A Prospective Analysis of Pelvic Examination Under Anesthesia in Determining the Need for Anterior and Posterior Pelvic Internal Fixation for “B-Type” Injuries.

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Introduction:

Historically, treatment algorithms for pelvic fracture have relied primarily on classification schemes that categorize pelvic fractures based on the mechanism of injury (Young-Burgess)1 and the presumed assumption of the degree of instability (Tile-Pennal)2 based on static radiographs and computed tomography. Standard of care has not changed appreciably in the past three decades, with the over-arching belief that all Tile “B-Type” injuries (partial instability) may be treated successfully with – at the most – anterior fixation only.

More recently there have been a number of publications suggesting 1) that static images alone do not completely characterize the degree of instability of the pelvic ring3,4 and 2) that a dynamic evaluation of the pelvic ring after traumatic injury can help to disclose further instability not previously appreciated on static imaging3.4 and 3) dynamic evaluation of the pelvic ring can help to determine the need and extent of fixation required in the treatment of pelvic ring injuries.5,6

However, the decision to add “supplemental” anterior or posterior fixation based on the results of such a dynamic evaluation is largely arbitrary and it’s actual effect on preventing malunion and improving functional outcome is completely unknown.

The purpose of this analysis is to perform a prospective evaluation of intra-operative dynamic stress testing of the pelvic ring prior to operative reduction and stabilization for presumed “B-Type” or partially unstable pelvic ring injuries.

Hypothesis:

The use of intra-operative dynamic stress testing of the pelvic ring in determining the need for anterior and posterior fixation will help to decrease the incidence of pelvic malunion, failure of fixation, and improve the functional outcome after partially unstable “B-Type” traumatic injuries to the pelvis.

Materials and Methods:

Inclusion criteria:

* Skeletally mature patient
* Traumatic disruption of the pelvic ring that would be classified as a Tile B injury to include both Young-Burgess APC-1, APC-2, and LC-1 mechanisms.
* Unilateral pelvic ring injury.
* Isolated pelvic trauma.
* Ability to follow-up for at least one year post injury.

Exclusion Criteria:

* Skeletal immaturity.
* Geriatric fracture from low energy injury (fall from standing height).
* Pathologic fracture related to metabolic bone disease or tumor.
* Pregnant patients.
* Prisoners.
* Inability to consent due to mental incapacity or language barrier.
* Fractures of the upper or lower extremity that would limit or alter the expected weight bearing status of the isolated pelvic fracture.
* Bilateral pelvic ring injury.
* Associated acetabular fractures.

Patients will be treated and managed as follows:

1. The pelvic fracture will be classified based on pre-operative static AP (antero-posterior), inlet and outlet radiographs and computed tomographic imaging.
   * + B-Type and APC-1 and APC-: symphysial diastasis with NO SI joint widening.
     + B-Type and APC-2: symphysial diastasis with SI joint widening anteriorly only.
     + B-Type and LC-1: pubic rami fractures with a unilateral complete sacral alar fracture.
2. Dynamic Stress Testing and pelvic Examination Under Anesthetic will then be performed using the technique described by Sagi et al.4 The pelvic fracture will then be re-classified as follows:4

* APC-1 will be re-classified as APC-2 if on EUA it is noted that one of the SI joints opens anteriorly.
* APC-2 will be re-classified as APC-2a if on EUA there is only a single plane of instability with external rotation.
* APC-2 will be re-classified as APC-2b if on EUA there is multiplanar instability defined as external rotation instability PLUS flexion/extension instability.
* LC-1 will be re-classified as LC-1a if there is no appreciable internal rotation deformity with dynamic stress testing.
* LC-1 will be re-classified as LC-1b if unacceptable internal rotation deformity is disclosed on dynamic stress testing.

1. Final treatment will be determined intra-operatively, which will allocate patients into one of three treatment groups. If the patient is found, after EUA, to have an APC-1 or LC-1a injury no further operative treatment or mechanical stabilization will be applied. If the patient is found, after EUA, to have one of the APC-2 variants or an LC-1b type injury as defined above, then the patient will be randomized intra-operatively to either Group 2 or Group 3, and treated as follows:
   * + Group 1: Non-operative treatment (APC-1 and LC-1a only).
     + Group 2: Anterior Fixation only:

* APC-2a = ORIF symphysis 6 hole 3.5mm symphysial plate.
* LC-1b = Distraction external fixator.
* Group 3: Anterior PLUS posterior fixation:
  + - APC-2b = ORIF symphysis PLUS a single iliosacral lag screw.
    - LC-1b = Distraction external fixator PLUS a single trans-sacral lag screw.

1. Post-operatively patients will be treated in the following manner:
   * + Group 1 = full weight bearing bilateral lower extremities.
     + Group 2 and Group 3 = weight of leg, foot flat for six weeks on the affected extremity and then full weight bearing bilaterally.
2. Follow-up will occur at the following intervals for clinical and radiographic evaluation (functional outcome scores with AP, Inlet and Outlet):
   * + 6 weeks, 3 months, 6 months and 1 year.
3. Data points for collection:
   * + Age.
     + Sex.
     + BMI.
     + Smoking status
     + Medical comorbidities.
     + Pre-operative fracture classification (Young-Burgess, Tile, OTA).
     + Intra-operative fracture classification following EUA.
     + Maintenance or loss of reduction at any of the above defined time points.
     + Complications related to Anesthesia or EUA or ORIF (failure of fixation).
     + Return to the OR for any reason.
     + Functional outcome scores at each of the above defined time points.
       - 1. Majeed pelvic score
         2. Iowa pelvic score
         3. SF-36
         4. sMFA
4. Risks to the Patient:
   1. There is no risk to the patient as both treatment methods are current standard of practice both nationally and locally. All patient identifiers will be kept private. All data will be stored on a password protected database available only to the study team.
5. Benefits:
   1. The study performed will provide information regarding the optimal treatment strategy for B-Type partially unstable pelvic fractures based on information gained using intra-operative dynamic stress testing to help determine fixation constructs. This information is of benefit to patients in that it will help to further characterize the full extent of pelvic instability and determine the extent of pelvic fixation that is required to prevent loss of reduction and provide optimal functional outcomes.
6. Procedures to Ensure Confidentiality
   1. No patient identifiers will be used during the formal study. Identifiers such as name and medical record numbers will be used to identify patients with a transverse tibia fracture, and will be stored on a password protected departmental network in a master file. Data files will be listed with subject number.
7. Statistical Analysis Plan
   1. Descriptive statistics will be presented as means and standard deviations for continuous variables and as frequencies and percentages for categorical variables. Statistical analysis of categorical variables utilized Fischer’s exact test with descriptive statistics reported as frequencies and percentages. For continuous variables, a Mann-Whitney U test was utilized with descriptive statistics reported as means and ranges. Significance set at p value less than or equal to 0.05. All statistical analyses were performed using IBM SPSS version 22 (Chicago, IL, 2013).

**Bibliography:**

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