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Original Research Article

A Hospital Bases Study to Evaluate and Compare the Efficacy and Safety of a Single Dose of Intravenous Paracetamol and Intravenous Tramadol for Post Operative Analgesia in Infra Umbilical Surgery

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Abstract

Aim: The aim of the present study was to evaluate and compare the efficacy and safety of a single dose of intravenous Paracetamol and intravenous Tramadol for post operative analgesia in infra umbilical surgery.

Methods: The present study was conducted in the Department of Anaesthesia, BMIMS for the period of one year. Total 100 patients from both the sexes aged between 18-60 years of ASA grade I and II scheduled for elective infra umbilical surgery under spinal anaesthesia were included in the study.

Results: Demographic data was comparable with respect to age, weight, ASA physical status, gender status and duration of surgery in both the groups. From 0 hour (at the end of surgery), till 2 hours postop, there was no significant difference in mean VAS scores between the two groups. However, at 4 hours and 6 hours postop, mean VAS score in Group-A was significantly lower as compared to that in Group-B. At 1 hour, 2 hour, 4 hour and 6 hour, mean sedation scores in Group-A was significantly lower as compared to that in Group-B. More number of patients from group B developed nausea and vomiting and the intergroup difference was statistically highly significant.

Conclusion: Paracetamol and Tramadol both produce adequate postoperative analgesia. However, intravenous paracetamol is a safer and more effective analgesic than intravenous Tramadol for the treatment of postoperative pain in patients undergoing infra umbilical surgeries.

Keywords: Paracetamol, Postoperative pain, Tramadol, VAS score

Introduction

Pain is the most common symptom of any illness. The International Association for the Study of Pain (IASP) has defined pain as "An unpleasant sensory and emotional experience in association with either actual or potential tissue damage or described in terms of such damage". [1] Perioperative analgesia has traditionally been provided by opioid analgesia. However, extensive use of opioids is associated with a variety of perioperative side effects. [2] NSAIDs have been advocated to provide "multimodal" or "balanced" analgesia that decreases opioid dose requirements and may reduce associated adverse events while reducing postsurgical pain intensity. [3-7] Acetaminophen has a well-established safety and analgesic profile.

For decades now, opioids and nonsteroidal anti-inflammatory drugs (NSAIDs) have been used and have not been entirely devoid of undesirable effects like postoperative nausea and vomiting (PONV), respiratory depression, sedation, gastrointestinal bleeding and renal injury among others. [8] With the advent of intravenous (IV) paracetamol, interest is now being shown as to its efficacy in mitigating pain especially against the backdrop of commonly used analgesics. [9] IV paracetomol was approved and made available in united states in 2010. IV paracetamol is an analgesic and antipyretic agent, recommended worldwide as a first-line agent for the treatment of pain and fever in adults and children. Paracetamol (acetaminophen), now also available for IV use, is not an NSAID and interferes neither with platelet nor kidney functions nor does it present the unwanted side effects of NSAIDs.

Adverse reactions emerging from the use of the IV formulation of paracetamol are extremely rare (<1/10,000). [10] Tramadol has been shown to provide effective analgesia after both intramuscular and IV administration for the treatment of

postoperative pain. While it is not recommended as a supplement to general anesthesia because of its insufficient sedative activity, tramadol has been successful in the treatment of postoperative pain. A randomized double-blind study reported acceptable analgesia with postoperative IV tramadol 50 mg, repeated once if required after 30 min. It produced an effect similar to that of morphine 5 mg or the alpha 2 agonist, clonidine 150 µg. Tramadol, a synthetic opioid of the aminocyclohexanol group, is a centrally acting analgesic with weak opioid agonist properties, and effects on noradrenergic and serotonergic neurotransmission. In addition, these opioids and nonopioids modes of action appear to act synergistically. [11] Tramadol is an isomeric drug, of which the (+) enantiomer is a weak mu-opioid agonist with an analgesic potency about 1/10th that of morphine. [12]

The aim of the present study was to evaluate and compare the efficacy and safety of a single dose of intravenous Paracetamol and intravenous Tramadol for post operative analgesia in infra umbilical surgery.

Materials and Methods

The present study was conducted in the Department of Anaesthesia, BMIMS Pawapuri, Nalanda, Bihar, India for the period of one year. Total 100 patients from both the sexes aged between 18-60 years of ASA grade I and II scheduled for elective infra umbilical surgery under spinal anaesthesia were included in the study. The patients were randomly divided into two equal groups by sealed envelope method. The infusion bottles were prepared and handed over to a blinded observer in a covered manner masking the contents of the bottle. The patients of ASA grade III/IV, patients undergoing laparoscopic surgeries, surgeries on upper abdomen, chest, limb, supramajor surgeries of duration more than 3 hours, surgeries under general anesthesia, epidural anesthesia or blocks were excluded from the study. Patients with renal, hepatic, cardiac, major respiratory disease, those receiving anti diabetic, anti hypertensive medications, anticoagulants were excluded from the study. Pregnant patients, those with body mass index greater than 35 kg/m2 were also excluded from the study.

Group A: IV Paracetamol 15 mg/kg (maximum 1 g in 100 ml infusion) over 15 minutes, 20 minutes prior to the end of surgery.

Group B: IV Tramadol 2 mg/kg (maximum150 mg in 100 ml NS infusion) over 15 minutes, 20 minutes prior to the end of surgery. In the preanaesthesia room baseline parameters to be studied were noted. All the patients received premedications and spinal anaesthesia as per standard protocol of the institution. Intraoperative monitoring was done as per standard protocols. 20 minutes prior to the end of surgery, the study drugs were given. All the patients were observed in post anaesthesia recovery room and later in high dependency ward as per institutional protocol. To assess effects of study drugs on postoperative analgesia in patients undergoing infra- umbilical surgeries, the 10cm standard Visual Analogue Scale (VAS) was used; where '0' indicated 'no pain' and '10' indicated 'worst imaginable pain'. VAS scores were assessed at an interval of 0, 1, 2, 4 and 6 hours in the postoperative period and rescue analgesic inj. Diclofenac sodium 75 mg IM was given when VAS was more than 3. Heart rate, Mean arterial pressure, respiratory rate and adverse effects like nausea, vomiting, sedation were noted. Sedation was assessed by using the University of Michigan Sedation Scale, where 0= awake and alert, 1= minimally sedated, 2= moderately sedated, 3= deeply sedated, 4= unarousable.

Statistical Analysis: The data was collected and compiled in excel sheet. Continuous variables were presented as mean +SD; Ordinal and Nominal data were presented as number or percentage of incidents. Comparison between the groups was made using student's t test for quantitative data and chi-square test for qualitative data. Hemodynamic parameters were analyzed using one-way ANOVA to find statistical difference within and between the groups. P value <0.05 was considered statistically significant. Statistical analysis was done using SPSS version 22.0.

Results

Table 1: Demographic data

Variables	Group-A N=50	Group-B N=50	P value
Age (year)	46.4±8.4	48.4 ±6.6	0.1173
Weight (kg)	58.6±4.6	55.35±4.6	0.3128
ASA I/II	40/10	36/14	0.1024
Sex (Male/Female)	38/12	35/15	0.1640
Duration of surgery	72.38±9.3	66.64±6.54	0.1536

Demographic data was comparable with respect to age, weight, ASA physical status, gender status and duration of surgery in both the groups.

Table 2: Comparison of mean VAS scores between two groups at different time intervals

Duration	Group-A Mean±SD	Group-B Mean±SD	P Value
0 hr	1.14±0.36	1.04±0.46	0.3136
1 hr	1.18±0.42	1.4±0.56	0.3132
2 hr	1.66±0.54	1.96±0.64	0.07284
4 hr	2.8±0.52	3.14±0.56	0.00016
6 hr	2.84±0.86	3.37±0.63	0.007

From 0 hour (at the end of surgery), till 2 hours postop, there was no significant difference in mean VAS scores between the two groups. However, at 4 hours and 6 hours postop, mean VAS score in Group-A was significantly lower as compared to that in Group-B.

Table 3: Comparison of mean Sedation scores between two groups at different time intervals

Duration	Group-A Mean±SD	Group-B Mean±SD	P Value
0 hr	0.64 ± 0.56	0.72 ± 0.58	0.560
1 hr	0.48 ± 0.62	1.18 ± 0.62	<0.0001
2 hr	0.19 ± 0.31	1.08 ± 0.62	<0.0001
4 hr	0.14 ± 0.26	0.94 ± 0.64	<0.0001
6 hr	0.08 ± 0.46	0.40 ± 0.50	<0.0001

At 1 hour, 2 hour, 4 hour and 6 hour, mean sedation scores in Group-A was significantly lower as compared to that in Group-B.

Table 4: Comparison of adverse effects between two groups

Parameter	Group-A	Group-B	P Value
Nausea and Vomiting	4	14	0.001
Bradycardia	0	0	-
Hypotension	0	0	-
Respiratory depression	0	0	-

More number of patients from group B developed nausea and vomiting and the intergroup difference was statistically highly significant.

Discussion

Pain is a predictable component of any surgical procedure, and postsurgical pain is commonly treated ineffectively. Inadequately treated postoperative pain may result in pain and suffering, as well as multiple physiological and psychological consequences (e.g., splinting, impaired gastrointestinal motility, and impaired wound healing) which may adversely affect perioperative outcomes and contribute to increased length of stay. Successful recovery from surgery includes comprehensive management of post-operative pain. [13] Postoperative pain paves the way for a host of complications in major surgeries like laparotomy, which can deleteriously impact convalescence. [14]

During the review of recent 14 randomized controlled trails 12 have supported the use of IV paracetamol for better postoperative analgesia. [15] Paracetamol, an active metabolite of phenacetin affords a central analgesic action secondary to a raised pain threshold and can be administered orally, rectally, intramuscularly and of late IV. Excretion occurs following conjugation in the liver. Action tends to peak by 1 h and lasts till 4–6 h. Hepatic toxicity can occur only if therapeutic doses are exceeded (for patients weighing 50 kg or more, the total daily dose of paracetamol should not exceed 4 g). [16] Demographic data was comparable with respect to age, weight, ASA physical status, gender status and duration of surgery in both the groups.

From 0 hour (at the end of surgery), till 2 hours postop, there was no significant difference in mean VAS scores between the two groups. However, at 4 hours and 6 hours postop, mean VAS score in Group-A was significantly lower as compared to that in Group-B. At 1 hour, 2 hour, 4 hour and 6 hour, mean sedation scores in Group-A was significantly lower as compared to that in Group-B. More number of patients from group B developed nausea and vomiting and the intergroup difference was statistically highly significant. Sinatra et al [17] found that the efficacy of IV paracetamol in orthopaedic surgeries to be superior to tramadol in terms of rapid onset of analgesia and significant reduction in morphine consumption over the 24 hour postoperative period and safety in terms of clinical and laboratory parameters. Intravenous acetaminophen was well tolerated in the elderly and high- risk (American Society of Anaesthesiologists physical status II and III) population. Paracetamol offers a historically low incidence of adverse effects and untoward drug interactions. However, higher-than-recommended doses have been associated with hepatotoxicity and hepatic failure. [18] The

intravenous route is especially advantageous in postsurgical situations when oral (e.g. infections with severe fever or vomiting or post-operative period where nil- per- oral is maintained) or rectal (e.g. high variability in uptake and bioavailability) routes are not suitable or effective. [19] Tramadol, a centrally acting synthetic agonist at μ opioid receptor, acts by modifying the transmission of pain impulses via inhibition of noradrenaline and serotonin uptake. The relative lack of respiratory depression, major organ toxicity or abuse potential affords credence to use of the drug.

Alhashemi et al [20] in their study concluded that IV paracetamol is an effective alternative to oral ibuprofen for post-cesarean section analgesia. Pen Deville PE et al [21] compared the post-operative analgesia between tramadol versus paracetamol in children who had undergone tonsillectomy. Surprisingly, they found that, the side effects of nausea and vomiting were comparable between the two groups, pain relief was higher and need for rescue medication was less in the Tramadol group. Paracetamol stands out among nonopioid analgesics due its effective analgesia and reduced side effect profile. Dejonckheere et al [22] compared IV tramadol to propacetamol for postoperative analgesia following thyroidectomy. They found more patients complained of nausea and vomiting (P = 0.01) in the tramadol group during first 2 h of the study, but PONV is comparable between the group during the entire study period. Paracetamol is a viable alternative to nonsteroidal anti-inflammatory agents, because of its less adverse effects.

Conclusion

Paracetamol and Tramadol both produce adequate postoperative analgesia. However, intravenous paracetamol is a safer and more effective analgesic than intravenous Tramadol for the treatment of postoperative pain in patients undergoing infra umbilical surgeries.

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