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PATIENTS WHO HAVE USED PARACETAMOL (IV) IN SPINAL SURGERY: A RETROSPECTIVE ANALYSIS

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ABSTRACT

The Objective of this study was to reduce the scores of pain and exposure of opioids in the spinal surgery patients, as well as opioid-related adverse events (Nausea, Constipation and Vomiting sense). The drug has been administered (i. v.) to 20 spinal surgery patients since it was added to our formulary. To collect post-operative opioid consumption, anti-emetic also the doses of laxatives, naloxone. The electronic medical records of all patients who received a dose preoperatively or postoperatively were accessed to access their VAS pain scores from arrival on the surgical unit to the second postoperative day. Patients who did not receive any drugs were matched with an equivalent number of patients who did not use opioids before admission, age, sex, surgery type, and surgeon. Drug by injection group and control group showed a significant difference ($p=0.015$) in opioid usage. The use of anti-emetics, laxative, and the scores of VAS did not differ significantly between the two groups. IP drugs may decrease opioid exposure after spinal surgery, but they do not reduce opioid-related pain or adverse effects afterward.

Key words: Post-operative; Spinal injuries, Opioids, pain management, Paracetamol.

INTRODUCTION

Acute post-operative pain management has for a long time relied on opioid medications. Postoperative pain can be effectively controlled with opioids, but they don't come without significant adverse effects. Opioids are commonly associated with nausea, vomiting, constipation, and depression in respiration, is the severe side effects. A patient's likelihood of experiencing one or all of these adverse effects may lead to the administration of more medications, a lower patient satisfaction score, or a longer hospital stay or higher treatment costs. It has been difficult for clinicians to develop pain management regimens that maximize effectiveness and patient satisfaction while effectively reducing side effects. Mild to moderate pain has long been managed with acetaminophen and opioids [1]. There were only oral and rectal forms available in the U.S. until recently. Acute pain in mild to moderate severity can be managed with intravenous Paracetamol, however Rectal preparations have lower bioavailability than i.v. preparations, and oral preparations take longer to act. According to a study conducted at Yale University's

Anesthesiology Department, this drug formulation rapidly reduced pain after orthopedic surgery in patients reporting moderate to severe pain within 24 hours of taking it. [2] Adjuvant opioid analgesics have been tested both as a monotherapy and as a multimodal therapy. Two doses of paracetamol were administered intravenously in a study of laparoscopic abdominal surgery patients, and both regimens significantly reduced post-operative pain intensity. [3].

Following surgery, including appendectomy, cesarean section, and hip fracture, several studies have shown a significant reduction in pain intensity and opioid use. [4] As far as other surgical populations are concerned, such as those undergoing spinal surgery, there have been no studies on the drug. By infusion over 15 minutes every six hours, paracetamol 1000mg/100mL is administered by intravenous route. As compared to oral or rectal administration, this route of administration requires more nursing time and is more expensive [4].

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Using paracetamol as an adjuvant pain management therapy may result in lower opioid use, and therefore lower consumption of antiemetics and laxatives. It was determined in this study whether paracetamol was significantly reduced post-operative opioid use and side effects related to opioid use in spinal surgery patients who received paracetamol by IV.

METHODS

In order to conduct this retrospective review of electronic charts, approval from the institutional review board was obtained. In order to collect postoperative opioid consumption (in morphine equivalents), antiemetic and laxative doses, naloxone usage, and visual analog pain scores between arrival and day two after surgery, all patients receiving paracetamol intravenously or postoperatively were accessed via the electronic medical record. We have injected paracetamol intravenously into twenty spinal surgery patients in the first year after adding it to our formulary. There were two approaches to fusing the spinal discs in this study: anterior or posterior. During the study period, patients in the control group did not receive any paracetamol via intravenous administration and were matched by opioid use prior to admission, sex, age, gender, type of surgery and its way of approach. The study excluded participants who received opioid intravenous injections or epidurals. Detailed demographic information was collected on all patients, including their age, sex, height, weight, and use of opioid pain relief after surgery. An opioid PTA is considered a "Yes" if a patient reports using any opioid within one week before surgery and has a current, valid prescription for that medication.

Paracetamol was given preoperatively to all patients but one through an intravenous injection lasting 15 minutes. It is estimated that patients treated with paracetamol by IV received four doses post-operatively on average. Postoperative pain was managed with an as-needed combination of intravenous and oral opioids in both groups. Medications administration records were used to convert total opioid doses to morphine equivalents (ME). Upon arrival at the patient care unit, opioid consumption (intravenous and oral) was collected and totalled for each surgery day. Buprenorphine,

Nalbuphine and Tapentadol were allowed to be used, however no conversion factor was available for these medications.

In the paracetamol i.v group, three patients used tapentadol at least once. At least one dose of buprenorphine was administered to 8 patients receiving paracetamol IV and 4 patients receiving a placebo. The control group included one patient who received nalbuphine. Each day's VAS pain score was averaged. We counted antiemetics and laxatives each day. Spinal surgery postoperative orders included both scheduled and as-needed prescriptions for anti-emetics and laxative.

A descriptive analysis was conducted to compare the demographic characteristics of patients in the paracetamol (i.v) group and control group. An ANOVA with a mixed-design was conducted for both groups overall as well as within each group to determine how opioid use and pain scores changed after surgery. The cumulative use of antiemetics and laxatives in the two groups was compared using Pearson's Chi-Square tests. In SPSS Statistics 20, IBM Corporation, Somers, New York, a p-value less than 0.05 was used to determine significant results.

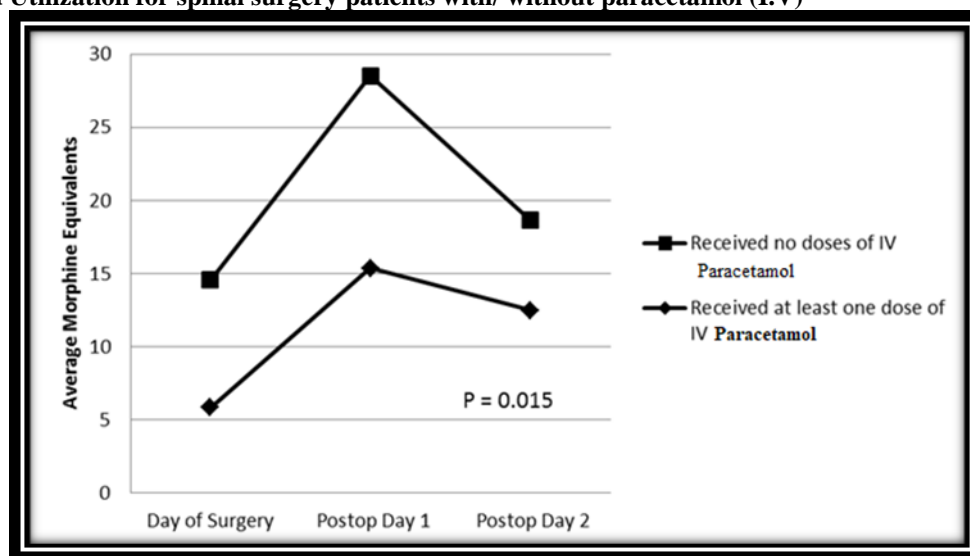
RESULTS

On average, the paracetamol (i.v) group used fewer opioids over the course of the study than the control group on every study day. In the i.v.group, paracetamol consumption averaged 12.3 mg per day, compared with 19.6 mg per day in the control group ($p=0.014$). The only dose of naloxone administered to the control group was to an individual in the control group. VAS pain scores did not differ significantly between the paracetamol and control groups (5.1 versus 5.6, $p=0.115$). Neither antiemetics nor laxatives were used significantly differently between the two groups throughout the study ($p=0.665$ for antiemetics and $p=0.679$ for laxatives). In each group, the number of patients who used zero, one, or more antiemetics or laxatives over the study period was totaled and presented as frequency of use. There could be no more number of patients having antiemetic or laxative uses per group, and the study could not exceed three days in duration.

TABLE 1: Baseline characteristic of patients.

Demographics	IV Paracetamol n=20	Control n=20	P values
Age	49.98 (18.98)	48.78 (18.88)	0.901
Height	65.7 (2.98)	66.9 (3.58)	0.324
Weight	84.01 (16.6)	83.54 (20.98)	0.312
Gender	75.4	72.6	1.000
Opioid PTA	35.45	35.41	1.000
Average operative time	215.99 (113.98)	186.98 (93.65)	0.257

Figure 1: Opioid Utilization for spinal surgery patients with/ without paracetamol (I.V)



DISCUSSION

In comparison to the control group, spinal surgery patients receiving paracetamol intravenously consumed significantly fewer opioids post-operatively than those receiving placebos. Based on literature for other surgical populations, these results are consistent with paracetamol used via i.v. Previous studies of paracetamol taken intravenously showed a reduction in VAS pain scores in surgical patients; this result was not observed in our study. Paracetamol (i.v.) has also been found to improve patient satisfaction with pain control in some of these previously published studies. In our retrospective study design, e-health records were unable to provide specific pain control scores to our study. This result might have been influenced by variation in nursing care since VAS pain scores were not required to be assessed on a regular basis.

While opioid utilization decreased, there was no statistically significant difference between the paracetamol group and the control group regarding antiemetic and laxative use. Therefore, both spinal surgery groups appear to use antiemetic and laxative medication at similar rates, regardless of their opioid consumption. This outcome may have been influenced by variations in nursing care and/or patient sensitivity as with VAS pain scores. The paracetamol i.v group showed a decreased opioid utilization, but not a decreased incidence of typical opioid-related adverse events. This may be because both groups utilized laxatives and antiemetics and administered naloxone similarly.

Despite not being prospective and randomized, the study successfully matched all paracetamol (i.v) patients from all opioid PTAs and surgical approaches, surgeons, and genders to appropriate controls. A number of limitations were associated with the VAS pain score system, such as inconsistent documentation of patient pain

scores and potential bias in selection. According to the statistical software, no VAS pain scores could be missed on any given patient day. A patient without documented VAS pain scores on any given day was not included in the analysis of opioid use, antiemetic and laxative use. The opioid utilization total in this study included patients who were concurrently taking tapentadol, buprenorphine, or nalbuphine, so this might be considered a limitation. Our results were not affected by whether these ancillary agents were included or not, as their utilization was low and equally distributed between both study groups. The administration of oral paracetamol was also permitted along with hydrocodone and oxycodone. Due to the lack of total paracetamol consumption in either of the two groups, it is possible that the results may have been influenced by this. Because opioid medications have to be taken after these surgeries in order to provide adequate postoperative pain management, we do not believe the results would have been adversely affected by this. Our institution had a novelty relating to paracetamol (i.v) and a limited number of patients who were included in the paracetamol (i.v) group. Despite the rapid growth in popularity of paracetamol (i.v.) among spinal surgeons at our institution, we wished to analyze the impact of paracetamol (i.v.) in this patient population to determine whether its use should be discouraged or continued. In addition, different surgeons were involved in the study. In light of identical technique, surgical approach, operative time, and anesthesia between the control groups, as well as matching of multiple factors, including matching surgeons, we believe any differences between them are negligible. In order to minimize possible variations in surgical technique and instrumentation, all patients underwent surgery within a 12-month period. Both small and large groups were found to benefit from paracetamol (i.v.).

Despite the fact that this study did not include cost analysis, consideration of costs might be beneficial when considering formulary addition and determining how it is used by patients and hospital administrators. The oral dosages of intravenous acetaminophen may also prove equally effective for managing preoperative and postoperative pain in addition to being an effective pain management therapy for traditional opioids. However, they are much less expensive and less likely to manipulate the injection site. Despite the difficulty of comparing relative efficacy between the IV route and the oral route, there is no conclusive evidence that the IV route reduces postoperative pain satisfaction better than the oral route [6]. The effectiveness of IV APAP remains controversial,

although some evidence indicates it achieves C_{max} more quickly and consistently than oral APAP. [7, 8].

CONCLUSION

In our institution, paracetamol (i.v.) was associated with a decrease in post-operative opioid utilization, but similar VAS pain scores for patients undergoing spinal surgery. Paracetamol (i.v.) group users used antiemetics and laxatives as much as the control group, despite reduced opioid usage. It appears paracetamol (i.v.) can decrease opioid exposure during spinal surgery in patients using paracetamol (i.v.) as an adjuvant pain management therapy. In particular surgical populations, a larger study on paracetamol (i.v.) is needed.

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