

Comparative Assessment of the Analgesic Efficacy of Tramadol and Diclofenac Sodium Rectal Suppository in Subjects Undergoing Laproscopic Tubal Ligation

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Abstract

Background: Several drugs such as NSAIDs or opioids can be used orally, intravenously or intramuscularly for treatment of post operative pain. The aim of our study was to compare the analgesic efficacy of tramadol and diclofenac sodium suppository and the secondary aim was to monitor and treat the complications if any. **Subjects and Methods:** Fifty female patients of ASA I and II in the age group of 24-42 posted for laproscopic tubal ligation were enrolled in the study. Verbal analogue scale (0- no pain to 10- worst possible pain) score reading was explained. In the pre operative room all the patients were randomly allocated in two groups by a computer generated list. Post operatively all the hemodynamic parameters and VAS score were recorded at regular intervals of 1, 2, 4, 6, 8, 10, 12hrs. Pain was assessed by a staff trained to VAS score assessment and was blinded to the study group. Side effects of nausea and vomiting were noted. **Results:** Group 2 had high mean age of the study participants compared to group 1 but the comparison was non-significant. ($p \leq 0.05$) Only one patient in group A (tramadol) complained of nausea and vomiting. In group A 69% patients needed 1 rescue analgesic at 8 hrs, 11% at 6hrs, 9% at 4hrs and 11% at 10 hrs whereas in group B 64.1% patients needed 1 rescue analgesic at 8hrs, 16.2% at 10 hrs and 19.7 % at 12 hrs. **Conclusion:** From above findings it was concluded that analgesic efficacy of tramadol and diclofenac sodium suppository is comparable. Rectal administration of tramadol reduces the incidence of nausea and vomiting.

Keywords: Diclofenac sodium, Hemodynamic parameters, Nausea, Tramadol.

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Introduction

Laproscopic sterilization is a very common procedure performed in India. It is much more painful than diagnostic laparoscopy. Davis and Millar studied that pain after lap sterilisation was much more than 1 diagnostic laparoscopy during the first four post operative hours. In India the method used for sterilization is by using Fallop rings. Application of Fallop rings is associated with greater lower abdominal pain may be because of excessive traction on mucosa and nerve fibers. Pain is an unpleasant sensory and emotional experience of varying intensity, caused by actual or potential damage or described in such type of damage.

Several drugs such as NSAIDs or opioids can be used orally, intravenously or intramuscularly for treatment of post operative pain. Tramadol hydrochloride is a centrally acting opioid analgesic, which acts on mu opioid receptors, and is classified as a phase II analgesic according to the WHO pain score.^[1] Tramadol is an analgesic with mixed opioid and nonopioid activities.^[2,3] The nonopioid component is mediated through alpha-2 agonist and serotonergic activity, which it exerts by inhibiting the reuptake of norepinephrine

and 5-hydroxytryptamine in the central nervous system and possibly by displacing the stored 5-HT from the nerve endings.^[4-8]

Tramadol is well tolerated by patients. Compared to morphine, tramadol has much less respiratory depression, cardiac depression, light headedness and sedative effect. Also addiction and abuse is much less with tramadol.^[9-11]

The only troublesome side effect of tramadol is nausea and vomiting. That can be prevented by antiemetic drugs.^[12,13]

Tramadol is available in all formulations i.e. oral, injectable and rectal. Tramadol used by different routes such as intravenous, intramuscular, rectal or local infiltration etc. have analgesic efficacy with different duration and variable incidence of side effects.^[14-17] However, after i.v. and oral administration, peak concentrations are reached rapidly, and this has been associated with postoperative nausea and vomiting.

Rectal administration of tramadol may be an alternative in this situation. It is convenient to use and is the established treatment for postoperative pain in adults. It is important to stress that rectal absorption of tramadol showed a low variability. Diclofenac sodium is a tried and tested known NSAID very well effective for post operative pain. It can be given intravenously, intramuscularly or rectally. Dose

may be adjusted as per intensity of pain in the range of 1-1.5mg/ kg.

Rectally administered drugs have greater bioavailability as more than 50% are absorbed directly into general circulation bypassing the liver. It also avoids the gastric irritation caused by oral drugs and avoids the pain of needle prick in intramuscular route. With above background in mind we decided to compare rectal tramadol with standard analgesic diclofenac suppository. The aim of our study was to compare the analgesic efficacy of tramadol and diclofenac sodium suppository and the secondary aim was to monitor and treat the complications if any.

Subjects and Methods

Fifty female patients of ASA I and II in the age group of 24-42 posted for laproscopic tubal ligation were enrolled in the study. Ethical approval was taken from the institutional ethical committee and written informed consent was taken from all of the participants. According to power 80% of the study sample size achieved was 50. Any patient of ASA III and above, having systemic diseases and undergoing MTP with tubal ligation were not included in the study.

Routine investigations such as complete haemogram, urine routine, chest Xray, ECG, coagulation profile were carried out. All the patients were visited preoperatively and informed about the procedure and the Verbal analogue scale (0- no pain to 10- worst possible pain) score reading was explained. In the pre operative room all the patients were randomly allocated in two groups by a computer generated list. In the operating room all the monitors including HR, NIBP, ECG, etCO₂ were attached. 20 G intravenous cannula was secured. Patients were premedicated with inj glycopyrolate 0.2 mg, midazolam 1mg, ondansetron 4mg, pentazocin 30 mg intravenously. Group A patients received tramadol suppository while patients in Group B received diclofenac suppository. It was introduced in lithotomy position after administration of premedication. Induction was done using inj thiopentone sodium 5-7mg/kg and inj succinylcholine 2mg/kg. Airway was secured using portex endotracheal tube. Vecuronium bromide was given as the long acting muscle relaxant (0.08-0.1mg/kg). General anaesthesia was maintained with 50% O₂ in N₂O with Sevoflurane (0.6-0.8%). Tubal ligation in all patients was done by application of Fallop rings. Intraoperatively all the vital parameters including heart rate, Spo₂, end tidal CO₂ and blood pressure (NIBP) were monitored and recorded every 5 mins. All patients received ringer lactate intravenously as per standard calculation. Extubation was done after thorough suctioning and reversing the neuro muscular blockade with neostigmine 0.5mg/kg and glycopyrolate 0.04mg/kg.

Post operatively all the hemodynamic parameters and VAS score were recorded at regular intervals of 1, 2, 4, 6, 8, 10,12hrs. Pain was assessed by a staff trained to VAS score assessment and was blinded to the study group. Side effects of nausea and vomiting were noted. Diclofenac sodium 75 mg intramuscularly was given as the rescue analgesic when the patients complained of VAS> 3. Post operative nausea and vomiting was treated with inj ondansetron 4mg intravenously.

Statistical analysis:

The recorded data was compiled and entered in a spreadsheet computer program (Microsoft Excel 2007) and then exported to data editor page of SPSS version 15 (SPSS Inc., Chicago, Illinois, USA).

Descriptive statistics included computation of percentages, means and standard deviations. For all tests, confidence level and level of significance were set at 95% and 5% respectively.

Results

According to table number 1 Group 2 had high mean age of the study participants compared to group 1 but the comparison was non-significant.(p<0.05) Only one patient in group A (tramadol) complained of nausea and vomiting. [Table 2]. In group A 69% patients needed 1 rescue analgesic at 8 hrs, 11% at 6hrs, 9% at 4hrs and 11% at 10 hrs whereas in group B 64.1% patients needed 1 rescue analgesic at 8hrs, 16.2% at 10 hrs and 19.7 % at12 hrs. There was a reduced consumption of intra muscular diclofenac in group B as compared to group A. There were no other significant side effects noted.

Table 1: Demographic information of study participants

Variable	Group 1 Tramadole (mean±SD)	Group 2 Diclofenac (mean±SD)	P value
Age in (years)	22.80±3.75	23.85±3.45	0.1
Weight in (kgs)	49.21±3.01	50.05±2.99	0.05*
Duration of Surgery (in min)	32.01±2.98	30.22±2.10	0.21

* indicates statistically significance at p<0.05

Table 2: Nausea and Vomiting

Nausea and Vomiting	Group A	Group B	Total
Yes	1	0	1
No	24	25	49
Total	25	25	50

Discussion

Postoperative pain has been associated with grave psychological trauma causing restlessness and uncooperation in patients.^[18] Pain after laparoscopy may be due prolonged pneumoperitoneum which may be associated with tearing of blood vessels, traumatic traction on nerves and release of inflammatory mediators.^[19]

Several treatment modalities are available such as local anaesthesia bilateral rectus sheath block where 15ml of 0.25% bupivacaine is infiltrated above the umbilicus.^[20] Local anaesthetic can directly be applied on fallopian rings.^[21] Analgesic regimen should be directed in providing safe and effective analgesia with minimal side effects. NSAIDS, opioids along with dexmedetomidine are good alternatives but with dexmedetomidine there is increased incidence of somnolence and bradycardia.

After intravenous and oral administration of tramadol the absorption is rapid but it is also associated with nausea and vomiting.^[22] Rectal route is a good alternative in this regard.

Zwaveling et al studied the pharmacokinetics of rectal tramadol and found a rectal dose of 1.5mg/kg-2mg/kg was therapeutic.^[23] Hence we had used 100mg of tramadol suppository. After administration via rectal route the absorption of active ingredient of tramadol was rapid but its metabolism quickly transformed the parent drug into high levels of N- desmethyl tramadol i.e M2 and N-didesmethyl tramadol i.e M5.

In group A 69% patients needed 1 rescue analgesic at 8 hrs, 11% at 6hrs, 9% at 4hrs and 11% at 10 hrs whereas in group B 64.1% patients needed 1 rescue analgesic at 8hrs, 16.2% at 10 hrs and 19.7 % at 12 hrs. Only one patient had nausea and vomiting in the tramadol group and this observation may be because of use of rectal route of administration. Zwaleing et al studied the pharmacokinetics of rectal tramadol in pediatric post operative patients and found that rectal tramadol is well absorbed with low variability in absorptions and clearance. In our study we noted that tramadol suppository administered rectally was well absorbed with longer duration of action as compared to intravenous or intramuscular route. Viitare et al, conducted a study to compare the analgesia of tramadol 2mg/kg intravenously with the placebo group in day care adenoidectomy in pediatric patients. They concluded that less number of patients needed analgesia after discharge in tramadol group. In our study the analgesic duration and efficacy of diclofenac sodium was longer than tramadol suppository but the difference was statistically not significant. Our results are consistent with the study of H. Gadani et al who compared rectal tramadol with intravenous tramadol in post tonsillectomy patients and concluded that rectal tramadol has longer duration of action without any gastric complication.

Conclusion

From above findings it was concluded that analgesic efficacy of tramadol and diclofenac sodium suppository is comparable. Rectal administration of tramadol reduces the incidence of nausea and vomiting. Hence intraoperative administration of tramadol suppository is a good alternative to diclofenac suppository for postoperative analgesia in laproscopic tubal ligation patients.

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