Study Title:
Opioid Free and Therapy Minimized Advantages Using HANA Table for Total Hip Arthroplasty

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Study Protocol

Objectives:

- To prove that anterior approach total hip arthroplasty using the HANA table can be performed with little, if any, need for opioids using a combination of education, optimized pre op and post op pain protocols and optimized recovery protocols.
- The secondary objective is to prove that nearly all patients can be treated as outpatient joint replacements

Design

- Prospective, consecutive elective total hip cases excluding mentally ill and mentally challenged patients
- All study patients will receive a standardized protocol
- All surgical procedures preformed by a single surgeon using the same implants, same approach, same pre op and post op optimization and same simplified pain protocol at a single hospital center and outpatient surgical center
- Researchers will attempt to minimize the number of anesthesiologists to further control variability in care

Research Team

- Andrew Wickline, MD – Principal investigator, surgeon – will review data weekly to ensure quality data collection
- Research associate Kim Strong PT, DPT

Methods

- Data Collection
    - Pre op assessment
    - Post op assessment – PACU, prior to discharge
    - Phone calls after discharge (POD 1, 2, 3, 10-14)
    - Follow up assessment in office (3, 6 weeks post op)
    - HOOS JR assessed pre op, three and six weeks post op
    - Return to driving (assessed POD 10-14, 3week, 6 week)
    - Sleep quality (assess POD 1, 2, 3, 10-14, 3week, 6week)
    - Return to work (assessed 3 week, 6 week)

    - Short Physical Performance Battery (SPPB) (assessed pre op, 3week, 6 week)
- Pre op Optimization
    - All patients enrolled in SwiftPath education program
    - All patients have optimized BMI, hemoglobin, albumin, glucose control (A1C), blood pressure
- Total joint procedure
    - Anterior approach using HANA table performed with intra-articular block
- Pain management regimen for THA
    - Pre op regimen patient education which includes pre op physical therapy teaching
    - Post up multimodal pain management regimen
        - Oxycodone 5mg q4-q6 prn or Tramadol 50mg q4-q6 prn
        - Acetaminophen 100mg tid
        - Celebrex 100mg bid or Mobic 7.5mg bid
        - Prednisone 5mg po daily
        - Cryotherapy
    - Patients are discharged when criteria met: ability to ambulate, to tolerate food/fluids, controlled nause8a/vomiting, ability to empty bladder, vital signs within pre op values, ability to pass physical therapy assessment for daily living skills
    - Anesthesiologist regimen: general vs spinal anesthetic

Inclusion Criteria

- Elective total hip arthroplasty
- Unilateral only
- Patient surgeries scheduled to be performed at the hospital and surgery center
- Patients must enroll in SwiftPath
- Ability to read and understand English

Exclusion criteria

- Patient conditions to exclude: schizophrenia, bipolar disease, dementia
- Previous burn to the affected extremity
- BMI >40
- Hemoglobin <12 female, <13 male
- Albumin less than 3.5
- A1C > 8.0

Primary Outcomes

- Post op opioid consumption (pill count)
- Pre op narcotic use

Secondary Outcomes

- Pain scores
- Sleep quality
- Adherence to prescribed post op recovery protocol
- Adverse events

- Length of stay in hospital
- HOOS JR scores
- Discharge location (home vs inpatient rehab facility)
- Number of physical therapy visits
- Return to work
- Return to Driving
- SPPB score

Analysis Plan

- Primary Outcomes
    - Pre-op Narcotic Use
        - The number of patients that used opioids pre-operatively will be reported. A simple percentage will be calculated by dividing this number by the total number of patients in the study.
    - Opiate Drug Use through 6 weeks
        - The number of patients that used any opioids throughout the 6 week follow-up period will be reported. A simple percentage will be calculated by dividing this number by the total number of patients in the study.
    - Short Physical Performance Battery at 6 weeks
        - The short physical performance battery (SPPB) assessment tool measures gait, balance and chair stand using a score measured on a scale of 0 to 4 where higher scores indicate a better outcome. The average score of each domain along with the standard deviation will be reported at the 6 week assessment.
- Secondary Outcomes
    - Numeric Pain Scores at 6 weeks
        - Patients were asked to assess their 'best' and 'worst' pain using a scale of 0 to 10 where 0 indicates no pain and 10 indicates the worst pain imaginable. The average and standard deviation will be reported at the 6 week assessment.
    - Sleep Quality at 6 weeks
        - Patients were asked at the 6 week assessment if pain interrupted their sleep. The possible answers were Never, Rarely, Sometimes, Often, and Always. The number of patients that answer Never or Rarely at the 6 week assessment will be combined together and reported. A simple percentage will be calculated by dividing this number by the total number of patients in the study.
    - Adherence to Prescribed Post-Operative Recovery Protocol through 6 weeks
        - The number of patients that adhered to the prescribed post-operative recovery protocol will be reported. A simple percentage will be calculated by dividing this number by the total number of patients in the study.
    - Length of Stay in Hospital
        - The number of days the patient stayed in the hospital after surgery will be recorded. The average of all patients as well as the minimum and maximum number of days will be reported. It is anticipated most patients will be discharged on the same day as the surgery.

- Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, Jr) at 6 weeks
    - HOOS Jr is an outcome assessment tool that combines pain, activities of daily living, and stiffness into a score on a 0 to 100 scale where 0 represents total hip disability and 100 represents perfect hip health. The average and standard deviation of the total score will be reported at the 6 week assessment.
- Return to Work 6 Weeks after Surgery
    - The number of patients that returned to work will be recorded for each patient at the 6 week assessment. A simple percentage will be calculated by dividing this number by the total number of patients in the study.
- Return to Driving 6 Weeks after Surgery
    - The number of patients that returned to driving will be recorded for each patient at the 6 week assessment. A simple percentage will be calculated by dividing this number by the total number of patients in the study.