Proposal for Carolinas Medical Center IRB Approval

Title of the Study: Operative and Non-operative treatment of Traumatic Arthrotomies: A Prospective Observational Study

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Abstract

For the last 70 years, orthopaedic dogma has dictated that all injuries that penetrate the joint capsule require formal irrigation and debridement in the operating room to minimize the risk of developing septic complications. The literature supporting this practice is sparse and stems primarily from wartime injuries that may not be generalizable to the smaller, less contaminated arthrotomies seen in the civilian population. Despite the classical teaching of all traumatic arthrotomies requiring irrigation, debridement, and closure in the operating room, numerous surgeons around the country are beginning to treat small traumatic arthrotomies without surgery. The purpose of this study is to evaluate the cost of treatment as well as incidence of adverse events, such as the development of septic arthritis, in patients undergoing operative and non-operative treatment of traumatic arthrotomies.

Background and Rationale

Soft tissue wounds around joints are common injuries that are carefully evaluated to identify intra-articular extension. Wound exploration, imaging, and intra-articular saline load injections are commonly utilized to diagnose the presence of a traumatic arthrotomy. The reason for such diligence is that the treatment is dramatically different for a wound that violates the joint compared to one that does not. As opposed to local wound care for simple soft tissue wounds, traumatic arthrotomies are thought to require formal irrigation and debridement in the operating room to minimize the risk of developing septic arthritis.

Septic Joints

An injury that penetrates the joint capsule and synovium violates the body's natural barriers that protect the joint from external pathogens. Microorganisms from the environment may enter the joint by direct inoculation or by contiguous spread through the now perforated barrier. By bringing patients to the operating room for formal irrigation and debridement, orthopaedic surgeons are theoretically attempting to minimize the burden of contamination and repair the body's natural barriers to reduce the risk of developing an intra-articular infection. Septic arthritis is an orthopaedic emergency that can result in severe cartilage damage causing long-term joint pain, stiffness, and potentially auto-fusion (Chander S, *Curr Infect Dis Rep,* 2011). If not dealt with in a timely manner, intra-articular infections can result in significant long-term disability, and in extreme cases, can result in overwhelming sepsis and death (Chander S, *Curr Infect Dis Rep,* 2011).

Orthopaedic Dogma

Clearly, minimizing the risk of developing septic arthritis is important to every orthopaedic surgeon. Over sixty years ago, Hampton published his observation of a high rate of septic complications in combat injuries that violated the joint (Hampton OP, *JBJS*, 1946). Since then, orthopaedic dogma has dictated that all injuries that violate the joint necessitate formal irrigation and debridement in order to minimize the risk of infectious complications. The literature on the topic is sparse and stems primarily from wartime observations in which the injuries sustained were commonly associated with high levels of contamination, intra-articular fractures, retained foreign bodies, and delayed treatment (Marvel JE, *CORR*, 1977). The characteristics of these injuries may limit the generalizability of these observations to the civilian population, especially for small, mildly contaminated arthrotomies without associated fracture or retained foreign body.

To date, no studies have prospectively evaluated the benefits of operative irrigation and debridement of traumatic arthrotomies compared to non-operative observation with antibiotics. A single study published in 1975 by Patzakis and others showed that patients with open joint injuries treated with operative irrigation and debridement had an infection rate of 2.1%, a value significantly lower than was previously observed in the non-operative cohort of combat injuries (Patzakis MJ, *JBJS,* 1975) (Hampton OP, *JBJS*, 1946) (Marvel JE, *CORR*, 1977). There is little question that large and heavily contaminated arthrotomies benefit from formal irrigation and debridement, but it is unclear if this benefit can extrapolated to smaller, less contaminated injuries. Nevertheless, orthopaedic surgeons continue to debride and irrigate open joints regardless of the burden of contamination or size of arthrotomy.

Small Arthrotomies are Commonly Missed Injuries

In an effort to identify and treat as many traumatic arthrotomies as possible, orthopaedic surgeons began looking for additional techniques to aid in their diagnosis. After it's introduction in 1975, saline arthrograms quickly became the gold standard for the diagnosis of small traumatic arthrotomies (Patzakis and Voit). This doctrine was called into question by Tornetta and others when they showed that saline load arthrograms, as they were commonly performed, had a sensitivity of only 43% (Tornetta P 3rd, *CORR,* 2008). Two years later, Nord and others recommended using 155-ml of saline to diagnose 95% of arthrotomies, a volume more than double what was previous used in clinical practice and not easily tolerated by most patients (Nord RM, *JBJS,* 2009). Most recently, Metzger et. al. demonstrated a false-negative rate of 67% when using 180-mL of saline for their arthrograms, a volume far beyond what would be tolerated in a conscious patient (Metzger P, *JOT*, Epub). Despite missing up to half of all small traumatic arthrotomies for the last 40 years, there has not been an outbreak in patients returning with septic arthritis from missed arthrotomies. The absence of such an occurrence raises the question if it is even necessary to formally debride and irrigate small traumatic arthrotomies in the operating room at a great cost to the patient.

Costs of Arthrotomy

Despite the relative dearth of evidence supporting the practice of formally irrigating and debriding all open joint injuries, significant healthcare expenditures and additional risks of general anesthesia are undertaken to address this problem. Although the administration of general anesthesia has become extremely safe, it still carries the risk of serious consequences such as heart attack, stroke, and even death (Lanier WL, *Am Surg,* 2006)(Botney R, *Int J Radiat Oncol Biol Phys,* 2008). Patients with multiple medical comorbidities are at an even greater risk of a serious perioperative complication (Wolters U, *Br J Anaesth,* 1996).

In addition to the risks of undergoing anesthesia, there are significant costs associated with any operation. A patient diagnosed with an isolated traumatic knee arthrotomy can expect to leave the hospital with a bill of at least $15,000 based on conservative estimates provided by the Department of Research Finance at Carolinas Medical Center. In an era where healthcare costs are spiraling out of control, determining which interventions are efficacious will be paramount in shaping healthcare resource utilization and maintaining long-term sustainability.

Conclusion

To our knowledge, there is no evidence to support the practice of prophylactic irrigation and debridement of traumatic arthrotomies that would otherwise be amenable to treatment in the emergency department. It is the opinion of the senior authors of this study, who are both experienced orthopaedic traumatologists at high-volume level 1 trauma centers, that small, mildly contaminated traumatic arthrotomies could be treated with antibiotics and close follow-up alone, if they are amenable to closure in the emergency department. Instead of a hospital admission and operative procedure, these patients could be safely discharged from the emergency department with local wound care and antibiotics alone resulting in significant healthcare savings and minimizing the risks of undergoing general anesthesia and a surgical procedure.

Research Plan

Specific Aim 1: To compare the cost of medical care in patients with traumatic arthrotomies treated with surgical irrigation and debridement versus non-operative treatment with local wound care.

> **Hypothesis 1:** Patients with traumatic arthrotomies will have an average hospital bill of $15,000 less than those treated with surgery.

Specific Aim 2: To determine the incidence of developing a septic arthritis in patients with a non-operatively treated traumatic arthrotomy.

> **Hypothesis 2:** Non-operative treatment of small traumatic arthrotomies will have an extremely low rate (<10%) of subsequent septic arthritis over a 3-month period.

Specific Aim 3: To determine the incidence of developing a septic arthritis in patients with operative treatment of a traumatic arthrotomy.

> **Hypothesis 3:** Operative treatment of traumatic arthrotomies will have an extremely low rate (<5%) of subsequent septic arthritis over a 3-month period.

Specific Aim 4: To determine the need for additional surgery (ex: foreign body removal) in patients with a non-operatively treated traumatic arthrotomy.

> **Hypothesis 4:** Non-operative treatment of small traumatic arthrotomies will have an extremely low rate subsequent surgery over a 6-month period.

Specific Aim 5: To provide a description of traumatic arthrotomies successfully treated non-operatively.

> **Hypothesis 5:** Arthrotomies will be less than 1 cm with a soft tissue injury amenable to closure in the ED. Arthrotomies will be more likely to be due to GSW's and scraping mechanisms rather than direct penetration.

Study Design

Prospective Multi-center Observational Cohort
Retrospective chart review

Study Population

Inclusion Criteria

1. Any patient 18 and older with a traumatic arthrotomy (of any major joint) confirmed by saline load test, direct visualization of a capsular rent or intra-articular contents, or air in the joint on CT or radiographs.
    a. Major Joints Include:
        i. Knee
        ii. Elbow
        iii. Wrist
        iv. Shoulder
        v. Hip
        vi. Ankle

Exclusion Criteria

1. Patients who will have severe problems with maintaining follow-up

Method for Selecting Samples
Potential patients will be prospectively identified at the time of the initial consultation or at the first clinic follow-up appointment based on the diagnosis of a traumatic arthrotomy (Diagnostic criteria noted in inclusion criteria above). Patients will be screened by their inclusion and exclusion criteria, and if met will be considered for enrollment in the study.

Retrospective chart review
The study will also conduct a retrospective chart review of patients who presented with a traumatic arthrotomy during the enrollment period., however were unable to be reached for consent after multiple attempts over a period of two years. Information about injury and treatment outcomes will be collected from the medical record.

Representativeness of the Sample
The study population will be representative of the typical trauma population. Patients of all ages, genders, ethnicities, and backgrounds will be included in this study. Based on previous clinical series of patients at our institution, we expect that 70% of our patients will be men and 25% minority patients.

Definition of Variables
Outcome Variables

- Primary Outcomes
    - Cost of treatment
    - Adverse Events
        - Development of septic arthritis
        - Return to operating room for any reason (ie: foreign body removal)
        - Rehospitalization
        - Development of osteomyelitis
- Secondary Outcomes
    - Superficial wound infection
        - Extra-articular infection requiring a prolonged course of antibiotics or local wound care.
    - Pain 1 – 10 Scale
        - Current
        - Worst in last 24 hours
        - At rest
        - Bearing weight
        - Ambulating
    - Return to work or previous level of activity

Demographic Variables and Covariates

- Demographic Information

    - Age
    - Gender
    - BMI
    - Mechanism of injury
    - Smoking Status
    - Comorbidities
    - Employment status
    - Workers compensation status
- Additional Injuries
- Arthrotomy Characteristics
    - Mechanism of arthrotomy
        - Abrasion
        - Laceration
        - Puncture
        - GSW
        - Blast injury
    - Degree of contamination
    - Size of arthrotomy (mm)
    - Shape of arthrotomy
    - Method of Diagnosis
        - Visualization
        - Air on CT or radiograph
        - Saline load
- Treatment Characteristics
    - Antibiotics administered
        - Timing
        - Duration
    - Indication for Surgery
        - OR for additional injury
        - Intra-articular fracture requiring operative fixation
        - Heavily contaminated
        - Intra-articular loose body
        - Large arthrotomy
        - Intra-articular hardware

Potential Confounders

As a prospective observational study, the patient's treatment will not be altered by their inclusion in the study. No guidelines will be provided to influence the treating surgeons' decision making. All surgeons will have treated patients based on their own expert opinion and biases, which will undoubtedly differ between surgeons. The purpose of the study is to show that some traumatic arthrotomies can be treated non-operatively based on surgeon discretion, and having a variety of different arthrotomies will add to the descriptive nature of the study.

The observational nature of this study will introduce a selection bias based on the surgeon's comfort level of treating traumatic arthrotomies non-operatively. Larger and more heavily contaminated arthrotomies will be far more likely to be treated operatively compared to smaller, less contaminated arthrotomies. Any comparisons made between operative and non-operative treatment will have to be made between a matched cohort of arthrotomies of similar severity.

Although the treatment of patients should not be altered by their inclusion in the study, the possibility of a Hawthorne (observer) effect bias exists. The treating surgeon's decision making may potentially be altered by participation in this study.

Patient Safety

Patients involved in the study will not have their medical care altered in any way by their participation. A data safety monitor will be appointed to periodically assess for adverse events. .

Methods

Patient Identification and Enrollment

Patients will be identified at the time of the initial consultation or first clinic follow-up visit based on the presence of a traumatic arthrotomy, of any major joint, based on the criteria outlined above. Patients meeting the inclusion and exclusion criteria will be deemed eligible for the study. Eligible patients will be approached by a member of the treatment team to further discuss the study. If the patient agrees, a member of the research staff will discuss the study in greater detail and obtain informed consent.

Intervention

There will be no alterations in patient care by their inclusion in the study. The attending surgeon will determine the treatment plan, follow-up frequency, and follow-up duration. The need for additional surgery will also be determined by the attending surgeon. The development of septic arthritis or need to proceed to the operating room for foreign body removal will be deemed as adverse events and will be reported to the data safety monitor as they occur.

Data Collection

At the initial consultation, patient demographic information, arthrotomy characteristics, treatment variables, and additional injuries will be obtained. At each follow-up appointments, pain level will be assessed by a member of the treatment team and recorded. Patient will complete the VR-12 to assess quality of health at 3 month after time of their injury. Patients may be followed prospectively for a total of one year after the time of their injury. Patients released from care prior to their one year appointment will be contacted via telephone by a member of the research staff to assess final outcomes. The total cost of care, including hospital and office charges, will be recorded at the one year mark. Patients still requiring care at the 3 month visit as a direct result of treatment of their traumatic arthrotomy will continue to be followed for a total of one year.

Follow-Up

A minimum necessary follow-up of 3 months or 1 year for patient requiring care as a direct result of treatment of their traumatic arthrotomy. Patients released from care after this time period without developing septic arthritis will be considered a successful therapy. If a patient is discharged from clinic prior to 3 months or 1 year, a member of the research team will contact the patient by telephone or by mail to obtain final follow up information.

Data Collection

All data will be entered into REDCap, a web-based data entry and management system that provides logic checks on input and checks for invalid entries. Data will be entered continuously as they are collected and stored in univariate form. We will also run standard checks for outliers, duplicates and other types of errors which may occur within a complex data file. All data files will be password protected and hard copies of blinded patient records will be maintained in locked cabinets in the research office.

Study Duration

Patients will continue to be enrolled for 2-years or until 25 patients are treated non-operatively, whichever comes first.

Statistical Analysis

Standard statistical tests will be used. Descriptive statistics including means and standard deviations, or counts and percentages will be reported. The principal analysis will compare cost of care using logisitic regression. Also, demographic and baseline variables will be compared between operative and non-operative patients using t-test and chi-square test where applicable.

A multivariate logistic regression analysis with cost as the dependent variables and a dichotomous variable indicating treatment modality will be performed to adjust for possible demographic or baseline differences between the two groups. Additional regression analysis will be conducted to determine if demographic factors, size or contamination or other factors predict poorer outcomes. A p-value of less than 0.05 will be considered statistically significant.

Citations:

[1] Hampton OP. The management of penetrating wounds and suppurative arthritis of the knee joint in the Mediterranean theater of operations. *J Bone Joint Surg.* 1946;28(4):659-680.

Historical military article.

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2.2 percent infection rate?

[4] Marvel JE, Marsh HO. Management of penetrating injuries of the knee. *Clin Orthop Relat Res.* 1977;122:268-272.
Historic war wounds

[5]Lanier WL. A three-decade perspective on anesthesia safety. *Am Surg.* 2006;72(11):985-989.

[6]Botney R. Improving patient safety in anesthesia: a success story? *Int J Radiat Oncol Biol Phys.* 2008;71(1 Suppl):S182-S186.

[7]Wolters U, Wolf T, Stutzer H, Schroder T. ASA classification and perioperative variables as predictors of postoperative outcome. *Br J Anaesth.* 1996;77(2):217-222.

[8]Chander S, Coakley G. What's new in the management of bacterial septic arthritis? *Curr Infect Dis Rep.* 2011;13:478-484.

[9]Tornetta P 3rd, Boes MT, Schepsis AA, Foster TE, Bhandari M, Garcia BS. How effective is a saline arthrogram for wounds around the knee? *Clin Orthop Relat Res.* 2008;466:432-435.

[10]Nord RM, Quach T, Walsh M, Pereira D, Tejwani NC. Detection of traumatic arthrotomy of the knee using the saline solution load test. *J Bone Joint Surg Am.* 2009;91:66-70.

[11]Metzger P, Carney J, Kuhn K, Booher K, Mazurek M. Sensitivity of the saline load test with and without methylene blue dye in the diagnosis of artificial traumatic knee arthrotomies. *J Orthop Trauma.* Epub ahead of print.

Traumatic Arthropathy **716.16** (ICD-9)
Knee Arthroscopy for Infection with Lavage and Drainage **29871** (CPT)
Knee Arthrotomy with exploration and draining or removal of foreign body (eg. Infection) **27310** (CPT)

OR = $8238.70 (1 hr in room time)
Recovery Room = $871.20 (1 hr)
Average ER visit = $435.00
Professional charge for CPT 29871 = $1780.00
Average room and board per night = $948.00
Anesthesia fee per unit = $452.75 x 4 units = $1,811.00
Total = $14,083.90 (Does not include any Abx or medications)