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ORIGINAL RESEARCH

TRAMADOL-PARACETAMOL COMBINATION FOR POSTOPERATIVE PAIN RELIEF IN ELECTIVE SINGLE LEVEL MICRODISCECTOMY SURGERY

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Abstract

Aim: To compare the postoperative pain score in patients receiving two different doses of tramadol 1mg/kg and 1.5mg/kg in combination with paracetamol 1gm for elective single-level microdiscectomy

Materials and Methods: Total 60 patients were included in the study. The study was planned as a prospective, randomized, double blind comparative study. Patients were allocated randomly into one of the two treatment groups of 30 each using chit in box method. Group A patients received injection tramadol 1mg intravenously and Group B patients received injection tramadol 1.5mg intravenously. Pain intensity was evaluated with a 10-cm VAS scale postoperatively at 30 minutes, 1 hour, 2 hours, 3 hours and 4 hours. At any point of time if the VAS equal to or more than 4 then rescue analgesia was administered in the form of injection Diclofenac sodium 1.5 mg/kg as slow intravenous infusion. The hemodynamic parameters were continuously monitored. We also studied the occurrence of any unusual event like bradycardia, hypotension, nausea, vomiting etc. and were prepared for appropriate management.

Results: At all times, no significant differencewas observed in the mean pain score except at30 minutes when the VAS was significantly lower in group1T. None of the patients experienced severe pain (VAS>6). In group 1.5T, 8 patients (26.67%) reported havingnausea or vomiting compared with 3 patients (10%) ingroup 1T. This difference was statistically significant at P=0.002.

Conclusion: Intravenous infusion of Paracetamol, as well as tramadol, can safely and effectively be recommended for postoperative pain relief in elective single-level microdiscectomy surgery.

Introduction

According to the American Society of Anesthesiologist practice guidelines for acute pain management in the perioperative setting, acute pain is defined as pain present in a surgical patient after a procedure.[1] The World Health Organization and International Association for the Study of Pain have recognized pain relief as a human right.[2] Poorly managed postoperative pain can lead to complications and prolonged rehabilitation.[3] Uncontrolled acute pain is associated with the development of chronic pain with the reduction in quality of life.[4]

The failure to provide good postoperative analgesia is multifactorial. Insufficient education, fear of complications associated with analgesic drugs, poor pain assessment, and inadequate

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staffing are among the causes. Recent trends in minimally invasive surgery and enhanced recovery protocols have addressed pain management.The goal of postoperative pain management is to relieve pain while keeping side effects to a minimum. This is often best accomplished with a multimodal approach. Effective postoperative pain control decreases postoperative pain-related complications and improves patient outcome[5]. Systemic opioids are regarded as the gold standard for the relief of postoperative pain, however, their use is limited by dose-related side effects[6]. To overcome this problem, the adjunctive administration of analgesics that act via different mechanisms during the preoperative period as preemptive analgesia is recommended for effective postoperative pain control.

Tramadol has recently been recommended as the first-line analgesic for postsurgical pain because it causes less respiratory depression, cardiac depression, dizziness and drowsiness than morphine does.[7] The aim of our study was to compare the postoperative pain score in patients receiving two different doses of tramadol 1mg/kg and 1.5mg/kg in combination with paracetamol1gm for elective single-level microdiscectomy.

Materials and Methods

The study was conducted after obtaining institutional ethics board approval and signed written informed patient consent. Total 60 patients were included in the study. Inclusion criteria were;a: age between 18-50 years, b: American Society of Anesthesiologists (ASA) grade I and II patients scheduled for elective single-level microdiscectomy. Preoperative exclusion criteria were: contraindications to NSAIDs, age less than 18 or more than 50 years, ASA grade III/IV, history of allergy to analgesics, patients with a history of drug abuse and patients with comorbidities like hypertension, diabetes, coronary artery disease etc.

The study was planned as a prospective, randomized, double blind comparative study. Patients were allocated randomly into one of the two treatment groups of 30 each using chit in box method. Group A patients received injection tramadol 1mg intravenously and Group B patients received injection tramadol 1.5mg intravenously. In addition, at the time of start of surgery, all patients received infusion of injection paracetamol in dose of 1g intravenously slowly over fifteen minutes. After the infusion was finished, injection tramadol was administered intravenously as per the group allotted. The study drug was supplied in pre filled syringe and neither the observer nor the patient knew about the details.

After receiving the patient in operation room, routine monitoring was applied which includes SpO2, ECG, Heart Rate, EtCO2 and non-invasive blood pressure. Pre oxygenation was done with 100% oxygen for 3 minutes. Patients were induced with injection fentanyl 3 μg/ kg, injection midazolam 0.05 mg/ kg and injection vecuronium 0.1 mg /kg through intravenous (IV) route. After 2 minutes, injection propofol was given intra venously in dose of 1-2 mg/ kg as per response with assisted ventilation. All patients were intubated with proper size endotracheal tube and ventilated with oxygen and inhalational anaesthetic agent (Isoflurane). Isoflurane 1% and top up doses of anaesthesia drugs was given throughout operative period.

Pain intensity was evaluated with a 10-cm VAS scale postoperatively at 30 minutes, 1 hour, 2 hours, 3 hours and 4 hours. At any point of time if the VAS equal to or more than 4 then rescue analgesia was administered in the form of injection Diclofenac sodium 1.5 mg/kg as slow intravenous infusion. The hemodynamic parameters were continuously monitored. We also studied the occurrence of any unusual event like bradycardia, hypotension, nausea, vomiting etc. and were prepared for appropriate management.

Statistical analysis

The statistical analyses were performed using SPSS 20.0 software (SPSS Inc., Chicago, IL, USA).Patient demographic characteristics were presented as means ± standard deviation for continuous variables and proportions for categorical variables. The comparison between the

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two groups was tested by Wilcoxon rank-sum test for continuous variables and by χ^2 test for categorical variables. The efficacy variables were after the changes in VAS for each time point were presented by each group and analyzed by the signed-rank test. The incidence of adverse events was analyzed by the χ^2 test and Fisher's exact test. All statistical tests of the efficacy parameters were conducted at the two-sided, 5% significance level.

Results

Demographic data are presented in Table 1.

Table 1: Comparison ofdemographical and ASA variables between groups

Variables	Group A (1gm T)		Group B (1.5gm T)		p –value
	Mean	SD	Mean	SD	
Age	46.13	11.87	51.40	16.51	0.123
Weight	71.93	9.36	65.80	11.83	0.181
Height	169.57	7.9	169.10	7.9	0.753
ASA					
1	23	76.67	22	73.33	0.87
2	7	23.33	8	26.67	
Male:Female	1.14:1		1.14:1		

Mean age among group A and B was 46.13±11.87 and 51.40±16.51 years respectively. Male:female was 1.14:1 in both groups.

Themean duration of surgery in group 1.5T was 118.93±36.59 minutes, which was significantly longerthan the mean duration of surgery in group 1T, whichwas 110±26.85 minutes (P=0.03) despiterandomization. Mean fentayl dose used during surgery among group A and B was 2.39±0.35 and 2.62±0.22ug/kg respectively (table 2).

Table 2: Assessment of duration of surgery and fentanyl used in surgery

Variables	Group A (1gm T)		Group B (1.5gm T)		p-value
	Mean	SD	Mean	SD	
Duration of Surgery (in min)	110.30	26.85	118.93	36.59	0.03*
Fentanyl used during surgery(ug/kg)	2.39	0.35	2.62	0.22	0.14
Post-op morphineconsumption (mg)	3.05	1.46	2.57	0.81	0.28

*: statistically significant

Mean pain scores at different time intervalsare given in Table 3. At all times, no significant differencewas observed in the mean pain score except at30 minutes when the VAS was significantly lower in group1T. None of the patients experienced severe pain(VAS>6) (Table 3).

Table 3: **Comparison of pain score between groups**

Time of Recording Pain Score After Arrival in Recovery	GROUP A		GROUP B		p-value
	Mean	SD	Mean	SD	
One Min	0.36	0.83	0.51	0.72	0.31
Fifteen Min	0.42	0.64	0.65	0.78	0.13
Thirty Min	0.63	0.91	1.08	0.92	0.02*
One Hour	1.29	1.08	1.14	1.04	0.49
Two Hour	1.32	1.14	1.38	1.19	0.73
Four Hour	1.83	1.42	1.99	1.52	0.06

*: statistically significant

In group 1.5T, 8 patients (26.67%) reported havingnausea or vomiting compared with 3 patients (10%) ingroup 1T. This difference was statistically significant atP=0.002(Table 4).

Table 4: Comparison of adverse effects between the groups

Adverse Effects	GROUP A	GROUP B	p-value

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	N	%	N	%	
Nausea and vomiting	3	10	8	26.67	0.002*
Sedation	2	6.67	3	10	0.08

*: statistically significant

Discussion

The goal of our study was to compare the efficacy of two different doses of tramadol i.e. 1mg/kg and 1.5mg/kg in combination with paracetamol 1gm for elective single-level microdiscectomy.

Microdiscectomy is one of the standard procedures for symptomatic disc herniation and they involve removal of the portion of the intervertebral disc compressing the nerve root or spinal cord. It is considered as a painful procedure thereby demanding adequate pain relief. The goal for postoperative pain management is to reduce or eliminate pain and discomfort with a minimum of side effects. Various opioid or nonopioid agents like morphine, meperidine, fentanyl paracetamol, diclofenac etc. are used for the purpose. Although traditionally the mainstay of postoperative analgesia is opioid-based, increasingly more evidence exists to support a multimodal approach with the intent to reduce opioid side effects (such as nausea and ileus) and improve pain scores. Also, Enhanced recovery (ERAS)protocols are becoming more prevalent and recommend multimodal opioid-sparing regimens as a critical component. Familiarity with the efficacy of available agents and routes of administration is important to tailor the postoperative regimen to the needs of the individual patient[7].

Postoperative pain was recorded by visual analog scale (VAS).It is a 10 point scale, a straight horizontal line of fixed length, usually 100 mm[8]. The ends are defined as the extreme limits of the parameter to be measured (symptom, pain, health)[9]orientated from the left (worst) to the right (best).

There are very few studies using the low-dose tramadolparacetamol combination after spinal surgery.Tramadol 1.5mg/kg alone was compared with a combinationof tramadol 0.75mg/kg and paracetamol 1 g inmultilevel vertebral surgery by Emir et al[10]. They foundthat pain scores were overall comparable between groups and the incidence of side effects was lower in the low-dosetramadol paracetamol combination group. They used paracetamol only in 1 group of patients receivinga lower dose of tramadol. In contrast to thesestudies, we used paracetamol in both groups. Our rationalewas to determine whether this analgesic advantage wasretained with paracetamol as the basal analgesic in bothgroups. We in our study wanted to determine whether thisanalgesic advantage was retained if we used paracetamol inboth groups. Another difference was that we studied single-level rather than multilevel spinal surgeries as performedby Emir and colleagues, thus reducing the impactof variability in the procedure on the results.We found that pain scores were comparable at almostall times in both groups, proving our hypothesis thatthere is no difference in pain scores between the lowerdose tramadol paracetamol combination and the higherdose tramadol paracetamol combination. The only differenceobserved was at 30 minutes in group 1.5T, wherethe scores were higher than those is group 1T. This couldhave happened because the duration of surgery wassignificantly longer in group 1.5T ($P<0.05$), whichhappened despite randomization.

Nausea and vomiting is one of the most commonside effect in the postoperative period. It is reported asone of the most distressing symptoms in the postsurgicalperiod[11,12]. In our study, the lower dose tramadol grouphad significantly lesser incidence of nausea and vomiting.In group 1.5T, 8 patients (26.67%) reported havingnausea or vomiting compared with 3 patients (10%) ingroup 1T. This is an important finding that should befurther evaluated in a larger study.There was also no significant difference in terms ofsedation between the groups at 2 hours. Using a lowerdose of tramadol is also cost-effective. This is important,especially for a developing country such as ours'.

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Paracetamol with its safety profile can prove to be an asset in managing perioperative pain, especially of mild to moderate severity[13]. Findings in the present study will pave the way for further work on the issue. More studies on use of drugs with fewer side effects and optimum analgesic efficacy are recommended.

Limitations of our study were small sample size, lack of placebo arm, and these were reasons we could not draw further conclusions.

Conclusion

On the basis of the present study, both Paracetamol and Tramadol were found to be safe and comparable in postoperative pain management. Thus intravenous infusion of Paracetamol, as well as tramadol, can safely and effectively be recommended for postoperative pain relief in elective single-level microdiscectomy surgery.

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