Intravenous Acetaminophen for Perioperative Pain Control in Adult Elective Neurospine Surgical Patients: A Retrospective Case-Control Study

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Adding intravenous (IV) acetaminophen to an opioid-based regimen as multimodal pain management for perioperative pain control in adults undergoing spine surgery can lead to effective pain control, reduce the risk of opioid-related adverse effects, and facilitate postoperative neurologic evaluation for surgical outcomes. This descriptive pilot study investigated the analgesic effect of a single dose of IV acetaminophen administered intraoperatively as routine practice for perioperative pain management for adults undergoing elective spine surgery. A retrospective comparative cohort study compared an IV acetaminophen group with a group not receiving IV acetaminophen for primary outcomes measured by visual analog scale (VAS) and associated secondary outcomes. The IV acetaminophen group had lower mean VAS scores than the group not receiving IV acetaminophen (4.33 vs 6.22, P = .01, at 60 minutes after entry into the postanesthesia care unit [PACU] for procedure level 4; 2.43 vs 3.11, P = .002, at PACU discharge for procedure level 3). The study did not show consistently lower VAS scores for the IV acetaminophen group vs the group not receiving IV acetaminophen. No difference was found for other secondary outcomes between groups. Future prospective studies are needed to assess the analgesic effects of IV acetaminophen for spine surgery cases.

Keywords: Acute surgical pain, intravenous acetaminophen, perioperative pain, multimodal analgesia, spine surgery.

Spine surgery causes more severe, intense pain than many other surgical procedures. The occurrence of referred pain is common in these patients, and pain scores on a visual analog scale (VAS) are higher in those patients. There are no significant differences in the severity of pain among cervical, thoracic, and lumbar spine surgeries. Postoperative pain after spinal surgery is proportional to the number of vertebrae involved in the operation and to its invasiveness. Most of the patients undergoing spine neurosurgical procedures have chronic pain and are receiving long-term pharmacologic analgesic therapy. Chronic pain is defined as “pain without apparent biological value that has persisted beyond normal tissue healing time (usually taken to be three months)”. Patients with chronic pain have high-severity postoperative pain requiring large doses of analgesics and opioids. Patients with surgical revision after so-called “failed back syndrome” have high baseline opiate requirements. An opioid-only regimen often presents a major barrier to achieve excellent analgesia, with about 30% of patients reporting an adverse central nervous system effect (depression, somnolence) and respiratory events occurring in 2.8% of patients. In addition, spine surgical patients require frequent neurologic examinations to assess for any possible postoperative deterioration that may require immediate intervention. Patients’ cooperation and awareness are vital to ensure a positive surgical outcome. Therefore, the challenge to manage patients undergoing spine surgery is the need to assess neurologic function while providing effective analgesia with minimal side effects. To achieve this goal, a multimodal approach to analgesia has been used.

Acetaminophen administered by the intravenous (IV) route is one of several novel pharmacologic agents that have emerged for multimodal analgesia for perioperative pain control. The IV formulation of acetaminophen was approved in 2010 for the management of fever, mild to moderate pain, or moderate to severe pain with adjunctive opioids. The efficacy of IV acetaminophen for acute surgical pain management has been supported by many randomized clinical trials (RCTs) across a variety of surgical procedures both inside and outside the United States. Adding IV acetaminophen to an opioid-based regimen as multimodal pain management for perioperative pain control in adults undergoing spine surgery can lead to better pain control with a reduced risk of opioid-related adverse drug effects, can increase patient
satisfaction, and may facilitate postoperative neurologic examination for surgical outcomes.²

The purpose of this retrospective comparative cohort pilot study was to investigate the analgesic effect and its associated clinical outcomes of IV acetaminophen administered intraoperatively as a multimodal component of perioperative pain management, as routine practice, for adult patients undergoing elective spine surgery, compared with patients without IV acetaminophen treatment, at Houston Methodist Hospital, Houston, Texas.

Materials and Methods
This was a descriptive study of differences between patients with and without IV administration of acetaminophen and with various motion segment levels of spinal surgery. It was not intended to be a predictive or causal study of the analgesic effect of IV acetaminophen for perioperative pain control of spine surgery; hence, the omnibus tests were not conducted. The study proposal was approved by the institutional review boards of the University of Texas Health Science Center at Houston, Houston, Texas, and Houston Methodist Hospital. No patient-identifiable data were collected. Data were retrieved from Picis version 8.1 Anesthesia Manager (Picis Clinical Solutions) by query language to identify stored patients records. Surgical procedures included anterior and posterior approach laminectomy; fusion/fixation of cervical spine; and posterior approach for thoracic, lumbar, and sacral spine. Because the severity of pain is related to the invasiveness of the surgery, for this study, the surgical procedure was further defined by vertebral levels based on the number of motion segments involved (eg, 1 motion segment involved indicated procedure level 1).

Of 2,491 spine surgeries from June 1, 2011, to December 31, 2012, a total of 1,696 patients were included for the final data analysis. Excluded were records with any of the following: (1) missing or inappropriate surgical procedure information; (2) missing ASA class, anesthesia duration, anesthesia types, gender, surgical duration, and VAS scores; and (3) medication documentation errors, general anesthesia with total intravenous anesthesia, surgery procedure with level above 5, and age below 18 years or above 90 years. Patients’ characteristics were not significantly different in ASA class and age between the excluded cases and study groups.

A history of chronic pain was documented during the preoperative anesthesia assessment based on the patient’s description of the type, timing, and location of the pain. If pain lasted for more than 3 months and was managed by pharmacologic therapy, it was diagnosed as chronic pain. Using Cohen d, the sample size used detects a small effect size of 0.14. The effect size detects differences in means of 0.14 standard deviations (SDs) and differences in percentages of 3.4% to 6.8% with a type 1 error of 0.05 and a power of 0.80.

For each anesthetic case, a preoperative history, physical examination findings, and intraoperative records were documented by anesthesia providers (Certified Registered Nurse Anesthetists, residents, and anesthesiologist attending physicians). Postanesthesia recovery data for patients were documented by registered nurses (RNs) via the postanesthesia care unit (PACU) manager. All required data elements were entered per hospital standard practice for routine care of surgical patients. Study data from the electronic databases, such as intraoperative physiologic monitoring data and anesthesia machine data were directly acquired via an automated, validated electronic interface from physiologic monitors (GE B850, GE Healthcare) and anesthesia machines (Datex-Ohmeda Aisys, GE Healthcare). Some data were acquired via an operating room (OR) manager documented by RNs and transferred to Anesthesia Manager through the interface between the 2 databases (eg, data of procedure closing time).

All patients received general anesthesia with endotracheal tube intubation and standard adult anesthetic maintenance with inhalation agents of sevoflurane, desflurane, and isoflurane; however, patients receiving isoflurane were excluded from this study. Muscle relaxants, including rocuronium, vecuronium, and cisatracurium, were routinely available for maintenance. Intraoperative choice of analgesics and prophylactic preoperative and intraoperative antiemetic therapy were administered according to the anesthesia providers’ judgment. Routinely used opioids included fentanyl, hydromorphone, morphine, and meperidine (only in the PACU). Because there was no protocol in place for the timing of administering IV acetaminophen intraoperatively, the timing of IV acetaminophen administered varied based on the anesthesia provider’s choice.

• Outcome Measures. The primary outcome was perioperative surgical pain control for adults undergoing spine surgery. Secondary outcomes included opioid-sparing effect both in the OR and PACU, requirement of antiemetics for postoperative nausea and vomiting (PONV), time for rescue analgesics used in the PACU, PACU recovery time, PACU discharge time, and Aldrete score. The primary outcome of effectiveness for pain control was measured by pain intensity via the VAS score on arrival to the PACU, then every 15 minutes and as needed until discharge from the PACU based on hospital policy. The VAS scores were documented by RNs based on patients’ self-reported numeric score for pain intensity and pain relief required by the hospital’s standard care. The opioid-sparing effect was calculated by total opioid consumption both in the OR and in the PACU. All opioid medications were converted to hydromorphone equivalent milligrams (Table 1). Time for rescue analgesics was measured by the time required for the first analgesics (opioids) after arriving in the PACU.
Patients were discharged from the PACU when their physical status met the required Aldrete score of 10 or less and VAS scores of 4 or less per standard hospital policy. Both PACU recovery time and PACU discharge time were analyzed. The PACU recovery time was defined as the time from entry into the PACU until meeting the PACU discharge criteria of VAS 4 or less and Aldrete score 10 or more. The PACU recovery time was used rather than the PACU discharge time because the latter was affected by many administrative factors, such as the inpatient bed availability, staffing issues, and transportation availability. Anesthesia providers entered the history of chronic pain from their preoperative evaluation. Time of administration of IV acetaminophen in the OR was calculated from the time that IV acetaminophen was administered to the time of the patient’s arrival in the PACU. All the data entries were visually checked for integrity and accuracy for final analysis.

**Statistical Methods.** The analyses used descriptive statistics to examine frequencies of categorical measures such as gender and history of chronic pain. Mean, median, and amount of variation (SD and range) described continuous measures such as VAS, Aldrete score, and body mass index (BMI). The bivariate analyses were conducted to test for a significant relationship between each measure and the treatment groups. For discrete variables, the contingency tables were created, and χ² tests were used. Fisher exact tests or the Mantel-Haenszel χ² test was used for ordered measures such as ASA scores. For continuous variables, 2-sample t tests, pooled or Satterthwaite, were used as appropriate. A 2-sided P value less than .05 was considered statistically significant.

**Results**

Patient characteristics for the 2 study groups are summarized in Table 2. There were no significant differences between patients’ age, BMI, and ASA physical status classification (all P > .05) for the 2 study groups. There was a significantly greater number of men in the group not receiving IV acetaminophen and women in the IV acetaminophen group (56.27% vs 50.45%; 49.55% vs 43.73%, respectively, P = .02). A history of chronic pain in the IV acetaminophen group was greater than in the group not receiving IV acetaminophen (58.13% vs 51.75%, P = .01).

Treatment characteristics are summarized in Table 3 and Figures 1 and 2. Variables of procedure levels were evenly distributed between groups. Surgery duration, anesthesia duration, and prophylactic antiemetics were comparable for both groups (all P > .05). The study found that the IV acetaminophen group received larger doses of dexamethasone and ondansetron in the OR compared with the group not receiving IV acetaminophen (58.13% vs 51.75%, P = .01).

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VAS for overall comparisons at all measured time points between the 2 study groups (all \( P > .05 \)) except for procedure level 4 at 60 minutes after entry into the PACU and procedure level 3 at PACU discharge. These findings demonstrated that the IV acetaminophen group had a lower mean VAS score (4.33 vs 6.62, \( P = .01 \), at 60 minutes for procedure level 4 and 2.43 vs 3.11, \( P = .002 \), at discharge for procedure level 3). The VAS score was proportional to the procedure levels involved (the more levels involved, the higher the VAS score) for both groups at 15 and 30 minutes when VAS peaked in the PACU. Cumulative opioid consumption in hydromorphone equivalents used in the OR and the PACU were not different between the study groups (all \( P > .05 \)). The PACU recovery times were not different for both groups (all \( P > .05 \)), but a relatively longer time was needed for procedure levels 3 and 4 to meet PACU discharge criteria compared with procedure level 1 (82 minutes vs 61 minutes). There was no difference for required rescue analgesics (opioids) time between the 2 study groups (\( P > .05 \)).

In a comparison of cumulative antiemetic treatments, the difference was not significant, and there was no difference in the use of multidrug treatment of PONV in the PACU between groups. The increased intraoperative use of dexamethasone and ondansetron for the IV acetaminophen group did not result in a decreased incidence of PONV by comparing the use of antiemetics in the PACU between groups (all \( P > .05 \)). The time from IV acetaminophen administered in the OR to the PACU admission was 73 minutes for the mean and 57 minutes for the median.

**Discussion**

A comparison of this study’s results concerning analgesic effects of IV acetaminophen for control of acute surgical pain in adults undergoing spine surgery with the results of previous studies conducted outside the United States is difficult because of the differences in study designs, study medication regimens, and outcome observation periods. To our knowledge, this is the first retrospective compara-
tive cohort pilot study in the United States to investigate the effectiveness of IV acetaminophen for perioperative pain management in adult spine surgical patients using an anesthesia information management system (AIMS). The study findings did not show consistent statistical differences for the primary outcome measure, VAS score, between the IV acetaminophen group and the group not receiving IV acetaminophen for overall and by procedure level when IV acetaminophen was given as a single dose of 1,000 mg before the end of surgery at a median time from 55 to 72 minutes for assessing VAS score in the PACU.

The study observational period and the time and dose of IV acetaminophen administration were similar to those between the IV acetaminophen group and the group not receiving IV acetaminophen for overall and by procedure level when IV acetaminophen was given as a single dose of 1,000 mg before the end of surgery at a median time from 55 to 72 minutes for assessing VAS score in the PACU.

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Table 4. Comparison of Outcome Characteristics for Intravenous (IV) Acetaminophen and No IV Acetaminophen Study Groups
Abbreviations: OR, operating room; PACU, postoperative anesthesia care unit.

<table>
<thead>
<tr>
<th>Medication</th>
<th>IV Acetaminophen group (N = 898)</th>
<th>No IV acetaminophen group (N = 798)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketorolac used in PACU, No. of patients; mean (SD), mg</td>
<td>14; 31.07 (9.24)</td>
<td>14; 28.93 (4.01)</td>
<td>.4364</td>
</tr>
<tr>
<td>Ketorolac used in OR, No. of patients; mean (SD), mg</td>
<td>260; 28.66 (5.10)</td>
<td>91; 28.57 (5.68)</td>
<td>.8928</td>
</tr>
<tr>
<td>Methocarbamol used in OR and PACU, No. (%) of patients</td>
<td>241 (26.84)</td>
<td>240 (30.08)</td>
<td>.1453</td>
</tr>
<tr>
<td>Antiemetics used in PACU, No. of patients; mean (SD), mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ondansetron</td>
<td>87; 4.09 (0.60)</td>
<td>63; 4.06 (0.50)</td>
<td>.7606</td>
</tr>
<tr>
<td>Promethazine</td>
<td>76; 7.51 (4.04)</td>
<td>51; 7.47 (3.39)</td>
<td>.9583</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>19; 17.41 (10.72)</td>
<td>6; 14.58 (5.103)</td>
<td>.5434</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>10; 9.60 (6.17)</td>
<td>7; 9.14 (2.55)</td>
<td>.8368</td>
</tr>
</tbody>
</table>

Figure 3. Postanesthesia Care Unit (PACU) Recovery Time (in minutes) for Procedural Level Overall and All Levels
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen.

Figure 4. PACU Duration (in minutes) for Procedural Level Overall and All Levels
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen; PACU, postanesthesia care unit.

Figure 5. PACU Aldrete Scores for on Arrival to PACU Until Discharge
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen; PACU, postanesthesia care unit.

Figure 6. PACU Analgesics Rescue Time (in minutes)
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen; PACU, postanesthesia care unit.
used by Grundmann et al.\textsuperscript{9} In their study, a single dose of IV acetaminophen was given 45 minutes before the procedure closure, which was close to this study time, to assess the analgesic effect of IV acetaminophen. The observation time was also limited to the PACU. They found that one of the comparators, metamizole, had a lower VAS score and fewer patients required opioids compared with IV acetaminophen and other comparators. There were no differences for cumulative opioid consumption among the study groups, which agrees with this study’s findings.

Hernández-Palazón et al\textsuperscript{10} compared IV propacetamol (a prodrug of IV acetaminophen; 2 g of propacetamol is converted to 1 g of paracetamol) with placebo alone for a 72-hour observation period. The first dose of 2 g of propacetamol was given in the OR at procedure closure, and the same dose was repeated every 6 hours postoperatively for 72 hours. The investigators also failed to demonstrate an analgesic effect of propacetamol in the early postoperative period (pain significantly lower in the treatment group at 40 and 56 hours).

Other RCTs were of spine surgical patients given repeated doses of IV acetaminophen from 24 hours to 72

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**Figure 7.** Hydromorphone Equivalents (in milligrams) Used in Operating Room
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen.

**Figure 8.** Hydromorphone Equivalents (in milligrams) Used in PACU
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen; PACU, postanesthesia care unit.

**Figure 9.** PACU Visual Analog Scale Pain Scores Not by Procedural Level
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen; PACU, postanesthesia care unit.

**Figure 10.** PACU Visual Analog Scale Pain Scores for Procedural Levels on Arrival to PACU Until Discharge
Abbreviations: APAP, intravenous acetaminophen; NOAPAP, no intravenous acetaminophen; PACU, postanesthesia care unit.
hours postoperatively, with the first dose given in the OR at skin closure. The findings among these studies were inconsistent in the evaluation of VAS scores and the opioid-sparing effect in spine surgical patients. The VAS scores were lower in the combination of nonsteroidal anti-inflammatory drugs (NSAIDs) and IV acetaminophen group for 2 studies compared with IV acetaminophen or NSAIDs alone and placebo. Uzun et al found that groups receiving the comparators of metamizole and dexketoprofen had lower VAS scores than in the IV acetaminophen group.

This study did not find an opioid-sparing effect for a single dose of IV acetaminophen given intraoperatively for perioperative pain management for adults undergoing spine surgery. The results agree with the results of other studies in which IV acetaminophen did not decrease cumulative opioid consumption of spine surgical patients. The study also did not find that IV acetaminophen decreased opioid-related adverse effects. Most of the studies included in a current meta-analysis demonstrated a morphine-sparing effect, but not a decrease in opioid side effects. The study was unable to calculate the incidence rate of PONV from PACU data entries; the antiemetics used in the PACU were not different between study groups, although the IV acetaminophen group received larger doses of dexamethasone and ondansetron resulting from anesthesia providers’ practice patterns. This study finding agrees with other study results. Fuentes et al found that patients who received IV acetaminophen had an earlier discharge from the PACU (32 minutes, n = 20) than those who had received placebo (48 minutes, n = 20, P < .05) in adults undergoing laparoscopic cholecystectomy. This study did not find any statistical significance for PACU recovery time between groups. There were small differences among each level; the fewer procedure levels involved, the quicker the PACU recovery time and the shorter length of PACU stay for both groups.

Although no consistent statistically significant differences were observed between groups in the adequacy of analgesia as assessed by VAS and other outcome measures in this study, there are some factors that warrant consideration. First, there was no protocol in place for the time of administering IV acetaminophen in the OR, although the observed median time of 55 to 72 minutes was reasonable to assess VAS score based on the pharmacokinetics and pharmacodynamics of IV acetaminophen. The inconsistent timing of IV acetaminophen administration might have affected the results. Second, the study involved a single dose and the observation period was limited only to the PACU. The single dose and the short time of observation may not have been long enough to give adequate long-term outcome information. Third, a history of chronic pain was found in 38% of patients in the IV acetaminophen group vs 51% in the group not receiving IV acetaminophen. Considering the pain characteristics of the chronic pain patient population who have higher VAS scores and require higher baseline opioid requirements, it is possible that IV acetaminophen has a limited effect to control pain for this group of patients. Last, the reason for the limited difference observed in VAS scores for the 2 groups could be because it was anticipated that there would be no difference in pain scores between groups because pain scores of the 2 groups were within the controlled “zone of analgesic success” of VAS.

Although postoperative pain after spine surgery can be very severe and difficult to control, it was possible to achieve effective and similar pain relief in both groups. This retrospective pilot descriptive cohort study has several limitations. It is not an RCT, which may introduce bias, especially because of the retrospective nature of the study. It was not possible to get required the study data (eg, a baseline VAS score for the study subjects and incidence of PONV in the PACU) and control many confounding variables. The confounding variables included timing of IV acetaminophen administration in the OR, stratification of surgery types (laminectomy, fusion and instrumentation), type of opioids given in the OR (short acting vs long acting), positioning difference (prone vs supine), severity of illness measurement, and control of other medications (ketorolac, methocarbamol, dexamethasone, and ondansetron).

Despite the study limitations, these multivariable analyses should be used for future studies. The accuracy, the exhaustive information, and the large volume of AIMS data allowed this multiple outcome analysis to be performed in less time and with less labor than use of paper charts.

Conclusion

The lack of consistent significant differences in the analgesic effects of IV acetaminophen for perioperative acute surgical pain control in adults undergoing spine surgery between the IV acetaminophen and no IV acetaminophen groups must be interpreted with caution. They could be real or could be related to the methods of the study, procedure-specific factors, or factors related to patient pain characteristics. Overall, this study serves as a pilot study for an hypothesis-generating description of the results from a single dose of IV acetaminophen (1,000 mg) administered intraoperatively for perioperative pain control in a population representing a daily clinical challenge for ensuring effective perioperative pain control and positive surgical outcomes. Future prospective studies are warranted. The effect of intraoperative IV acetaminophen on extubation time and the expanded use of IV acetaminophen postoperatively for at least 24 hours should be studied to give adequate long-term outcome information.

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