Does Opioid Tapering Prior to Spinal Fusion Improve Surgical Outcomes: A Randomized Controlled Trial
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Purpose
The purpose of the proposed research is to determine whether a structured preoperative opioid tapering regimen can successfully reduce postoperative opioid and pain medication use and improve outcomes in spinal fusion surgery.

Hypothesis
Our hypothesis is that patients tapering their opioid use prior to surgery will have reduced postoperative opioid and pain medication usage, less postoperative pain, and improved patient reported outcomes relative to patients not tapering prior to surgery.

Method of Research
The proposed research comprises a randomized controlled trial of spinal fusion patients taking daily opioid medication prior to surgery. Patients undergoing spinal fusion in the Stanford Orthopaedic Surgery and Neurosurgery Departments will be screened, consented, and complete baseline patient reported outcomes (PROMs, including the numeric pain rating scale, NPRS, and relevant PROMIS computer adaptive tests) at their preoperative planning visit 4 to 6 weeks prior to surgery. Eligible patients will meet the following criteria:

Inclusion:
- Lumbar, lumbosacral, or thoracolumbar spinal fusion surgery
- Daily opioid use for at least the past 4 weeks prior to the preoperative planning visit

Exclusion:
- Buprenorphine use
- Patients using long-acting or non-oral opioid formulations
- Unable to complete PROMs

Patients will be randomized based on a block design by surgeon with 2 patients tapering for every 1 control. The tapering regimen will consist of a 10% reduction in opioid consumption per week for a total of 50% prior to surgery. Patients will be monitored and guided through the tapering process via 10-15 minute weekly phone calls, in which the research coordinator will record the patients’ adherence to the tapering protocol and monitor withdrawal symptoms and pain levels. The non-tapering group will also receive weekly phone calls to track opioid and pain medication use and pain levels, and ensure that these two groups are treated as similarly as possible.

Surgery will proceed according to the standard of care and perioperative outcomes will be collected, including in-hospital opioid and pain medication use. Following surgery, the research coordinator will continue weekly phone calls for 6 weeks to track opioid and pain medication use and record pain levels. The PROMIS computer adaptive tests will also be collected at the 6 week call and the 3 and 6 month follow-up visits, and surgical complications will be recorded.

The primary outcomes will be the NPRS, opioid medication use, and the PROMIS computer adaptive tests. Primary analyses will be performed on an intention-to-treat basis and examine differences in
these outcomes between patients assigned to the tapering regimen versus those not tapering. Secondary analyses will be performed to examine relationships between these outcomes and baseline factors such as the duration of opioid use, baseline opioid dosage, degree of tapering, and final opioid dosage after tapering.

**Expected Results**
The expected results of this research are several fold. First, we will gain insight into the feasibility and challenges associated with opioid tapering prior to lumbar spine surgery. Secondly, we will determine whether tapering prior to surgery reduces the need for opioids and other pain medication postoperatively and improves patient reported outcomes.