Narcotic-Free Percutaneous Nephrolithotomy: A Randomized Controlled Trial

Introduction: The opioid epidemic in the United States is an ongoing public health crisis that is in part fueled by excessive prescribing by physicians. Percutaneous nephrolithotomy (PCNL) is a procedure that conventionally involves opioid prescription for adequate postoperative pain control. However, there lacks a consensus on the utility of narcotics for postoperative pain relief following PCNL in the literature. Physicians and surgeons have been entrusted with devising effective and strategic methods for lowering opioid prescription in light of the present national opioid epidemic. In place of opioid-based pharmaceuticals, urologists are increasingly recommending nonsteroidal anti-inflammatory drugs (NSAIDs) for postoperative analgesia due to encouraging findings, albeit anecdotal. We conducted a prospective randomized study to demonstrate the noninferiority of NSAIDs (especially ketorolac) against opioid-based medications following PCNL.

Methods: This study is a randomized controlled trial (RCT). Patients scheduled to undergo PCNL were randomized in a 1:1 ratio into one of two groups: 1) an opioid group, in which patients were discharged home with 12 tablets of oxycodone in addition to the standard post-procedural, stent-related medications of oxybutynin and phenazopyridine; 2) an NSAID group, in which patients were discharged home with 12 tablets of ketorolac in addition to the standard post-procedural, stent-related medications of oxybutynin and phenazopyridine. Block randomization took place prior to study initiation and surgeons were blinded to each patient's allocated study group. After informed consent, patients underwent PCNL as per standard of care.

Patients were asked to provide their visual analog scale (VAS) pain score at multiple time points including postoperative day (POD) #0 (just prior to discharge from hospital), and POD#1-5 (via telephone call). At each of these time points, maximum and average VAS scores for the preceding 24 hours were collected. Patients had their stents removed on POD#10 in the office. During this office visit, patients provided a VAS pain score, and completed the Patient-Reported Outcomes Measurement Information System (PROMIS) survey. Pain scores were compared between the opioid and NSAID group. Pill counts were also performed for all prescription medications. Additionally, any pain-related office phone calls and ED visits were recorded. If pain control was inadequate with study medications, participants may have been prescribed additional rescue medication as deemed fit by the treating physician. Recruitment occurred in the office of the two operating surgeons in the study. Target enrollment in the study was set to 80 patients. This study was approved by the institution's IRB.

Preliminary Results: To date, 31 patients have been enrolled in the study (opioid group = 15, NSAID group = 16). At the time of measurement, mean VAS pain scores on POD#0, #1, #2, #3, #4, #5, and #10 were not significantly different between opioid and NSAID groups (POD#0: 0.38 vs 0.53, $p = 0.772$; POD#1: 3.13 vs 2.87, $p = 0.759$; POD#2: 2.64 vs 2.13, $p = 0.528$; POD#3: 1.80 vs 2.36, $p = 0.562$; POD#4: 2.27 vs 1.64, $p = 0.420$; POD#5: 1.69 vs 1.46, $p = 0.759$, POD#10: 1.23 vs 1.71, $p = 0.534$). For patient-reported maximum pain experienced that day, mean VAS pain scores were similarly not significantly different between opioid and NSAID groups for all measurements (POD#0: 7.75 vs 7.43, $p = 0.732$; POD#1: 6.60 vs 7.27, $p = 0.435$;

POD#2: 4.93 vs 6.13, p = 0.221; POD#3: 4.67 vs 5.14, p = 0.668; POD#4: 4.67 vs 5.00, p = 0.777; POD#5: 3.31 vs 4.23, p = 0.398, POD#10: 1.69 vs 3.21, p = 0.166). Response ratings for the PROMIS survey questions “How much did pain interfere with your ability to concentrate?”, “How much did pain interfere with your day to day activities?”, “How often did you feel emotionally tense because of your pain?”, “How much did pain interfere with your ability to work (include work at home)?”, and “How often was your pain so severe you could think of nothing else?” did not significantly differ between both groups. Pain-related office phone calls did not occur in either group of patients. One complication (Clavien-Dindo Grade 1) occurred in the opioid group (1/15, 6.7%) while no complications were reported in the NSAID group. Similarly, one patient in the opioid group experienced a 30-day ED visit (1/15, 6.7%) while no ED visits were reported in the NSAID group.

Preliminary Conclusions: Our results show that there were no significant differences in VAS pain scores, ratings of pain-related questions in the PROMIS survey, nor differences in rates of pain-related encounters between those who received a non-opioid or opioid-based pain regimen following PCNL. This suggests that non-opioid-based pain management regimens following PCNL may be equally effective as opioid-based strategies in alleviating post-operative PCNL pain, while avoiding potential risks associated with opioid usage. While the preliminary results of this trial are promising, it is necessary to enroll additional patients to confirm these initial findings.