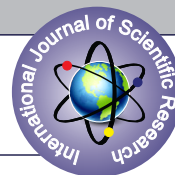


COMPARATIVE STUDY OF THE USAGE OF RECTAL TRAMADOL SUPPOSITORY VERSUS WITHOUT SUPPOSITORY FOR POST-OPERATIVE PAIN MANAGEMENT IN CASES OPERATED UNDER SPINAL ANESTHESIA



General Surgery

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ABSTRACT

Introduction: Various techniques and medications are employed to lessen postoperative discomfort. Present study aimed to assess the efficacy of pre-operative tramadol suppository administration for the management of post-operative pain in patients undergoing surgery under spinal anaesthesia, requirement of analgesia and duration of hospital stay. **Material & Method:** The present comparative study with patients presenting to the department of General Surgery, AVMCH who were posted for elective surgeries & with no evidence/signs of inflammation/infection consenting were included in the study. Patients were grouped based on utility of tramadol suppository, cases were with administration of rectal suppository and control group was with no pre-operative administration of rectal suppository. The patients were assessed for the post-operative pain at different point of time, mean duration of hospital stay and any side effects like nausea, vomiting between the groups. **Results:** Total 152 patients included in the study, with mean age of 47.57yrs. The pain score was significantly lower among the cases compared to control at 1st hr, 6th hr, 12th hr and 24th hr post-operative period. ($p < 0.05$) There was significant shorter duration of hospital stay among the cases (2.3days) compared to controls (3.2days). ($p < 0.05$) **Conclusion:** A significant pain management in post-operative period with the utility of tramadol suppository administration compared to the patients without suppository.

KEYWORDS

Pain, Visual Analogue scale, Tramadol, Nausea, Vomiting.

I. INTRODUCTION

Post-operative pain has not been well managed despite of several advancement in medical science.¹ Incidence of poorly managed post-operative pain is 80% in USA.² Although it varies depending upon factors like type of procedure done, type of anaesthesia, dose of analgesics, time elapsed after surgery etc. Studies on post-operative pain says on current scenario "appalling high rates of significant postoperative pain".^{3,4} A recent report published in 2011 from US National Institute of Health states that > 80% of the patients suffer from post-operative pain out of those only 50% receive adequate pain relief.² So, pain relief after surgery is still a major challenge. Inadequately managed post-operative pain may lead to increased morbidity, impairment of functional & quality of life, delayed discharge & recovery, prolonged duration of opioid use, higher health care cost, giving poor outcomes & ultimately it increases absenteeism at work place which affects a country's economy.^{1,2,5}

Tramadol hydrochloride is the centrally acting analgesic which acts on mu opioid receptors and has been classified as phase II analgesic by WHO pain score.⁶ Analgesic effect of tramadol by the stimulation of mu opioid receptors is contributed by O-demethylated metabolite.¹ Tramadol has both opioid & non-opioid mode of action.^{7,8} The non-opioid action is mediated by α -2 agonist & serotonergic activity which is done by the inhibition of the reuptake of the NE & 5-HT in CNS.^{9,10}

Peak plasma concentration is reached rapidly on iv administration of tramadol causing side effects like nausea/vomiting while it is delayed in oral administration leading to inadequate post-operative analgesia. So, rectal administration of tramadol can be a good alternative in such situations. Convenience of rectal suppository & established effect of tramadol for the treatment of post-operative pain can be major factors that can be exploited.^{11,12} Also it is important to note that rectal absorption of tramadol shows low variability.¹

The study provides: (i) A better understanding of the use of tramadol rectal suppository for the treatment of post-operative pain (ii) A comparison between the effects and the side effects of the use of tramadol suppository and the conventional treatment of post-operative pain. (iii) It also helps us to reduce morbidity, hospital stay & reduce health care cost.

PRIMARY OBJECTIVES:

(i) To study the efficacy of tramadol suppository administration for the management of post-operative pain in patients undergoing surgery under spinal anaesthesia. (ii) To study the possible reduction in the requirement of intravenous analgesics to achieve adequate analgesia. *Secondary Objective:* (i) To identify the possible side effects of tramadol suppository and its comparison with side effects of conventional treatment for post-operative pain. (ii) To compare the mean duration of the hospital stay in all the groups.

II. MATERIALS & METHODS

It was a comparative study design done on the patients presenting to the department of General Surgery, AVMCH who were posted for elective surgeries & with no evidence/signs of inflammation/infection done for 2 years (Nov 2020 - Nov 2022) including patients with age group >18yrs of age & <60yrs of age with no co-morbidities with no signs of infection/inflammation posted for the following surgeries: (i) All inguinal/ umbilical/ incisional/ epigastric hernias undergoing open meshplasty. (ii) Orchidectomy (iii) Jaboulay's Procedure And excluding (i) patients with co-morbidities (renal/ hepatic/ cardiac/ dysfunctions) (ii) All contaminated cases (iii) Immunocompromised patients (iv) Recurrent cases (v) Patients who are not willing.

Study group was divided in case and control: (i) Study Group: Administration of rectal suppository on table. (ii) Control Group: No administration of rectal suppository.

III. Statistically Analysis

Sample population were the patients of age >18yrs & <60 years presenting to the department of General Surgery, AVMCH who has been posted for elective surgeries & has no evidence/signs of inflammation/infection. 152 cases were enrolled with 76 cases in control group & 76 cases in control group. Sample Size Calculation: $n = 2 (Z\alpha + Z [1-\beta])^2 \times SD^2 / d^2$; $\alpha = 0.05$ Power = 85%; M = case/control = 1, $d = 1.02$, $SD = 0.5$; Power & sample size calculation for t test.

Variables tested were : A. Independent Variables: Age, Sex; B. Outcome Variables: (i) Severity of pain at 6th hour after surgery (ii) Severity of pain at 12th hour after surgery (iii) Severity of pain at 24th hour after surgery (iv) Post-operation mean hospital stay (v) Side

effects of suppository like nausea, vomiting, altered sensorium (vi) Dose of extra iv analgesics required to achieve pain relief in control group (vii) Cost of treatment of post-operative pain management in both groups

Variable wise statistical test will be used for data analysis. Continuous variables represented in mean, median, mode and standard deviation. Categorical variables represented in frequencies and percentage. For test of significance t-test will be used.

All the data were collected in proforma and entered in excel sheet. The collected data demographic data was summarized as frequency, percentage, mean and standard deviation. The summarised data were represented using tables, figures, bar diagram and pie charts. The mean difference between the continuous data was analysed using t-test, for follow-up data paired t-test and for categorical data Chi-square test was used to determine the significance between the parameters observed in this study. $P < 0.05$ was accepted as significant. Statistical analysis was performed using SPSS version 22.0 (IBM SPSS, US) software operating on windows 11.

IV. RESULTS

In present study total of 152 patients fulfilling inclusion criteria are included after obtaining the informed consent. The mean age of patients was found to be 47.57yrs. Patients were divided into two groups as 76 patients in cases and 76 patients in control group.

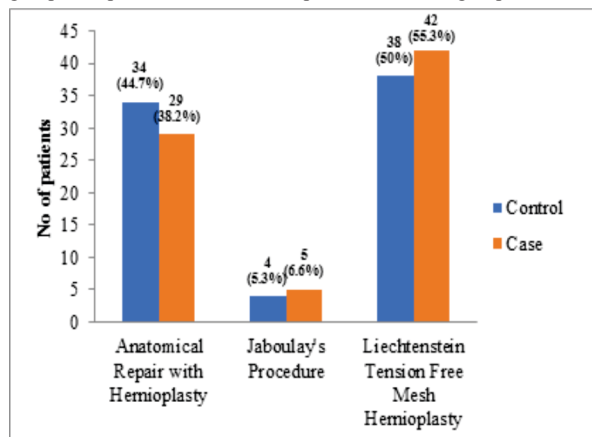


Figure 1: Comparison of management of patients

Fig 1 shows patients who underwent anatomical repair with mesh hemioplasty for ventral abdominal wall hernia were 34 (44.7%) in case group & 29 (38.2%) in control group.

Patients who underwent Jaboulay's Procedure for primary vaginal hydrocele were 4 (5.3%) in case group & 5 (6.6%) in control group. While 38 patients (50%) in case group and 42 (55.3%) patients in control group underwent Liechtenstein Tension Free Mesh Hemiplasty for inguinal hernia. ($p = 0.702$)

Table 1: Showing the presence of headache and vomiting between the case and controls

		Control		Case		Chi-square (p-value)
		Count	N %	Count	N %	
Headache	No	62	81.6%	69	90.8%	2.707 (0.100)
	Yes	14	18.4%	7	9.2%	
Vomiting	No	60	78.9%	73	96.1%	10.168 (0.001)*
	Yes	16	21.1%	3	3.9%	

Table 1 shows that 62 patients (81.6%) in control group and 69 patients in case group (90.8%) didn't complain of headache within 24 hours of surgery.

While 14 patients (18.4%) in control group and 7 (9.2%) patients in case group had complaints of headache within 24 hours of surgery which was found to be statically not significant ($p = 0.100$) additionally 60 patients (78.9%) in control group and 73 patients (96.1%) in case group didn't have episode of vomiting within 24 hours after surgery while 16 patients (21.1%) in control group and 3 patients (3.9%) in case group had episode of vomiting within 24 hours of surgery which was found to be statistically significant. ($p < 0.05$)

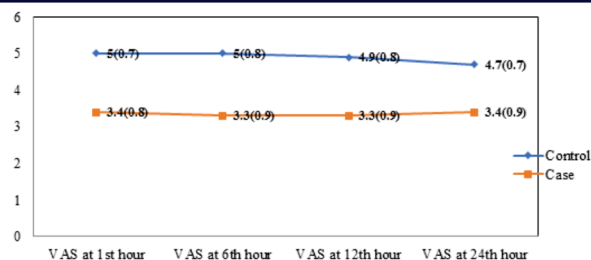


Figure 2: Comparison of mean VAS score

Fig 2. shows analgesic effect duration among the cases was significantly higher compared to the controls. ($p < 0.05$) On assessment of pain using VAS scale, the pain score was significantly lower among the cases compared to control at 1st hr, 6th hr, 12th hr and 24th hr post-operative period.

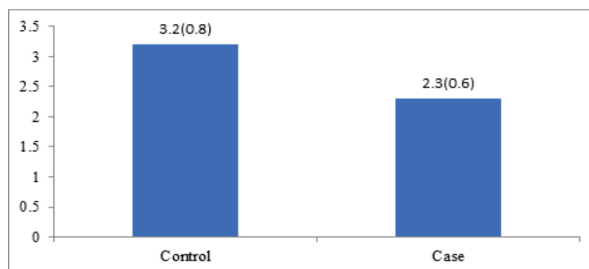


Figure 3: Comparison of the total duration of hospital stay

Fig 3 shows days of hospital stay, there was significant shorter duration of hospital stay among the cases (2.3days) compared to controls (3.2days). ($p < 0.05$)

V. DISCUSSION & CONCLUSION

In present study total of 152 patients fulfilling inclusion criteria are included after obtaining the informed consent. The presence of headache was comparable between the group, with no statistically significant difference. However, the incidence of headache was higher in control group compared to cases. The presence of vomiting was significantly higher among the control (21.1%) compared to the patients in case group (3.9%). ($p < 0.05$). Similar to present study, Patel et al., documented a significant lower incidence of the nausea and vomiting in post-operative period among the patients with rectal tramadol use.²¹

Rectal tramadol's analgesic effectiveness in comparison to intravenous tramadol for adult tonsillectomy was researched by Gadani et al., They discovered that the duration of analgesia was much longer in the rectal group than in the intravenous tramadol group. Additionally, they discovered a 15% PONV incidence in the group receiving intravenous tramadol compared to a 5% incidence in the group receiving rectal suppository medication.²³

On assessment of the analgesic effect, the duration among the cases was significantly higher compared to the controls. ($p < 0.05$) On assessment of pain using VAS scale, the pain score was significantly lower among the cases compared to control at 1st hr, 6th hr, 12th hr and 24th hr post-operative period. ($p < 0.05$) On assessment of the days of hospital stay, there was significant shorter duration of hospital stay among the cases (2.3days) compared to controls (3.2days). ($p < 0.05$). In study by Patel SJ et al., found that rectal tramadol can be better alternative to intravenous tramadol for postoperative analgesia in appendectomy.²²

Present study documented a significant pain management in post-operative period with the utility of tramadol suppository administration compared to the patients without suppository. The study also documented a significant reduction in requirement of the rescue analgesic in the post operative period, reduced PONV and early discharge from the hospital with lesser days of hospital stay compared to control group.

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