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Pre-optimization of spinal surgery patients: Development of a neurosurgical enhanced recovery after surgery (ERAS) protocol

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ABSTRACT

Objective: Despite surgical, technological, medical, and anesthetic improvements, patient outcomes following elective neurosurgical procedures can be associated with high morbidity. Enhanced recovery after surgery (ERAS) protocols are multimodal care pathways designed to optimize patient outcomes by addressing pre-, peri-, and post-operative factors. Despite significant data suggesting improved patient outcomes with the adoption of these pathways, development and implementation has been limited in the neurosurgical population.

Methods/Results: This study protocol was designed to establish the feasibility of a randomized controlled trial to assess the efficacy of implementation of an ERAS protocol on the improvement of clinical and patient reported outcomes and patient satisfaction scores in an elective inpatient spine surgery population. Neurosurgical patients undergoing spinal surgery will be recruited and randomly allocated to one of two treatment arms: ERAS protocol (experimental group) or hospital standard (control group). The experimental group will undergo interventions at the pre-, peri-, and post-operative time points, which are exclusive to this group as compared to the hospital standard group.

Conclusions: The present proposal aims to provide supporting data for the application of these specific ERAS components in the spine surgery population and provide rationale/justification of this type of care pathway. This study will help inform the design of a future multi-institutional, randomized controlled trial.

Results: of this study will guide further efforts to limit post-operative morbidity in patients undergoing elective spinal surgery and to highlight the impact of ERAS care pathways in improving patient reported outcomes and satisfaction.

1. Introduction

Spinal disorders are among the most frequently encountered problems in clinical medicine and can result in significant pain and neurologic dysfunction. Specifically, low back pain (LBP) is one of the most common health problems worldwide and affects as many as 80% of people at some point in their lifetime, with 1% to 2% of the United States adult population disabled because of LBP [34]. In particular, LBP is the second most common cause of adult disability in the United States with prevalence greater than that due to heart conditions, stroke, and cancer combined [22].

Direct medical costs to insurers, patients, and families as well as indirect cost estimates to the health care system, insurance companies, and society from loss of work productivity demonstrate the significant socioeconomic problem created by degenerative spinal disease [28,108]. Approximately 9% of all health-care cost is attributed to spine pain in the United States, and the total cost of low back pain exceeds $100 billion per year in the United States alone [69]. Two-thirds of these costs are related to lost wages and decreased productivity at work. Indeed, this population endorses worsening self-reported measures of mental health, physical functioning, work or school limitations, and social limitations over time [92]. In addition, complication rates, including mortality, associated with treatments for spinal disease are on the rise.

Though significant advances have been made in neuroanesthesia and peri-operative neurosurgical care, spinal surgery still often results in significant post-operative morbidity. Excluding complications related to anesthesia or surgery, the surgical stress response, with its increased metabolic demands on the body, serves as a critical pathogenic factor in post-operative morbidity. Introduced in 1997 by Henri Kehlet, Enhanced Recovery after Surgery (ERAS) proposes a multimodal, evidence-based approach to prepare patients for surgery [71]. The

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Fig. 1. ERAS is a novel protocol in the elective neurosurgical spine patient that aims to improve patient satisfaction as well as patient reported and clinical outcomes.

principles of ERAS have been implemented for a variety of surgeries such as colonic [52], pancreaticoduodenectomy [80], cystectomy [23], gastrectomy [95], and rectal/pelvic surgery. [98] The evidence to support ERAS in major spinal surgery has been proposed previously and implemented in a minimally invasive lumbar fusion population most recently [133,134]. Application of ERAS in the neurosurgical arena has the potential to enhance productivity gains and cost savings. However, explicit guidelines are lacking for the neurosurgical spinal patient population. We propose the first American randomized controlled prospective clinical trial to assess the feasibility and efficacy of a novel ERAS protocol in the neurosurgical spinal population in order to improve patient satisfaction as well as patient reported and clinical outcomes (Fig. 1).

2. Design

2.1. Recruitment

Participants will be recruited within the University of Pennsylvania Health System following the neurosurgical outpatient clinic visit in which the patient is recommended to undergo elective spinal surgery based on clinical criteria. If the patient meets eligibility criteria, he or she will be provided with an overview of the study objectives and design. The patient will undergo informed consent and randomization.

2.2. Eligibility criteria

The inclusion criteria include: clinical history and diagnostic imaging that support the need for elective inpatient spinal surgery, age over 18 years without an upper age limit, and the ability to understand and actively participate in the program as deemed by the study team. The exclusion criteria include: contraindications to elective spinal surgery, liver disease, and pregnancy.

2.3. Randomization

Patients will be randomized following a computer-generated list of random numbers. An independent research assistant blinded to the patient assignment will sequentially number the envelopes containing intervention assignments according to the computer-generated randomization. Opaque and sealed envelopes will be opened in front of the participants at the end of the initial assessment visit. Patients will be randomly allocated to one of the two following groups: 1) experimental group (ERAS protocol), and 2) control group (hospital standard management).

2.4. ERAS pathway

The ERAS pathway will be divided into three distinct chronological time periods: pre-op (Fig. 2), peri-op (Fig. 3), and post-op (Fig. 4). The components of each stage will be reviewed here.