVT prophylaxis and admission labs (lactate, base deficit, pH, Hb).

Pelvic fracture Data: Pelvic fracture classification using Young Burgess system, type of fracture if not included in Young Burgess classification system and management of fracture. Additionally, we will collect REBOA centered information such as presence of zone 3 hematoma, availability and utilization of REBOA.

Angiographic data: Date and time of admission and angiography, length of angiographic procedure, results of initial angiogram and interventions performed including material used for embolization. NSE will be defined as embolization of the main internal iliac artery, either unilaterally or bilaterally and SE as any embolization distal to the main internal iliac artery.

Outcomes: ICU and hospital length of stay, mortality, transfusion requirements in the first 24 hours, and the use of MTP. Inpatient complications will be recorded and focus placed on those thought to possibly be due to embolization such as wound infections/breakdown, gluteal/skin necrosis, osteomyelitis and pelvic abscesses. Outpatient follow up including functional status and complications possibly related to embolization including claudication, urogenital complications, sexual dysfunction, numbness or pain of the pelvis and lower extremities and late wound complications or nonunion. Occurrence of thromboembolic complications will be collected such as DVT or PE as well as DVT location.

Primary outcome measures include mortality, transfusion requirements and thromboembolic events. Additional outcomes will include the occurrence of those complications seen as theoretical complications of limiting pelvic blood flow which are listed above.

Limitations:

The decision when and where to embolize will be largely based on interventional radiologist and surgeon preference however, as this is not designed as a randomized trial, patient factors or intraoperative findings may influence that decision. In order to accommodate this potential bias, we will correct for patient and injury characteristics and, in addition, include questions regarding reasoning for management decisions.

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