

A MULTICENTER PROSPECTIVE COHORT STUDY OF SACRAL FRACTURES USING PATIENT BASED AND OBJECTIVE OUTCOMES.

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Study Summary

There is wide variation in the current treatment of pelvic ring trauma. This divergence in practice patterns includes the use of either operative or non-operative care for the same fractures. Sacral fractures are the most commonly observed posterior pelvic ring injury and comprise up to 75% of cases reported at most institutions. The optimal and appropriate treatment of these fractures is vigorously debated despite the common goal of improving patient outcomes. While significant posterior pelvic displacement is universally considered an appropriate operative indication in healthy individuals, the threshold for “significant” is poorly defined and difficult to accurately measure. Further, lesser and minimal displacement patterns are currently being treated operatively and non-operatively, depending on the institution and the experience of the surgeon, and without adequate guidelines. This lack of consensus in the treatment of sacral fractures is due to a poor understanding of patient outcomes following operative and nonoperative treatment, a poor understanding of how the morbidities associated with a specific treatment affect patient outcome, and a lack of data that allows any meaningful comparison of operative and non-operative treatment.

The purpose of this study is to define the patient-based and radiographic outcomes of sacral fractures based on injury pattern, fracture displacement, and treatment method. This will aid the orthopaedist in determining the best treatment course for those patients with mild to moderate displacement. Multiple centers will be included and not asked to change their protocols for management. The prospective evaluation will gather specific data points on mechanism of injury, displacements, position at union, and disease specific and general health outcomes.

Null hypothesis: We note that a null hypothesis is most effective with a comparison study. With the understanding that this is an observational cohort study, we have two purposes that we phrase as null hypotheses:

Hypothesis #1: The patient based outcomes reported by patients will demonstrate significant impairment as compared with their initial baseline scores.

Hypothesis #2: In the group of patients with similar displacements, those treated operatively will have the same patient based outcomes as those treated nonoperatively.

Previous Work

Historically, neurologically intact patients with limited soft-tissue compromise and a stable pelvis have been treated nonsurgically. However, few evidence-based studies comparing surgical versus nonsurgical treatment exist. Some surgeons have advocated surgical management of possibly stable lateral compression fractures to limit early post-injury pain, or to prevent fracture displacement.

Few prospective studies of surgical results of sacral fractures are available. Such studies are difficult, given the nature of the injury, limited experiences by single centers, and the scarcity of protocol-driven treatment guidelines (Dujardin). Most studies have focused on displaced and clearly unstable sacral fractures. Aside from a retrospective study of Denis et al, long-term outcomes data are limited. Reported outcomes depend in part on the methods of posterior pelvic stabilization selected. The cohorts studied are small, with considerable selection bias, variable timing of surgery, and poor documentation of the neurologic injury (Kim). The incidence of infection for operatively treated displaced posterior ring fractures varies widely, from 5% to 50%. Neurologic deterioration ranges from 2% to 5% and may result from compression of sacral fracture fragments. Fracture union is usually achieved in 85% to 90% of patients with displaced posterior ring fractures, but residual pain is present in approximately 30% of patients, more often related to residual neurological injury than to initial or residual fracture displacement (Sabiston, Schmidek)

Templeman et al reviewed 30 patients with displaced sacral fractures and noted that although open reduction and iliosacral screw fixation leads to better reduction of the fracture site than closed reduction and percutaneous fixation, the presence of a neurologic injury is the most important predictor of compromised outcome in patients with displaced sacral fractures.

Tornetta and Matta reported on 48 operatively fixed unstable posterior pelvic ring disruptions that were observed for an average of 44 months. Two thirds of the patients returned to their original jobs and 16% changed jobs because of an associated injury. Sixty-three percent of the patients had no pain or pain only on strenuous activity and ambulated without limitation. However, 35% of the patients had significant neurologic injuries that compromised their final result. They noted that properly performed open reduction and internal fixation of unstable posterior pelvic ring injuries may be expected to yield good functional results in the majority of patients, but that associated injuries continue to be a major source of disability.

Zelle et al used outcome measures to measure the effect of neurologic decompression on the extent of residual neurological injury. Patients were assessed at an average follow-up of 27 months using the modified SOFCOT Index and the SF-36. Patients undergoing surgical decompression had a significantly better neurological improvement as measured by the modified SOFCOT Index ($p=0.014$), and patients undergoing surgical decompression had a significantly better physical function than the patients that were managed without surgical decompression, as measured by the SF-36 ($p=0.044$). The authors concluded that neurological decompression appears a useful part of treatment.

More recently, small series with intermediate-term follow-up of surgically treated displaced posterior pelvic ring injuries have been reported with selective outcomes measured. Totterman et al reported on 31 patients with displaced sacral fractures treated surgically, with one-year functional outcomes. Outcome measurements included work status, independence in ADL, and SF-36. Fifteen months after injury, 65% of the patients had regained independence in functions pertaining to daily activities, 33% had returned to work. All dimensions of perceived health were affected. Polytrauma and impairments relative to voiding and sexual function had a detrimental effect on outcome. Fracture characteristics were not predictive of poor outcome.

Wright et al enrolled 1160 patients in a multicenter trauma outcomes study and evaluated sexual and excretory dysfunction one year after pelvic fracture. Sexual limitations and excretory dysfunction (bladder/bowel incontinence) were defined based on responses from the Functional Capacity Index. Health related quality of life was determined using SF-36. The relationship between specific fracture patterns and dysfunction along with the effect of dysfunction on quality of life in patients with pelvic fracture were evaluated by multivariate

analysis. Of 1,160 eligible patients 292 (26%) had pelvic fractures. Sexual dysfunction was reported in 21% vs 14% of those with vs without pelvic fractures and bowel or bladder incontinence was reported in 8% vs 4%. On multivariate analysis men with sacroiliac fractures were at higher risk for sexual and excretory dysfunction. In women symphyseal diastasis was associated with sexual and excretory dysfunction. Of patients with pelvic fractures men with sexual dysfunction and women with excretory dysfunction had significantly worse quality of life than those without dysfunction.

Major functional limitations appear to be related to associated neurological, urological, and other injuries not directly attributable to the pelvic ring disruption when the pelvic ring is restored close to a noninjured position. Other functional limitations and pain have not been evaluated for pelvic ring fractures with apparent stable configurations. Defining the natural history of subgroups of patients with apparently stable pelvic injury patterns will help to define the effect and appropriateness of interventions currently used in treatment of these injuries.

Vulnerable populations

Patients will be evaluated by a trained research nurse or physician to determine eligibility. Once the clinical staff has determined that the patient is eligible for the study, the patient will be informed about the research study and asked if he/she wants to participate. Patients are informed of the risks and benefits associated with their participation. Patients willing to consider participating are asked to review a formal consent form and then are provided with the opportunity to have any additional questions addressed. Patients will be informed that their care will be the same regardless of their decision to participate. If the patient is to undergo surgery for the fracture, informed consent must be signed prior to surgery in order to be eligible for the study. Enrolled patients will be assigned individual study ID numbers. Patient identifying information will be kept confidential following HIPAA guidelines.

English is the language chosen since the study design is using standard outcomes that are not available in languages other than English.

A pregnant woman with a sacral fracture will undergo the same amount of radiation and length of treatment regardless of her participation in the study. There is an inherent risk to the fetus with radiographs and numerous precautions are taken by the radiology department on a routine basis to minimize this risk. This risk is no different to a pregnant woman with a sacral fracture in or out of this study.

Design

Observational, prospective

This project is a prospective observational cohort study of all unilateral sacral fractures seen across 19 trauma centers. Inclusion criteria are all patients 18 – 80 years old with unilateral sacral fractures. Patients unable to comply with outcome measures, prisoners, pregnant women, those with APC injuries, Zone 3 sacral fractures, and those unable to comply with follow-up will be excluded. As there is substantial variation in the treatment protocols between centers, the study is designed as observational, with comparisons of outcomes for similar injuries being performed apriori after the study is complete. In particular, there is interest in evaluating the VAS and outcomes data for “minimally” displaced fractures treated operatively and nonoperatively. Minimally displaced will be defined as less than 8mm displacement of the sacrum. Thus, operative and nonoperative cases will be included. All patients will follow the same postoperative protocol if possible based on additional injuries. Multiple trauma patients will be included. Data on operative cases will be gathered including the

method of reduction, the implants utilized posteriorly and anteriorly. Radiographic, physical examination, as well as patient based disease specific and general health outcome measures will be recorded prospectively.

Radiographic data

The anatomic location of all fractures (such as symphysis versus rami injury and the zone of the sacral fracture), the displacement of each injury on the three standard pelvic radiographs including ischial height to represent flexion, and the sacral displacement (translation, impaction, gapping) will be recorded. The initial CT scan will be used to record the specific sacral displacement in mm for anterior and posterior gapping and impaction, translation, and rotation (based on the quadrilateral surface). Post injury measurements (in operative and nonoperative cases) will also be recorded through union. Injury and united films will form the basis of the anatomic outcomes.

Patient based outcomes

Baseline information on each awake and alert patient will be obtained during his or her initial hospitalization. The Majeed pelvic score, the SMFA, MMSE, and a visual analog scale for pain will be utilized. The VAS pain will be obtained within the first 24 hours, at 1 week, at 3 weeks, and at 6 weeks in addition to all scheduled follow-ups. The validated outcome scores will be obtained at the initial hospitalization, the 3-month, 6 month, 9 month, 12 month, and the 24-month follow-up if available.

Physical exam

A standardized physical exam will be obtained documenting assistive device use, walking ability, hip motion and strength at 6 weeks, 3, 6, 9, 12, and 24 months. The time to ambulation, defined as the ability of the patient to ambulate with or without assistive devices will be captured.

Sample Size

The goal of the study will be to enroll over 1000 pelvic fractures and follow them. As approximately 75% of all pelvic injuries are minimally displaced, an a priori subgroup analysis of operative vs. nonoperative treatment is possible. Although all scores including the VAS will be compared, data on VAS is not available to calculate the number needed to study. Using the Majeed score, assuming an average score of 87 (Majeed, 1989), and a standard deviation of 20, a two tailed alpha of 0.05 and a power of 80%, approximately 100 patients would be needed to see a 7 point difference in outcome. We are basing our analysis on this number for the subgroup analysis. With the centers involved, we anticipate that less than half of the “minimally” displaced fractures will be treated operatively, thus we plan to enroll a minimum of 500 fractures of this type in order to reach the needed power. Additionally, the correction needed to define a difference in VAS, etc will be required due to multiple evaluations and greater numbers will aid in finding a difference if one exists. Finally, multiple trauma patients will be analyzed for homogeneity prior to including them in the overall results.

Outcomes will be reported separately for the various outcome scores. Comparisons will be made between “displaced” fractures and “minimally” displaced fractures, and within the “minimally” displaced group, operative and nonoperative will be compared.

Data Collection Grid

Case Report Form	Completed By	Pre-Op	Day of Surgery	Post-Op (24hrs)	1 week	3 weeks	6 weeks	3 mo	6 mo	9 mo	12 mo	24 mo
Inclusion/Exclusion Criteria	Physician	X										
Patient Information	Physician	X										
Fracture Characteristics Form	Physician	X										
Radiographic Evaluation form	Physician	X		X (ct optional)				X (no CT)				
Radiographic form AP only	Physician	X		X (ct optional)			X		X		X	
Majeed Pelvic Score	Physician	X						X	X	X	X	X
SMFA	Patient	X						X	X	X	X	X
MMSE	Patient	X						X	X	X	X	X
VAS	Patient	X		X	X	X	X	X	X	X	X	X
Surgical Summary	Physician		X									
Follow-up Clinical Evaluation	Physician						X	X	X	X	X	X
Adverse Event	Physician	As Needed										

Inclusion criteria

Inclusion criteria will be all patients 18 - 80 years of age with unilateral sacral fractures.

Exclusion criteria

Patients unable to comply with outcome measures, prisoners, those with APC injuries, symphysis dislocations, or Zone 3 sacral fractures, and those unable to comply with follow-up will be excluded.

Procedure

All patients with a sacral fracture will be identified from radiographs by the PI or designee. Patients with eligible fractures (as determined by the Inclusion/Exclusion Criteria) will be approached by the PI or designee for enrollment into the study. A screening record from patients that do not meet criteria or patients that meet criteria but do not consent will be kept. There will be no PHI collected on this form and will be completely anonymous.

Patients who consent will discuss with their doctor their treatment options. At the present time, there is no commonly accepted management protocol for the treatment of the sacral fracture of interest. Consequently, these injuries are managed non-operatively or operatively according to physician and patient preference. Since this is an observational study only, not treatments are prescribed by this protocol. Treatment is entirely dictated by the physician and patient.

The following standard of care procedures will take place: Radiographic evaluation and physical examination will be recorded prospectively.

The following forms are research and not standard of care: Patient based outcomes: Baseline information on each awake and alert patient will be obtained during their initial hospitalization. The Majeed pelvic score, the short Musculoskeletal Functional Assessment (SMFA), the MMSE, and a visual analog scale for pain (0-10) will be used. The VAS pain will be obtained within the first 24 hours, at 7-10 days, and at 21 ± 7 days in addition to all scheduled follow-up visits. The validated outcome scores will be obtained at the initial hospitalization, the 3 month, 6 month, 9 month, 12 month, and if available, the 24 month follow-up visit.

The total study duration, including data analysis, will last until approximately December 31, 2011.

Patient Population

Patients will be recruited primarily from the emergency departments and orthopaedic clinics of the co-investigator sites. 19 orthopaedic surgeons are participating in the study and are primarily located at academic medical centers in the Northeast, South, Southeast, Midwest, and Northwest regions of the United States. The outcome assessments are only validated in English and therefore English speaking patients are a requirement for inclusion. Bone maturity is also necessary for inclusion and thus the study will exclude children. The ethnic background and health status of the patients are expected to be representative of the patient population at the participating sites.

Age range: 18-65+
Sex: Male and Female
Ethnicity: Representative of site's patient population
Health Status: Representative of site's patient population

Inclusion of Children, Women and Members of Minority Groups

We include all individuals who are skeletally mature. Skeletal maturity is typically achieved by age 18 in males and age 16 in females but in this study skeletal maturity will be based on appearance of growth plate. We are not including individuals with open growth plates (i.e. skeletally immature patients) because these individuals are most often treated by non-operative means due to their better healing potential. We are also collecting information on gender and race/ethnicity in our baseline evaluation forms. Reports will detail patients' (males, females, unknown) enrolled in the study by the following categories: American Indian, Asian or Asian American, Native Hawaiian or Pacific Islander, Hispanic or Latino, Black or African American, White or Caucasian, Other or unknown.

Informed Consent

Informed consent must be obtained by either the PI or his/her research associate before any study procedures are performed. Any patient presenting with a unilateral sacral fracture will be evaluated to determine eligibility. Once the clinical staff has determined that the patient is eligible for the study, the patient will be informed of treatment options as recommended by the surgeon. Upon this review, the patient will then be informed about the research study examining the outcomes of unilateral sacral fractures and asked if he/she wants to participate. The surgeon will explain that this study is observational, meaning all treatment follow-up care will be the same regardless of participation in the study. The only study related measures are the questionnaires, which will take no more than 15 minutes to complete at each standard of care follow-up visit. If the patient is willing to consider participating, he/she is asked to review a formal consent form and is given the opportunity to have any additional questions addressed.

The following measures will be used by each site to enhance the likelihood of complete follow-up:

- Individuals who are likely to present problems in with follow-up will be excluded (see exclusion criteria).
- The patient will provide the name and address of their primary care physician, and the name, address and phone number of two people at different addresses with whom the patient does not live who are likely to be aware of the patient's whereabouts. The research coordinator will confirm that these numbers are accurate prior to the patient's discharge from hospital.
- Participants will discuss in detail treatment of unilateral sacral fractures, complications and the potential treatment effects, and motivation for adherence with follow up visits and research protocols.
- Patients will receive reminders for upcoming clinic visits from local study personnel.
- Follow up schedules will coincide with normal clinic visits.
- Study personnel will contact patients no less frequently than once every three months to maintain contact and obtain information about any planned change in residence.
- If a patient refuses to return for a follow up assessment, his/her status will be determined by phone contact with the patient or the patient's family physician and outcome forms may be completed and returned.

Data Analysis

We plan to report descriptive data for all injuries based on initial displacement. A comparison will be done (student T) on the patient based outcome scores for the patients treated operatively vs. non-operatively given same displacements.

Potential Risks/Discomforts

This is a prospective, observational study and the risks are the same whether or not the patient decides to participate. Pain and stiffness is a common discomforts associated with this injury. Follow-up care is recommended for this injury because of the possibility of long-term complications such as bursitis and posttraumatic arthritis.

Patients who decide to participate will be asked to complete three questionnaires that will take approximately 15 minutes to complete. They will be obtained at the initial hospitalization, the 3 month, 6 month, 9 month, 12 month, and if available, the 24 month follow-up visit.

The Data Safety Monitoring Plan (DSMP) will involve the PI and co-investigators to monitor adverse events and report on any safety findings patient enrollment is met (50 patients locally or 1000 patients worldwide). There are no findings will cause the study to stop as all patients are being treated within standard of care for their injuries and the research component is limited to the patient outcome questionnaires.

Potential Benefits

There is no direct benefit anticipated for participants. The benefit is directly related to future standard of care for sacral fractures.

There is potential benefit to society as baseline information on outcomes may identify a group of patients in whom we are currently not obtaining good results, potentially leading to improvement.

Risk-to-benefit ratio

This study will help identify which patients (if any) may benefit from surgery and which patients (if any) may benefit from non-operative treatment. Because the risks to a patient participating in this study are no different than those not participating, the benefits outweigh the potential risks.

Recruitment

Patients will not be recruited, but rather, evaluated for eligibility as they present as trauma patients to our institution. Each sacral fracture will be evaluated, at time of presentation, against the inclusion/exclusion criteria using the criteria on the Inclusion/Exclusion Form (attached in Section S). Patients meeting criteria will be approached as a potential study participant and given the Informed Consent Form. Patients who sign the consent form will be followed for 2 years (standard of care).

Consent Procedures

Patients will be evaluated radiographically to determine eligibility. Once the PI or designee has determined that the patient is eligible for the study and explained to the patient that the options for treatment, the patient will be informed of the possible procedures. Upon this review, the patient will then be informed about the research study examining the outcomes of their fracture and asked if he or she wants to participate. The common procedures are discussed and patients are informed that at this time a study is being done to more carefully evaluate the functional outcome of this injury. Patients are informed that they are eligible to participate in this study and informed of the risks and benefits associated with their participation. Patients willing to consider participating are asked to review a formal Informed Consent Form. Patients are then given the opportunity to have any additional questions addressed. Patients will be informed that their decision to participate has no bearing on the course or quality of their care. Informed consent will be obtained by either the PI or designee prior to any study procedures being performed.

Confidentiality

The same strict adherence to ethical and legal confidentiality which is applied by clinicians treating patients with sacral fractures will be applied to the study patients. All data collected will remain confidential. Sources of protective health information (PHI) that will be used in this study include: hospital/medical records; physician/clinic records; radiology results; and interviews/questionnaires. Every effort will be taken to protect the names and PHI of the participants in this study. Patients will be required to give their authorization and sign an informed consent in order to participate. The research team will only use and share the information as it pertains to the study. Research data will be kept by the research coordinator or nurse who coordinates patient follow-up appointments. This data will be kept in a locked file cabinet. Data will ultimately be analyzed with a password protected computer program, but no identifying information will be included. Data will be stored for at least 3 years after the study closes. All data will be destroyed 3 years after the study closes unless the PI determines that the data needs to be kept longer for research/analysis purposes. If so, the PI will make the appropriate IRB amendment with justification.

The patient demographics form is the only form that will contain identifiable information. This information is necessary to determine potential confounders (age, gender, etc.) and to provide information necessary for follow-up.

After the patient completes this form, the PI or research nurse will assign the patient a unique study ID (BMC001, BMC002, etc). This study number will be used on all subsequent forms. The master key to link ID with the demographics form will be kept in a separate and locked cabinet in the research coordinators office.

All data will be entered into a password protected database. All forms will be stored in a locked file cabinet in the research coordinators office. No identifiable data (patient name, MRN, phone number, address, etc.) will be entered into the database. Patient data will be linked to study ID number only.

Cost/Payment

There will be no additional cost to patients in terms of co pay or out of pocket costs; there will be no additional costs passed on to insurance companies beyond the care administered per standard of care for any sacral fracture in terms of radiographs, therapy, or follow-up visits.

The patients will not be paid any money as this is observational research that coincides with normal standard of care for their injury.