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Original Research Article

Comparative study between injection parecoxib and butorphanol for postoperative analgesia in laparotomy patients

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ABSTRACT

Background: Pain is a complex, subjective experience comprising both physical and emotional components. Upper abdominal surgeries cause most intense pain and distress. Opioids and Nonsteroidal anti-inflammatory drugs are used for postoperative analgesia. Aim of this study was to compare the efficacy of analgesia between injection parecoxib and butorphanol.
Methods: Prospective randomised comparative study included total 60 patients posted for laparotomy under general anaesthesia. Patients were randomly allocated in two groups. One group received injection paecoxib sodium (Group-P) and other group received injection Butorphanol (Group- B) half an hour before extubation. Pain score was recorded as per visual analogue scale at 0, 4,8,12 hours. The side effects if any were recorded and vomiting and sedation score was recorded.
Results: Immediately in postoperative period VAS was less in Group B, but at 8 hours. VAS was less in Group P.
Conclusions: Parecoxib has better quality of pain relief, minimal side effects compared to butorphanol which has good analgesia in immediate postoperative period.

Keywords: Analgesia, Butorphanol, Laparotomy, Parecoxib sodium

INTRODUCTION

International Association for pain defines pain as an unpleasant sensory and emotional experience associated with actual tissue damage, or described in term of such damage.[1] Pain serves a number of useful functions such as protective, defensive, diagnostic. Anaesthesiologist plays a very important role in the management of postoperative pain.

Intensity of postoperative pain depends on site of surgical incision and nature of surgery. Upper abdominal and thoracic surgeries cause most intense pain and distress. Pulmonary complications are known due to inadequate ventilation and retention of secretions if pain is not relieved.[2] Hence management of pain is a must in postoperative period after thoracic and abdominal surgeries.

There are various methods to relieve postoperative pain like drugs (nonsteroidal anti-inflammatory, opioids), epidural analgesia and blocks (intercostal, paravertebral block). Nonsteroidal anti-inflammatory drugs (NSAIDS) are commonly used drugs for postoperative pain.[3] Non selective cyclo-oxygenase inhibitors cause side effects, so new drugs having cyclo-oxygenase 2 inhibitor activity are evaluated for analgesic efficacy and side effects. Parecoxib sodium, a parenteral prodrug of valdecoxib is first highly selective cyclo-oxygenase 2 inhibitors used in the management of post-operative pain. Parecoxib

sodium is as efficacious as older NSAIDS and is much safer as it spares COX-1 dependent physiological processes in tissues, particularly the stomach, intestine and platelets.[4] Another group of drugs used in the management of postoperative pain are opioids, with potent central acting analgesic activity. Morphine is the major analgesic drug and prototype agonist; main limiting factors for its use are side effects like nausea, vomiting, sedation, pruritus, addiction, urinary retention. Hence, there is always on-going research to design new synthetic molecule with properties of morphine with nil or minimal side effects and having better safety profile. Butorphanol possesses mixed agonist antagonist activity at opioid receptors. Receptor specificity has been used to limit respiratory depression, gastrointestinal side effects and reduce the risk of dependency.[5] Objectives of present study were to compare the efficacy of analgesia, duration and side effects of injection parecoxib sodium and injection Butorphanol tartrate.

METHODS

Total 60 patients of ASA physical status I and II were included in the study after obtaining institutional ethical committee approval and written informed consent of patients. Patients of age between 18 to 60 years, posted for laparotomies under general anaesthesia, were randomly allocated to one of the two study groups (n=30).

Group P: received injection parecoxib sodium 0.6 mg/kg intramuscularly (maximum 40 mg) half an hour before extubation. Group B: received injection Butorphanol tartrate 0.05 mg/kg intramuscularly (maximum 3 mg) half an hour before extubation.

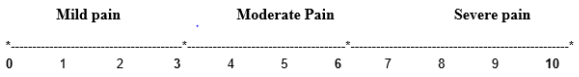
The patients with known hepatic, renal dysfunction, myocardial infarction, coagulation disorder, pregnant and lactating mothers were excluded from study. Investigations like blood grouping, complete blood count, liver, kidney function tests, blood sugar, ECG and X-RAY chest were done. Day before surgery patients were explained about visual analogue scale (VAS).

In the operation theatre heart rate, non-invasive blood pressure, respiratory rate, SpO_2 were recorded. Intravenous line was established. Patients were premedicated with injection glycopyrrolate 4 microgram/kg, injection midazolam 0.02 mg/kg and injection ranitidine 1mg/kg.

After preoxygenation, patients were induced with intravenous thiopentone sodium 5 mg/kg. Suxamethonium was administered intravenously at a dose of 2 mg/kg to achieve muscular relaxation for intubation. After laryngoscopy, trachea was intubated with appropriate size endotracheal tube. After securing airway, anaesthesia was maintained in both the groups with oxygen 50%, nitrous oxide 50%, isoflurane (1%) and titrated doses of intravenous vecuronium bromide as muscle relaxant. Patient ventilation was controlled on closed circuit with circle absorber. Patients were monitored for heart rate, non-invasive blood pressure, SpO_2 intraoperatively.

At the end of surgery approximately 30 minutes before reversal and extubation, injection parecoxib sodium 0.6 mg/kg or injection Butorphanol tartrate 0.05 mg/kg was given intramuscularly (I.M.) in outer, superior quadrant of gluteal region with all aseptic precautions. After completion of surgical procedure, neuromuscular blockade was reversed with injection neostigmine 0.05 mg/kg and injection glycopyrrolate 0.01 mg/kg and patients were extubated after thorough oropharyngeal suction.

Immediately after extubation, heart rate, respiratory rate, blood pressure, SpO_2 were recorded. Pulse rate, blood pressure, pain scores were recorded as per visual analogue scale at 0 hour, 4 hours, 8 hours, and 12 hours. The side effects if any were recorded and vomiting, sedation score was noted. Postoperatively when the patient complained of pain, time since surgery was noted as well as type and intensity of pain was assessed by visual analogue scale.[6,7]



Vomiting score:[7] 0-No nausea or vomiting; 1-Nausea but no vomiting; 2-Episode of vomiting

Figure 1: Visual analogue scale.

Sedation score:[8] 1- Anxious; 2- Cooperative; 3- Responds to command; 4- Brisk response to auditory response; 5- Sluggish response to auditory response; 6- No response.

If satisfactory analgesia was not achieved after extubation, rescue analgesia in the form of injection pentazocine 0.5 mg/kg was given intravenously and patients were excluded from the study. Presence of other complications like respiratory depression, pruritus, urinary retention, excessive sedation were noted.

Statistical analysis

Continuous clinical parameters were presented in mean ± standard deviation. Continuous variables were analysed with the help of unpaired t test. Categorical data were presented in percentages. Analysis of categorical data was done by Mann Whitney Test. The p value of less than 0.05 was taken as statistically significant.

RESULTS

Patients with respect to age in both the groups were comparable. Male and female patients in two groups were comparable. When the pulse rate was compared from 0 to

12 hours, changes in mean pulse rate in two groups were statistically not significant.

Table 1: Comparison of age of patients.

Parameters	Group P	Group B	P Value
Age in years	32.30±10.32	35.77±12.87	0.2546, NS

Table 2: Sex distributions in two groups.

Sex	Group P	Group B
Male	22 (73.33%)	20 (66.67%)
Female	8 (26.67%)	10 (33.33%)
Total	30 (100%)	30 (100%)

Table 3: Comparison of changes in mean pulse rate from baseline in group P and group B.

Time (Hours)	Group P	Group B
0	87.66±6.74	87.06±5.87
4	88.93±6.45	88.00±8.321*
8	90.83±6.56	88.53±8.74*
12	90.67±6.18	90.13±5.75*

*p>0.05 N.S. (Non-Significant)

Table 4: Comparison of changes in mean systolic blood pressure from baseline in group P and group B.

Time (Hours)	Group P	Group B
0	114.63±5.94	113.26±6.40
4	115.2±7.54	114.13±7.31
8	113.6±6.44	116.06±8.31*
12	116.0±6.94	116.2±8.15

*p=0.0067 (significant)

There was a rise in mean systolic blood pressure at 8hrs. in group-B compared to group-P which was statistically significant(P-0.0067). The difference in mean systolic blood pressure at 0, 4 and 12 hours. was not significant in both the groups.

Table 5: Comparison of changes in mean respiratory rate from baseline in group P and group B.

Time (Hours)	Group P	Group B
0	17.06±1.55	15.86±1.56
4	16.86±1.63	16.33±1.18
8	17.46±1.04	17.33±1.21
12	17.53±1.35	17.93±1.11*

Respiratory rate was low in group- B at 0 hour. compared to group P. There was gradual rise in respiratory rate from o to 12 hours. in group- B that was statistically significant (P-0.0060). Changes in respiratory rate in group-P at all the time points were not significant.

VAS was increasing from 0 to 12 hours. in group-B and decreasing from 0 to 8 hours. in group-P. When intra and inter groups comparison was done, the difference in mean VAS was significant at all-time points. Incidence of vomiting was non-significant in group P and group B (Table 7).

Table 6: Comparison of changes in mean VAS from baseline in group P and group B.

Time (Hours)	Group P	Group B
0	4.26±1.01	1.73±1.01*
4	3.5±0.93	2.06±0.69*
8	2.7±0.83	3.4±0.56*
12	4.36±0.55	4.5±0.68*

Table 7: Comparison of vomiting score in group P and group B.

Score	0	1	2	Total
Group P	25 (83.32%)	4 (13.35%)	1 (3.33%)	30 (100%)
Group B	23 (76.59%)	5 (16.65%)	2 (6.66%)	30 (100%)

p=0.3175 N.S. (Non-Significant)

Table 8: Comparison of sedation score in group P and group B.

Score	1	2	3	4	5	6	Total
Group-P	0	30 (100%)	0	0	0	0	30 (100%)
Group-B	0	14 (46.62%)	13 (43.29%)	3 (9.99%)	0	0	30 (100%)

p=0.0000 H.S. (Highly Significant)

Sedation score was high for patients in group B in comparison with group P which was statistically highly significant. Most of patients in group B had duration of analgesia in between 4 to 8 hours and 8 to 12 hours for group P. Difference in the duration of analgesia in both the groups was statistically highly significant.

Table 9: Duration of postoperative analgesia in group P and group B.

Time (Hours)	Group P	Group B
0-2	0	0
2-4	0	4 (6.66%)
4-8	6 (20%)	26 (93.34%)
8-12	24 (80%)	0
Total	30	30
Mean duration ± S.D.	9.33±1.17	4.53±1.01

DISCUSSION

Good postoperative pain management in laparotomy surgeries reduces respiratory complications and duration of hospital stay. Non-steroidal anti-inflammatory drugs and opioids are gold standard for the treatment of postoperative pain. New drugs like parecoxib sodium emerged as selective cox-2 inhibitor. Opioid like butorphanol is as potent as morphine with devoid of side effects of morphine. So the present study was conducted to compare the efficacy of post-operative analgesia between parecoxib and butorphanol in patients posted for laparotomy.

Patients in both the groups were comparable demographically. In present study, we used maximum dose of injection parecoxib 40mg intramuscularly which was found safe. Karim et al observed that single intramuscular 40 mg dose of parecoxib was safe and well tolerated.[9] Maximum dose of butorphanol 3 mg intramuscular was found safe in our study as well as in some studies.[10]

Postoperatively, we monitored pulse rate and systolic blood pressure along with VAS, as pulse rate and blood pressure indirectly reflect the quality of pain. Change in mean pulse rate at 0, 4, 8, 12 hours was statistically not significant when compared in group-P and group-B.[11] Significant rise in systolic blood pressure was observed in group-B at 8 hours. This can be explained on the basis of duration of action of butorphanol, which is less than 8 hours. There was no change in respiratory rate in parecoxib group, but in butorphanol group, respiratory rate was low immediately after surgery and gradually increased till 12 hours. Statistically this change was significant. Decreased respiratory rate in immediate post-operative period may be due to central respiratory depressant action of butorphanol. When analysis of VAS was done at 0, 4, 8, 12 hours, the difference was statistically highly significant. VAS at 0, 4 hours was more in parecoxib group and at 8, 12 hours it was more in butorphanol group.

This indicates that the quality of analgesia was good with butorphanol in immediate post-operative period. At 8 hours, mean VAS in parecoxib group was less as compared to butorphanol group, indicating that analgesia lasted up to 8 hours with parecoxib.[12] Borton et al observed good analgesia in laparotomy surgeries with 40 mg parecoxib sodium.[13] Some studies reported parecoxib as effective as morphine in relieving postoperative pain.[14] Some authors evaluated opioids sparing property of parecoxib and observed opioids sparing effect with good analgesia.[15]

One patient in parecoxib group and two patients in butorphanol group had vomiting. Statistically, incidence of nausea and vomiting in both the groups were non-significant.[16] In butorphanol group 13 (43.29%) patients were sedated. Statistically, sedation was highly significant in butorphanol group.[17]

In present study mean duration of analgesia in group-P was 9.33±1.17 and in group-B, it was 4.53±1.01. In parecoxib group, 80% patients. In parecoxib group, analgesia lasted for 8-12 hours in 80% patients.[18] Duration of analgesia was longer with intramuscular parecoxib than intravenous route.[19] No patients in butorphanol group had duration of analgesia more than 8 hours.

CONCLUSION

Present study concluded that injection parecoxib has longer duration of action, better quality of pain relief with minimal side effects as compared to injection butorphanol which has shorter duration of action with good analgesia in immediate postoperative period with few side effects like sedation. Thus injection parecoxib appears to be a promising drug with potent analgesic properties, no sedation and minimal side effects and can be advocated routinely in the management of postoperative pain relief.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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