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Comparison of the analgesic efficacy of tramadol and diclofenac sodium rectal suppository in patients undergoing laproscopic tubal ligation

KEYWORDS: Diclofenac sodium, Laparoscopy, Suppository, Tramadol, Tubal ligation

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ABSTRACT **Background:** The aim of our study was to compare the analgesic efficacy of tramadol and diclofenac sodium used as rectal suppository in patients undergoing laproscopic tubal ligation and also to compare their side effects if any. **Materials and methods:** We had designed a prospective, randomized, double blind and hospital based study. Sixty patients of ASA I and II posted for laparoscopic tubal ligation were randomized to receive rectal suppository of either tramadol 100 mg or diclofenac 100 mg in group A and B respectively .Postoperative Pain was measured using visual analogue scale (VAS). VAS score was assessed at regular intervals of 1, 2, 4, 6, 8, 10, 12 hrs. Inj Diclofenac sodium 75 mg was administered intramuscularly as rescue analgesic when VAS >3 in the postoperative period. Side effects such as nausea and vomiting were noted. **Results:** We observed that diclofenac suppository provides longer duration of analgesia without any nausea and vomiting and using tramadol via rectal route avoids the side effects of nausea and vomiting. **Conclusion:** We conclude that analgesic efficacy of tramadol and diclofenac sodium suppositories equivalent. Rectal administration of tramadol reduces the incidence of nausea and vomiting. Hence tramadol suppository is a good alternative to diclofenac suppository.

INTRODUCTION:

Laproscopic sterilization is a very common procedure performed in India. It is much more painful than diagnostic laproscopy. Davis and Millar studied that pain after lap sterilisation was much more than diagnostic laproscopy during the first four post operative hours.[1]

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 execessive traction on mucosa and nerve fibres.[2]

Several drugs such as NSAID s or opiods can be used orally, intravenously or intramuscularly for treatment of post operative pain.

Tramadol is synthetic 4-phenyl piperidine analogue of codeine. It is a central analgesic and has low affinity to μ receptor. It acts by direct modulation of central monoaminergic pathways.[3]

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 bioavalability 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.[4]

With above background in mind we decided to compare rectal tramadol with standard analgesic diclofenac suppository.

The primary 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.

METHODOLOGY:

After obtaining the institutional ethical committee clearance and written informed consent 60 female patients of ASA I and II in the age group of 25-40 posted for laproscopic tubal ligation were included in the study. Taking Zα = 1.64, Zβ=0.83 and power = 80%, a sample size of 10 in each group was arrived at. In our study a sample size of 60 (30 in each group) was taken to achieve power of more than 80%.

Any patient of ASA III and above, altered coagulation profile, history suggestive of any major illness or allergy to drugs including the study drugs, 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. All the patients were kept nil by mouth after 10pm on the night prior to surgery. In the pre operative room all the patients were randomly allocated in two groups by a computer generated list. Ours was a double blind study where both the patient and obsersver were blind about the randomization and grouping.

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, midazolam1mg, ondensetron 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 endotrachel 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, Spo_2, 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 glycoprolate 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 ondensetron 4mg intravenously.

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Statistical analysis was done using spss software and data was analysed using unpaired t test. P value <0.05 was considered significant.

The time for first dose of rescue analgesia that is the duration of analgesia and the total doses of rescue analgesics required in 24 hrs postoperatively was recorded.

RESULTS: Demographic parameters were comparable in both the groups (Table 1).

TABLE 1: Demographic and perioperative clinical parameters.

	parameters	Group A Tramadol (mean ±SD)	Group B Diclofenac (mean±SD)	P value	Significance
1.	Age (In yrs)	22.57±2.64	23.60±3	0.16	None
2.	Weight (In kgs)	50.37±2.74	50.33±3.09	0.042	None
3.	Duration of surgery (In min)	31.00±3.07	30.33±2.45	0.66	None
4.	Baseline mean HR	80.38±6.11	79.74±6.69	0.618	None
5.	Baseline mean MAP	77.39±6.17	76±6.11	0.264	None
6.	Intraoperative mean HR	79.76±7.53	82.14± 7.14	0.108	None
7.	Intraoperative mean MAP	78.57±7.74	76.20±4.05	0.478	None
8.	Postoperative mean HR	98±6.31	95.88±7.72	0.136	None
9.	Postoperative mean MAP	73.14±9.17	72.68±10.04	0.816	None

Only one patient in group A (tramadol) complained of nausea and vomiting. (Table 2).

TABLE 2: Nausea and Vomiting

Nausea and vomiting	GroupA	Group B	Total
Yes	1(3.33%)	0(0.00%)	1
No	29(96.66%)	30(100.00%)	59
Total	30	30	60

In group A 70% patients needed 1st rescue analgesic at 8 hrs, 10% at 6hrs, 10% at 4hrs and 10% at 10 hrs whereas in group B 63.3% pts needed 1st rescue analgesic at 8hrs, 16.6 % at 10 hrs and 20.1 % at12 hrs. (Table 3)

TABLE 3: VAS Score in group A and B

VAS score	Time (In hrs)													
	1		2		4		6		8		10		12	
	No. of patients (n)													
	A	B	A	B	A	B	A	B	A	B	A	B	A	B
0	26	29	26	29	15	28	15	20	3	8	22	21	21	18
1	3	1	3	1	9	1	4	1	5	1	4	4	7	2
2	1	0	1	0	3	1	8	8	1	2	2	2	1	4
3	0	0	0	0	3	0	3	1	21	19	3	3	1	6

There was a reduced consumption of intra muscular diclofenac in group B as compared to group A. 3 patients in group A received a second dose of rescue analgesic as compared to 1 patient in group B. There were no other significant side effects noted.

DISCUSSION:

Postoperative pain has been associated with grave psychological trauma causing restlessness and uncooperation in patients.[5] 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.[6]

Several treatment modalities are available such as local anaesthesia bilateral rectus sheath block where 15ml of 0.25% bupivacaine is infilterated above the umbilicus[7]. Local anaesthetic can directly be applied on fallopian rings.[8] The analgesic regimen should be directed in providing safe and effective analgesia with minimal side effects.

NSAIDS, opioids along with dexmeditomidine are good alternatives but with dexmeditomidine 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.[9] 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.[10] Hence we had used 100mgof 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.[9]

In our study we found that in Group 'A' 70%pts needed first rescue analgesic at 8 hrs, 10% at 6 hrs, 10% at 4 hrs and 10% at 10 hrs. The mean VAS score was 2.53 at 6hrs and 2.93 at 8hrs after which the rescue analgesic was given. Only one patient had nausea and vomiting in the tramadol group and this observation may be because of use of rectal route of administration.

In group 'B' 63.3% pts received the first rescue analgesic at 8hrs, 16.6%at 10hrs and 20.1% at 12 hrs. The mean VAS score was2.33 at 6hrs and 2.86 at 8hrs.There was no nausea and vomiting in patients of this group.

Zwaleing etal studied the pharmacokinetics of rectal tramadol in pediatric post operative patients and found that rectal tramadol is well absorbed with low variability in absorptionz and clearance. In our study we noted that tramdol suppository administered rectally was well absorbed with longer duration of action as compared to intravenous or intramuscular route.

Viitare etal, 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 (59% vs 74% in placebo 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 etal 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:

We conclude that analgesic efficacy of tramadol and diclofenac sodium suppository is comparable. Rectal administration of tramadol reduces the incidence of nausea and vomiting. Hence intraopertive administration of tramadol suppository is a good alternative to diclofenac suppository for postoperative analgesia in laproscopic tubal ligation patients.

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