RESEARCH



Received : 05/06/2022 Received in revised form : 01/08/2022 Accepted : 11/08/2022

Keywords: Pre-emptive analgesia, Elective abdominal surgeries, Postoperative pain management.

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DOI: 10.47009/jamp.2022.4.3.51

Source of Support: Nil, Conflict of Interest: Nonedeclared

Int J Acad Med Pharm 2022; 4 (3); 222-225



COMPARISON OF PRE-EMPTIVE PARACETAMOL-DICLOFENAC AND PARACETAMOL -TRAMADOL COMBINATION ON POSTOPERATIVE PAIN AFTER ELECTIVE ABDOMINAL SURGERY UNDER GENERAL ANAESTHESIA

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Abstract

Background: To attain effective analgesia in a postop period is one of the integral parts of anaesthesia & to achieve that with a minimal resource is a challenging task. Today many multimodal methods & combinations of analgesic drugs are used to manage postoperative pain. Hence we took this study to assess the postoperative pain relief with pre-emptive paracetamol-diclofenac and paracetamol-tramadol in elective abdominal surgeries in our institute. Materials and Methods: Prospective study was conducted on 60 patients who were posted for elective abdominal surgery & they were randomised into two groups, group A & group B. Group A received inj. Paracetamol 1gm IV and inj. Diclofenac 75 mg IM, whereas group B received inj. Paracetamol 1gm IV and inj. Tramadol 100 mg IV 1 hour prior to induction of anaesthesia. Numerical Rating Scale was used to assess the postoperative analgesia in the postoperative period until the request for next analgesia dose by the patient. Result: The statistical analysis in our study showed p value of < 0.001 which was significant. The pain free duration was longer in group B (paracetamol and tramadol) with 150+12.5 min as compared to group A with 110+10 min.Conclusion:Pre-emptive combinations of both paracetamol-diclofenac and paracetamol-tramadol effectively alleviate the postoperative pain but the paracetamol-tramadol significantly increase postoperative analgesia as compared to the paracetamoldiclofenac.

INTRODUCTION

According to international association for study of pain., it is defined as unpleasant emotional and sensory experience due to actual or potential tissue damage.^[]] In postoperative period following abdominal surgeries majority of the patients complain of varying degrees of pain as documented in various studies conducted in postoperative period if pain is not managed well,^[2,3] it may lead to various complications such as deep vein thrombosis, hypertension, myocardial ischemia, cardiac arrhythmias, respiratory distress & poor wound healing.^[4,5,6,7,8]

Combination of simple NSAIDS and opioids remain suitable postoperative analgesics alternative to epidural and USG guided blocks in a minimal resource set up. $\frac{9,10,111}{10}$ The multimodal therapy for analgesia is recommended in the management of postoperative pain as per recent guidelines which improves the recovery process. $\frac{112,13,14,15}{10}$

Pre-emptive analgesia is a method of administering analgesics prior to surgery which acts by blocking central nervous system hyper excitability and thereby reducing the postoperative pain. Paracetamol, Diclofenac and Tramadol were assessed in combination in our study as they are easily accessible in the market.

Hence we took this study to compare postoperative analgesia using combination of paracetamoldiclofenac and paracetamol-tramadol as a preemptive analgesia.

MATERIALS AND METHODS

This study was undertaken at Raichur Institute of Medical Sciences teaching Hospital and RGSSH Hospital, Raichur from 1st July 2021 to 28th February 2022.

A randomised controlled clinical trial was conducted at Raichur Institute of Medical Sciences

Hospital and RGSSH Hospital, Raichur from 1st July 2021 to 28th February 2022.

Ethical Committee approval was obtained from institutional ethical committee(IEC). The informed written consent as well as purpose of the study was explained to the participants in their own language

Patients above 18 years old and with ASA grade I-II were included in the study whereas patients with comorbidities like Anaemia, HTN, arteritis, moderate or severe renal dysfunction, DM and asthma were excluded from the study.

Sample size was calculated using prior power analysis and it was estimated to be 60 in our study. Time duration for request of first analgesia, Numeric rating scale score & mean total analgesic consumption between group A & group B were evaluated

A day before surgery at midnight Tab. Alprazolam 0.5 mg was given orally to both the groups. Prior to surgery (60mins before surgery) 1gmiv (intravenous infusion) Paracetamol and 75mg inj. Diclofenac IM (intramuscular) were administered to the patients belonging to group A whereas for Group B patients, Inj. Diclofenac 75 mg intramuscular (IM) and tramadol 100mg intravenous (IV) was given to the patients allocated randomly.

In preoperative room baseline vital signs were recorded & pre medication drugs of Inj. Ondansetron 4 mg iv, Inj. Midazolam 1mg iv and Inj. Glycopyrolate 0.2 mg iv was given.

In the operative room standard monitors were connected which included, pulse-oximeter, electrocardiography, non -invasive blood pressure. Following 3 minutes of pre oxygenation general anaesthesia was induced by Inj. propofol 2.5mg /kg, Inj. Fentanyl (2mg/kg) and inj. succinylcholine (2mg/kg) followed by endotracheal intubation.

Isoflurane with oxygen and nitrous oxide mixture was used to maintain the anaesthesia. Ini. Vecuronium was given for neuromuscular blockage after completion of surgery & it was reversed with inj. myopyrolate (inj. glycopyrolate 0.01mg/kg and neostigmine 0.05mg/kg) after surgery. Patients were monitored in surgical ICU post operatively for postoperative pain. The rate of pain intensity according to standard numeric rating scale ranging from 0 to 10 was recorded & it was further graded as mild, moderate, severe depending on NRS scale 0-3(mild),4-6(moderate) and NRS: 7-10 (Severe)respectively.

Till 12th hour every 2hrly, and later at 24th Hour NRS Score were recorded at recovery.Consumption of analgesia in 24hrs postoperatively, request by the patient for first analgesia and analgesia duration was documented.

Inj ondansetron (IV) was administered if there was nausea & vomiting. whenever patient complaints of pain post operatively according to the study protocol intravenous tramadol 50mg was given as rescue analgesic.

RESULTS

The statistics were analysed using SPSS V 23 software. Analysis of variants (ANOVA) was used for normally distributed continues data. Chi-squired Test was used to analyse categorical data. Statistical analysis showing p value of <0.05 is significant

In our study 60 patients were included in the study as per our inclusion criteria. Among group A & group B there was no difference in gender, age, weight and ASA physical status. Paracetamoltramadol group had lower NRS score compared to paracetamol-diclofenac.

Table1: Sociodemographic details of patients given in mean +/- SD

	Group A	Group B	P value
Age(yrs)	44.33+/-	41.10+/-8.07	0.376
	6.72		
Gender(M/F)	11/9	9/12	0.378
Weight(Kgs)	57.52+/-3.54	56.26+/-2.57	0.200
ASA I/II	17/4	19/5	0.634
Operation	102.38+/-	110.05+/-	0.580
duration(mins)	16.34	18.51	
Anaesthesia	123.66+/-	129.14+/-	0.683
duration(mins)	17.97	16.52	

	Group A	Group B	P-value
Age(year) ^a	44.33±6.72	41.10±8.07	0.376
Gender(M/F) ^b	11/9	9/12	0.378
Weight(kg) ^a	57.52±3.54	56.26±2.57	0.200
ASAI / II ^b	17/4	19/5	0.634
Operation duration(min) ^a	102.38±16.34	110.05±18.51	0.580
Anaesthesia duration(min) ^a	123.66±17.97	129.14±16.52	0.683

Median NRS score were not significant at 2nd ,12th & 24 hours (p>0.05) between 2 groups during coughing as per Kruskal walls test. At the 4,6th and 8th hour between groups statistically significant difference was noted (p=0.009 and 0.006). During 24h (p>0.06) all the time between the two groups statistical difference was not found. However, paracetamol – diclofenac NRS scores were higher than paracetamol – tramadol at all time.

First analgesia requirement time in the paracetamol – diclofenac group A (M \pm SD:110.01 \pm 15.02min) was significantly shorter than in the paracetamoltramadol group B (150.01 \pm 10.53min p=0.030), similarly analgesia requirement for the first time in the paracetamol – diclofenac was significantly higher than paracetamol – tramadol group (p<0.001) [Table 2].

Within 24hrs the mean total tramadol consumption between the groups was statistically significant as shown in the [Table 2]. It was observed that total tramadol consumed in 24h shown significantly higher in group A (p -0.007) compared to group B (p-0.02) that is paracetamol & tramadol. Group B showed less significant statistically compared to group A Nausea and vomiting were lower (15%) in Group A compared to group B (20%) which was not statistically significant (p=0.6) as well as no serious complications observed in either group.

DISCUSSION

Over 24 hr the total tramadol consumption was less in paracetamol – tramadol compared to paracetamol – diclofenac combination in our study. The mean total tramadol consumption was 160.76 ± 30.53 mg in paracetamol – tramadol group as compared to 190.81 ± 80.49 mg in paracetamol diclofenac group with p value of 0.001.

	Group A	Group B	P value
First dose	110.01+/-	150.05+/-	< 0.001
analgesic	15.40	10.52	
requirement			
time (mins)			
Total	190.21+/-	160.76+/-	< 0.001
analgesic	80.29	30.54	
consumption			
of Tramadol			
in mg(IV)			

Data: mean +/- SD

In our study first dose of analgesia mean time was shorter in paracetamol - diclofenac group (M \pm SD:110.62 \pm 15.95min) compared to paracetamol – tramadol group (150.01 \pm 10.53 min, p=0.001), Similar observation were made in the study conducted by Samimi et al (p<0.05).

In patients who received the paracetamol-diclofenac combination in the first 24 hrs had markedly lower mean total morphine consumed compared to diclofenac group $(20.1 \pm 3.6 \text{ mg})$ with p< 0.05 was noted in a study done by Samimi et al.

In the present study the weakest opioid (tramadol) was used for post-operative pain management in order to compare our result with the study done by Samimi et al using opioid conversion factor tramadol to morphine (0.1). An estimated mean of 17.4 mg morphine was consumed in paracetamol-diclofenac group in our study.

In Monotgomery et al study, it was shown that total morphine consumed postoperatively in paracetamoldiclofenac group (18.5–35.8) (mean, 95% CI) was less compared to paracetamol group (36.1–53.6) with p<0.01. Monotgomery et al showed that the use of paracetamol- diclofenac combination is known to reduce the consumption of morphine by 1/3rd in comparison to paracetamol group alone.

Similar results were observed in a study done by Moussa and Riad, which showed total morphine consumed by patients in paracetamol-diclofenac group was significantly lower than paracetamol group alone

To limit the nervous system sensitisation by noxious stimuli multi modal analgesia holds a greatest promise.^[15] Multimodal analgesia is combining many modalities of analgesia into a single analgesic regimen. Multilevel interruption to the nociceptive

inputs as well as to enhance the pain threshold & to decrease the activation of nociceptor can be done by using effective pre-emptive analgesic techniques. Through blockade of nociceptive stimuli at different site before tissue damage is explained by decreasing the excitability in central nervous system which further leads to decrease in pain score especially in combination groups.^[16,17]

CONCLUSION

In elective abdominal surgeries the first analgesic dose request for paracetamol – tramadol combination has increased time interval compared to paracetamol-diclofenac, hence paracetamol tramadol combination has better postoperative analgesia in comparison to combination of paracetamol – diclofenac.

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