Study Title:
Functional Outcomes after Post-Traumatic Pelvic Embolization

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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:


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?