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An observational study to evaluate the effects of intravenous diclofenac in comparison to tramadol on early postoperative pain relief in patients following spinal anaesthesia

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Abstract

Background: Pain in early post-operative period is the most common complaint after elective surgeries under spinal anaesthesia and important impediment of recovery time. Postoperative pain management is a vital factor contributing towards speedy recovery of the patient. The present study was undertaken to compare the efficacy of injection tramadol verses injection diclofenac on early postoperative pain relief in patients who underwent surgery under spinal anaesthesia.
Methods: Total 200 patients of either sex, aged between 18 to 65 years, ASA grade I or II were enrolled and divided into two groups of 100 patients each, receiving either inj. Diclofenac (group D) or inj. Tramadol (Group T). Pain assessment was done using VAS score up to 8 hours.
Results: Mean VAS score in group T was significantly lower as compared to group D throughout up to 8hrs. In group D mean onset of analgesia was less (27.7±3.5) as compared to group T (39.2±3.3) which was statistically significant, (P<0.01)**.** Mean duration of analgesia in group D was less (442.0±54.0) as compared to group T (467.4±7.3), (P<0.05)**.** In group D, 31% patients required rescue analgesia as compared to 8% in group T, (P<0.05). In group T more number of patients (13%) suffered from adverse effects as compared to group D (7%) but difference was insignificant (p>0.05).
Conclusion: Intravenous infusion of injection tramadol is having more pronounced analgesic effect as compared to intravenous infusion of injection diclofenac. However, further study is required in the post-operative period upto 48 hours to observe the incidence of side effects in both the groups.
Keywords: Pain; Tramadol; Diclofenac; Spinal anaesthesia; VAS score; Analgesia.

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1. Introduction

Spinal anaesthesia is the most consistent block for lower abdomen and orthopaedic surgery (Lower extremity). Early post-operative pain is the most common complaint after elective surgeries under spinal anaesthesia and important impediment of recovery time [1]. The goal for postoperative pain management is to reduce or eliminate pain and discomfort with a minimum of side effects [2]. Various agents (opioid Vs. non opioid), routes (oral, intravenous, neuraxial, regional) and modes (patient controlled Vs. as needed) for the treatment of postoperative pain exist. 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 and improve pain scores [3].

Diclofenac is an inhibitor of key enzyme cyclooxygenases involved in metabolism of arachidonic acid into various prostaglandin mediators of pain and inflammation. It is phenyl acetic acid derivative belonging to carboxylic class of NSAIDS. It also appears to exhibit bacteriostatic activity by inhibiting bacterial DNA synthesis [4].

Tramadol is a synthetic analogue of codeine. It has two different mechanism of action. First it bind to mu-opioid receptor. Second it inhibits reuptake of serotonin and norepinephrine at synapses in descending inhibitory pain pathway. Tramadol acts on the opioid receptors through its major active metabolite desmetramadol, which has as much as 700-fold higher affinity for the μ-opioid receptor relative to tramadol [5]. Additionally, it also works by inhibiting reuptake of uptake of norepinephrine and serotonin. In the treatment of mild-to-moderate pain, tramadol is as effective as morphine or meperidine. It has got 100% bioavailability by intramuscular route and rapid onset of action. There is no ceiling dose for tramadol; therefore, pain management can be individually tailored to patient/pain response. Thus, it provides additional advantage to prefer it for postoperative analgesia [6]. Hence the present observational study was carried out to know the efficacy of intravenous tramadol as compared to intravenous diclofenac in preventing early post-operative pain relief in patients undergoing surgery under spinal anaesthesia.

2. Materials and Methods

After obtaining institutional ethics committee approval, this prospective observational study was conducted in total 200 patients of either sex, age group between 18 to 65 years, ASA grade I and II undergoing various lower abdominal surgeries and orthopaedic surgeries (lasting up to 2 hours) under spinal anaesthesia during a period of 18 months. Patients supplemented with epidural or general anaesthesia, patients with known allergy to tramadol or diclofenac, patients with history of peptic ulcer or GI bleeds, opioid use in last 30 days, pregnant and lactating mothers, patients not willing to give consent were excluded from the study. The selected patients were divided in to two groups of 100 patients each. Group D received injection Diclofenac 75mg IV in 100 ml normal saline (NS) and group T received injection Tramadol 100 mg IV in 100 ml normal saline (NS).

A complete pre-operative assessment was carried out and all relevant investigations were checked. The grading of the pain intensity was explained to the patient at pre-anaesthetic visit. After confirming informed consent & checking for starvation period, patient was taken on operation table and monitors were attached. All baseline vital parameters were noted like electrocardiogram, Blood Pressure, Respiratory rate and Heart Rate. Intravenous line was secured on dorsum of the non-dominant hand with 20 G cannula. Intravenous infusion of Ringer Lactate was started at 2ml/kg/hr. With due aseptic precaution, spinal anaesthesia was given with a 25 gauze spinal needle in the L3/L4 vertebral space by injection Bupivacaine 0.5% (heavy) 3- 3.5 ml as per the institutional standard protocol. Patients received either injection diclofenac (75mg) or injection tramadol (100mg) in an infusion of 100 ml of Normal Saline over 20 minutes, once they came out of spinal anaesthesia effect and started complaining of pain at the operative site (started moving toes). Time of administration of the analgesic drug given was noted. Patients were observed for intensity of pain for 8 hours thereafter.

In all patients, intensity of pain relief following analgesic drug administration was assessed using VAS scores .The onset of analgesia was noted. Intensity of pain was evaluated hourly till 8 hours from the time of administration of analgesic drug. Patients received rescue analgesic drug when postoperative VAS was noted higher than 5 in the form of intravenous infusion of injection paracetamol 15 mg per kg body weight. Duration of effective analgesia until the requirement of rescue analgesic drug for the first time and side effects of the drugs, if any such as nausea, vomiting, drowsiness, pruritus, bradycardia, respiratory depression and hypotension were noted.

2.1 Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements were presented as Mean SD (Min-Max) and results on categorical measurements were presented in Number (%). Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square test has been used to find the significance of study parameters on categorical scale between two groups, Non-parametric setting for Qualitative data analysis.The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data. Significance was assessed at 5% level of significance.

3. Observations and Results

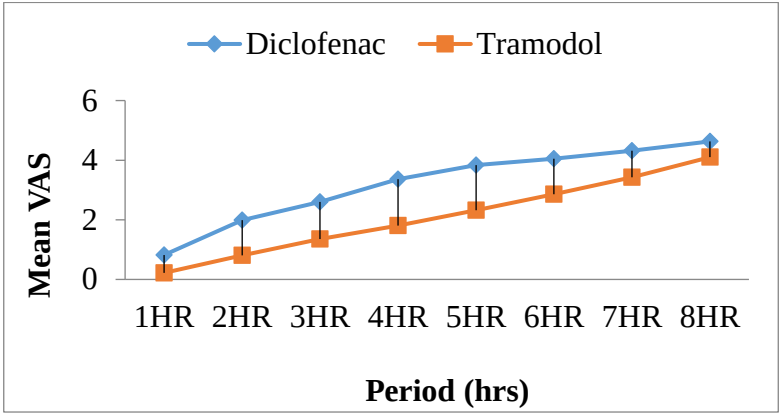
A total of 200 patients were enrolled in the study and divided into two groups of 100 patients in each group. Both the groups were comparable and found no significant difference in regards to demographic profile of the patients as shown in table 1.

Table 1: Demographic profile of the patients

Demographic data		Group D	Group T	P value
Age group	18 – 34	33 (33.0%)	29 (29.0%)	0.245
	35 – 49	54 (54.0%)	49 (49.0%)	
	50 – 65	13 (13.0%)	22 (22.0%)	
	Mean ± SD	38.45±9.49	41.44±11.15	-
Gender	Female	42 (42.0%)	37 (37.0%)	0.47
	Male	58 (58.0%)	63 (63.0%)	
BMI (kg/m²)	<18.5	12 (12.0%)	5 (5.0%)	0.283
	18.5 – 24.9	52 (52.0%)	60 (60.0%)	
	25.0 – 29.9	29 (29.0%)	30 (30.0%)	
	≥30.0	7 (7.0%)	5 (5.0%)	
ASA Grade	Grade I	50(50%)	47(47%)	0.671
	Grade II	50(50%)	53(53%)	

The mean VAS score was significantly lower in group T as compared to group D throughout the duration of 8hrs after the administration of analgesic test drug as depicted in figure 1.

Figure 1: Comparison of Mean VAS score between two groups



In group D mean onset and duration of analgesia was less as compared to group T. This difference was statistically significant, (p value<0.01) as shown in table 2. However, in group D 31% patients required rescue analgesia as compared to 8% in group T which was statistically significant (p value <0.05).

Table 2: Onset and Duration of Analgesia (min) in both the groups

Parameters	Group D	Group T	P value
Onset of analgesia	27.7±3.5	39.2±3.3	<0.001
Duration of Analgesia	442.0±54.0	467.4±7.3	<0.001

There was no statistically significant difference noted in hemodynamic parameters like heart rate (HR), MAP, respiratory rate (RR) in two groups (p value>0.05) as shown in table 3

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Table 3: Comparison of mean of hemodynamic parameters between two groups

Time intervals	HR (beats/min)		MAP in mmHg		RR (breaths/min)		P Value
	Group D	Group T	Group D	Group T	Group D	Group T	
0 hour	79.94	79.5	74.84	73.46	14.19	13.78	>0.05, Non-significant
1 hour	81.7	80.9	75.99	74.13	14.53	14.29	
2 hours	82.44	81.9	78.68	76.63	14.57	14.34	
3 hours	82.46	82.09	80.52	78.51	15.15	14.86	
4 hours	83	82.85	82.7	80.53	15.61	15.45	
5 hours	83.18	83.72	84.33	82.39	15.23	15.57	
6 hours	83.3	83.78	85.8	83.95	15.57	15.61	
7 hours	83	83.84	87.46	85.4	14.99	15.09	
8 hours	83.58	84.03	88.36	87.16	15.29	15.33	

Out of 200 patients, 180 patients did not suffer from any adverse effect. Only 20 patients suffered from adverse effect. In group D 7% patients (vomiting 5% and nausea 2%) suffered from adverse effects as compared to 13% in group T (Vomiting 13%) which was statistically insignificant, (p value >0.05).

4. Discussion

Pain is not just a sensory modality but is an experience. The International Association for the study of pain defines pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. All surgical operations are followed by pain, which may amplify endocrine metabolic responses, autonomic reflexes, nausea, ileus, muscle spasm, and which increase postoperative morbidity and mortality. Optimal postoperative pain relief is therefore mandatory to enable early mobilization and rehabilitation, to enhance recovery and to reduce morbidity [4]. Pain control is such an important factor that it has permitted surgery to progress enormously; however, postoperative pain still tends to be underestimated, is generally treated inadequately, and therefore, is not assessed with regard to how it harms the patient and impedes successful recovery [7].

In the present study, all patients in both groups were comparable (p>0.05) with respect to demographic parameters like age, sex, BMI, ASA grade. The mean onset of analgesia in group D was earlier than group T which was 27.7±3.5 min and 39.2±3.3 min respectively and this difference was statistically significant, (p value<0.01). Mean VAS score in group T was significantly lower as compared to group D from 1st hour throughout till 8 hours, (p < 0.05). These findings are comparable with the study conducted by Shareef et al [8] and Sinha et al [9]. The mean duration of analgesia in group D was 442.0±54.0 minutes which was significantly lower as compared to group T where it was 467.4±7.3 minutes. So we found that tramadol showed significantly longer duration of action than diclofenac and the time to onset of analgesia was found to be shorter with diclofenac which is also comparable with the study conducted by Pati et al [4]. In group D more number of patients required rescue analgesia as compared to group T. This difference was statistically significant, (p value<0.05). Thus tramadol was more effective in reducing post-operative pain than diclofenac and requirement of rescue analgesia was significantly higher in diclofenac group. Similar findings are reported in Paudel et al [7] and Rajesh et al [10] study.

Shukla et al [11] found that Diclofenac provides effective and better analgesia in acute post-operative pain than tramadol and tramadol requires more frequent administration than diclofenac. These findings were in contrast to current study. It may be due to the reason that we observed post-operative analgesia for 8 hours only and both drugs were given intravenously in our study as compared to intramuscular route of administration in the above mentioned study. However, Courtney et al [12] reported that oral tramadol can deliver the same analgesic efficacy as oral diclofenac for posttonsillectomy pain relief. But in our study we found that tramadol was more effective in controlling early postoperative pain than diclofenac. This difference in observation could be because of intravenous infusion of the analgesic drug used in our study and not oral route as mentioned in the above study.

In the current study, there was no statistically significant difference noted in hemodynamic parameters like heart rate, MAP, respiratory rate in two groups (p value>0.05). Only 5 patients in diclofenac group and only 13 patients in tramadol group suffered from vomiting. Only 2 patients of diclofenac group suffered from nausea. The difference between two groups was statistically insignificant. These findings are comparable with the previous studies [10, 13-15].

5. Conclusion

From the results of present study it can be concluded that intravenous infusion of injection tramadol causes more pronounced analgesia and longer duration of analgesic action as compared to intravenous infusion of injection diclofenac. Both the study drugs were well tolerated with no incidence of serious side effects throughout the study. Further study is required in the post-operative period upto 48 hours to observe the incidence of side effects in both the groups. The choice of use of analgesic drug should be individualised with due consideration to patient characteristics and cost effectiveness of the analgesic drug.

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