



## **EAST MULTICENTER STUDY PROPOSAL**

*(Proposal forms must be completed in its entirety, incomplete forms will not be considered)*

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### **GENERAL INFORMATION**

**Study Title:**

**Functional Outcomes after Post-Traumatic Pelvic Embolization**

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**Primary investigator / Senior researcher:**

**Ravi R Rajani, MD**

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**Co-primary investigator:**

**JJ Dubose, MD**

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### **BACKGROUND AND SIGNIFICANCE**

Pelvic embolization following trauma is often acutely required to assist with hemorrhage control. While there is limited data suggesting a higher complication rate following non-selective embolization, there is limited information available assessing the long-term functional outcomes following pelvic vessel sacrifice. Buttock necrosis and impaired wound healing are known complications when such procedures are performed in non-traumatic sessions. However, more subtle complaints – including buttock claudication, sexual dysfunction, and exercise intolerance – have not been previously examined as a possible outcome.

**The specific aims of this multicenter study are:**

Primary aim:

**To assess the long-term functional outcomes and complications following post-traumatic pelvic embolization.**

Secondary aims:

**To assess the short term influence on orthopedic healing following pelvic embolization.**

**To correlate post-embolization outcomes with technique utilized, including methodology of embolization and specificity of embolization.**

## **EXPERIMENTAL DESIGN/METHODS**

### **Inclusion Criteria:**

**Victims of blunt trauma with known pelvic fracture requiring angioembolization**

### **Exclusion Criteria:**

**Standard exclusion criteria, including children, pregnant individuals, and disadvantaged populations.**

### **Therapeutic Interventions:**

**Prospective observational study. Interventions would be performed per individual hospital standard-of-care. Patients will be enrolled post-embolization, and followed with subsequent objective and subjective evaluation.**

### **Outcomes Measures:**

#### **Primary Outcome:**

#### **Mortality**

**Short- and long-term wound healing**

**Buttock claudication**

**Sexual dysfunction**

**Gluteal necrosis**

#### **Secondary Outcomes:**

**Length of stay**

**Discharge disposition**

**Bony nonunion**

**Other orthopedic complications**

**Pelvic sepsis**

**Variables:**

Demographics

Age  
Sex  
Comorbidities

Injury characteristics

Mechanism  
Injury Severity Score  
Type and grade of pelvic fracture  
Initial heart rate, blood pressure, and base deficit  
Length of stay  
Discharge disposition

Embolization characteristics

Methodology of embolization (glue, coils, etc.)  
Specificity of embolization (degree vessel obliterated)  
Embolization-specific complications

Outcomes

Lower extremity ankle-brachial index (3, 6, and 12 months)  
Edinburgh Claudication Questionnaire (3, 6, and 12 months)  
Pain-free walking distance (3, 6, and 12 months)  
IIEF erectile dysfunction survey (males only at 3, 6, and 12 months)  
Wound non-healing or bony non-union (3, 6, and 12 months)  
Presence of buttock or lower extremity rest pain (3, 6, and 12 months)  
Presence of buttock or thigh tissue loss (3, 6, and 12 months)

**Data Collection and Statistical Analysis:**

Standardized data will be collected for each patient. Functional outcomes will be assessed via standardized validated patient-performed surveys at outpatient follow-up. Risk factors for complications of post-embolization functional complications will be assessed using standard univariate and multivariate analysis.

**Consent Procedures:**

Consent will be sought following embolization during the same hospital stay. Surveys will be administered at outpatient follow-up, and data will be stored in a secure de-identified database.

**Risk/ Benefit Analysis:**

The incidence of functional impairment after post-traumatic pelvic embolization remains unknown. In addition, the impact of embolization specificity on rates of wound healing and post-embolization complications remains unclear in a young patient population without pre-existing atherosclerotic disease. If very selective embolization is associated with improvements in functional outcome, then every attempt at selective embolization should be made during initial management. Conversely, if there is no difference in outcomes, expeditious main trunk embolization may be appropriate to facilitate early hemorrhage control.

**Instructions for submitting data collection tools:**

All data submissions should be entered through the EAST Multicenter Trial Taskforce website portal. Instructions can be found on the EAST website. The data collection sheet located under the Multicenter Trial Taskforce heading for this study can be utilized to record the data, and then the information transferred to the portal entry system. For any questions regarding this study, please contact the PI.

## References:

1. Papadopoulos IN, Kanakaris N, Bonovas S, et al. Auditing 655 fatalities with pelvic fractures by autopsy as a basis to evaluate trauma care. *Journal of the American College of Surgeons*. 2006;203(1):30–43. doi:10.1016/j.jamcollsurg.2006.03.017.
2. Cullinane DC, Schiller HJ, Zielinski MD, et al. Eastern Association for the Surgery of Trauma practice management guidelines for hemorrhage in pelvic fracture--update and systematic review. *J Trauma*. 2011;71(6):1850–1868. doi:10.1097/TA.0b013e31823dca9a.
3. Costantini TW, Bosarge PL, Fortlage D, Bansal V, Coimbra R. Arterial embolization for pelvic fractures after blunt trauma: are we all talk? *Am J Surg*. 2010;200(6):752–7– discussion 757–8. doi:10.1016/j.amjsurg.2010.06.006.
4. Katsura M, Yamazaki S, Fukuma S, Matsushima K, Yamashiro T, Fukuhara S. Comparison between laparotomy first versus angiographic embolization first in patients with pelvic fracture and hemoperitoneum: a nationwide observational study from the Japan Trauma Data Bank. *Scand J Trauma Resusc Emerg Med*. 2013;21(1):82. doi:10.1186/1757-7241-21-82.
5. Velmahos GC, Toutouzas KG, Vassiliu P, et al. A prospective study on the safety and efficacy of angiographic embolization for pelvic and visceral injuries. *J Trauma*. 2002;53(2):303–8– discussion 308. doi:10.1097/01.TA.0000021534.02435.35.
6. Matityahu A, Marmor M, Elson JK, et al. Acute complications of patients with pelvic fractures after pelvic angiographic embolization. *Clin Orthop Relat Res*. 2013;471(9):2906–2911. doi:10.1007/s11999-013-3119-z.
7. Papakostidis C, Kanakaris N, Dimitriou R, Giannoudis PV. The role of arterial embolization in controlling pelvic fracture haemorrhage: a systematic review of the literature. *Eur J Radiol*. 2012;81(5):897–904. doi:10.1016/j.ejrad.2011.02.049.
8. Travis T, Monsky WL, London J, et al. Evaluation of short-term and long-term complications after emergent internal iliac artery embolization in patients with pelvic trauma. *J Vasc Interv Radiol*. 2008;19(6):840–847. doi:10.1016/j.jvir.2008.02.011.
9. Karch LA, Hodgson KJ, Mattos MA, Bohannon WT, Ramsey DE, McLafferty RB. Adverse consequences of internal iliac artery occlusion during endovascular repair of abdominal aortic aneurysms. *Journal of Vascular Surgery*. 2000;32(4):676–683. doi:10.1067/mva.2000.109750.
10. Farahmand P, Becquemin JP, Desgranges P, Allaire E, Marzelle J, Roudot-Thoraval F. Is hypogastric artery embolization during endovascular aortoiliac aneurysm repair (EVAR) innocuous and useful? *Eur J Vasc Endovasc Surg*. 2008;35(4):429–435. doi:10.1016/j.ejvs.2007.12.001.
11. Lee WA, Nelson PR, Berceci SA, Seeger JM, Huber TS. Outcome after hypogastric artery bypass and embolization during endovascular aneurysm repair. *Journal of Vascular Surgery*. 2006;44(6):1162–8– discussion 1168–9. doi:10.1016/j.jvs.2006.08.047.
12. Allen CF, Goslar PW, Barry M, Christiansen T. Management guidelines for hypotensive pelvic fracture patients. *Am Surg*. 2000;66(8):735–738.
13. Margolies MN, Ring EJ, Waltman AC, Kerr WS, Baum S. Arteriography in the management of hemorrhage from pelvic fractures. *N Engl J Med*. 1972;287(7):317–321. doi:10.1056/NEJM197208172870701.
14. Metsmakers WJ, Vanderschot P, Jennes E, Nijs S, Heye S, Maleux G. Transcatheter embolotherapy after external surgical stabilization is a valuable treatment algorithm for patients with persistent haemorrhage from unstable pelvic fractures: outcomes of a single centre experience. *Injury*. 2013;44(7):964–968. doi:10.1016/j.injury.2013.01.029.

15. Hoffer EK. Transcatheter embolization in the treatment of hemorrhage in pelvic trauma. *Semin Intervent Radiol.* 2008;25(3):281–292. doi:10.1055/s-0028-1085928.
16. Fu C-Y, Liao C-A, Liao C-H, et al. Intra-abdominal injury is easily overlooked in the patients with concomitant unstable hemodynamics and pelvic fractures. *Am J Emerg Med.* 2014;32(6):553–557. doi:10.1016/j.ajem.2014.02.013.
17. Brun J, Guillot S, Bouzat P, et al. Detecting active pelvic arterial haemorrhage on admission following serious pelvic fracture in multiple trauma patients. *Injury.* 2014;45(1):101–106. doi:10.1016/j.injury.2013.06.011.

## Addendum 1: Data Dictionary

**Angioembolization:** Includes percutaneous or open introduction of an intravascular catheter with subsequent delivery of any vascular occlusive device.

**Type and Grade of Pelvic Fracture:** Young-Burgess Classification (APC 1, 2, or 3; LC 1, 2, or 3; VS)

**Specificity of embolization:** Common iliac artery, internal iliac artery, anterior division, posterior division, or selective

**Ankle-brachial index:** The higher of the DP or PT systolic blood pressure divided by the highest brachial artery blood pressure

**Edinburgh Claudication Questionnaire:** See addendum 2.

**Pain-free walking distance:** Number of standard city blocks the patient can walk prior to stopping due to lower extremity pain.

**IIEF Erectile Dysfunction Survey:** See addendum 3.

**Wound non-healing or bony non—union:** Inadequate healing of pelvic, buttock, or thigh soft tissue wounds or inadequate bony union as determined by any treating physician.

Addendum 2: Edinburgh Claudication Questionnaire

Addendum 3: International Index of Erectile Function (IIEF) selected questions

- How often were you able to get an erection during sexual activity?
- When you had erections with sexual stimulation, how often were your erections hard enough for penetration?
- When you attempted sexual intercourse, how often were you able to enter your partner?
- During sexual intercourse, how often were you able to maintain your erection after you had entered your partner?
- During intercourse, how difficult was it to maintain your erection to completion of intercourse?
- How do you rate your confidence that you could get and keep an erection?