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# Effect of injectable tramadol v/s diclofenac suppository in post operative gynaecological patients

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**Abstract**
**Introduction:** Provision of effective post gynaecological pain relief with minimal side effects is a major concern for any gynaecologist. For decreasing post-operative pain various methods and medications are used, of which opioids and NSAID'S are cost effective and are very commonly used. This study was designed to evaluate efficacy of these two drugs in post operative gynaecological pain relief in women.
**Aims and Objectives:** To study the efficacy and duration with intravenous and rectal suppository drug administration and to study the presence of side effects, if any.
**Methods:** This is a comparative study where in 150 patients undergoing gynaecological surgeries were included in the study to receive either Tramadol 100mg intravenously (Group A) or diclofenac rectal suppository (Group B) at the end of surgery. First onset of pain, VAS score, rescue analgesic requirement and side effects if any were noted.
**Conclusion:** In the present study, diclofenac rectal suppository provides effective and better analgesia in acute post gynaecological pain than Intravenous tramadol with fewer side effects.

**Keywords:** Post operative pain, tramadol, diclofenac, VAS

## Introduction
Pain after surgery is the main concern that a patient has to deal with [1] Post operative pain may be a significant reason for delayed discharge from hospital with increased morbidity and reduced patient satisfaction, as pain is the most distressing effect of the disease [2].
The intensity of post operative pain; as ultimately perceived by the patient, is multifactorial and depends on variables such as type and duration of the operation; type of anesthesia and analgesia used and patient's mental and emotional status [3].
Drugs used for pain is classified as simple analgesics (e.g.: Paracetamol); NSAID's; opioids and adjuvants (e.g.: Anti epileptics, Antidepressants). The cause of pain must also be considered when selecting treatment [4].
Pain is classified as acute or chronic and it is the acute pain category that has to dealt with in the immediate post operative period [5]. This acute pain accompanies inflammation and tissue injury which results from local stimulation of pain fibers and enhanced pain sensitivity with increased excitability of central neurons in the spinal cord [6].
Diclofenac has analgesic, anti-inflammatory antipyretic activities. Its potency against COX-2 is substantially greater than that of Indomethacin; Naproxen or several other non-steroidal anti-inflammatory drugs [7]. Common routes of administration are oral, intramuscular, intravenous, intradermal and rectal routes. Anaphylaxis is rarely reported with intravenous route of administration [8]. Diclofenac is useful for short term treatment of post operative pain, acute musculoskeletal pain and dysmenorrhea [9].
Tramadol is a centrally acting drug which is effective in the treatment of moderate to severe pain [10]. Common routes of administration are intramuscular, intravenous, and oral. Its analgesic effects are mediated by at least 3 different mechanisms: It is a weak μ opioid receptor agonist; it inhibits the re uptake of neurotransmitter hydroxy tryptamine and nor epinephrine in the descending inhibitory pain pathways and facilitates hydroxy tryptamine release [11].

## Objectives
The aim of this study to determine the efficacy and duration with intravenous and rectal suppository drug administration and to study the presence of side effects, if any.

## Subjects and Methods

After approval from institutional ethics committee, this randomized, comparative study was conducted in Navodaya hospital. Total 150 patients were included in the study after written informed consent.

### Inclusion criteria

1. Age 20-40 years.
2. Weight 40-80 kg.
3. Height 150-170cm.
4. Patient willing to undergo surgery under spinal anesthesia.

### Exclusion criteria

1. Contraindications to spinal anaesthesia like bleeding diathesis, local or generalized sepsis and patients on anticoagulants, patients with acid peptic disease,
2. Patients with known allergy to NSAIDs,
3. Patients with known allergy to opioids.
4. Patients with neurological lesions or psychiatric illness
5. Any cardiovascular diseases like arrhythmias, IHD and valvular heart disease
6. Any Liver, Respiratory, Kidney disease.
7. Hemodynamically unstable patients

### Procedure

After taking an informed consent from the patient, pre operative preparation of the patient was done. Postoperatively immediately after surgery, patients were randomly allocated to any of the three groups.

**Group A:** Diclofenac sodium suppository 100mg BD for 2 days.

**Group B:** Injection Tramadol 2mg/kg in Normal saline BD for 2 days.

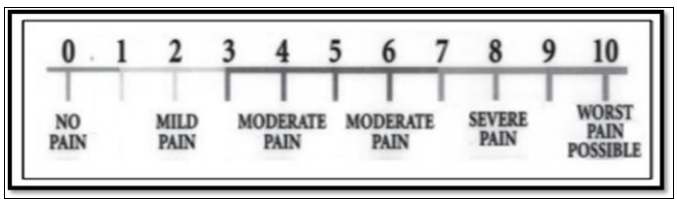
**Group C:** Injection Placebo BD for 2 days.

After giving first dose of analgesic, Pain score was noted by Visual Analogue Scale, along with pulse rate, blood pressure, and respiratory rate. Level of sedation was monitored by Four Point Scale. The scoring was recorded as follows:

- 0= Awake and alert.
- 1= Sedated but responding to verbal stimulus.
- 2= Sedated, responding to mild physical stimulus.
- 3= Sedated, responding to moderate or strong physical stimulus.
- 4= Not arousable.

Pain was assessed by Visual Analogue Scale (VAS). Visual analogue scale (Figure 1). Visual analogue scale consists of a 10cm line, marked at 1 cm each. The patient made a mark on the line that represents the intensity of pain he or she experienced. Mark "0" represents no pain and mark "10" represents worst possible pain. The numbers marked by the patient was taken as units of pain intensity.

- 0 = no pain
- 10= maximum pain.




Pain score, sedation and vitals were observed at 2hrs, 4hrs, 8hrs, 16hrs, 24hrs on first postoperative day and 8hourly on second postoperative day. Complications like nausea, vomiting, headache, dizziness and many more were assessed simultaneously. If patients complains of nausea or vomiting, inj. Ondansetron 4mg I.V was given for treatment.

Pain at injection site in group B and C and discomfort for rectal route in group A were particularly enquired in each visit.

### Statistical analysis

1. Analysis of quantitative data between the two groups was done using student unpaired t-test.
2. Qualitative data was represented in form of frequency and percentage Association between qualitative variables was assessed by Chi-Square test.

## Results

The present study was carried out to evaluate the safety and efficacy of diclofenac suppository, I.V. tramadol and placebo for post-operative analgesia in infraumbilical gynecological surgeries. Total 150 patients were enrolled in the study in the group of 50 each.

Patients were comparable with respect to demographic characteristics such as age, weight, height and duration of surgery.

**Table 1:** comparison of pulse rate between the groups

| Groups (n=150) | P value at 8hours | P value at 24 hours | P value at 48 hours |
|---|---|---|---|
| A v/s B | 0.863 | 0.872 | 0.784 |
| A v/s C | 0.563 | 0.456 | 0.567 |
| B v/s C | 0.901 | 0.234 | 0.345 |

On intergroup comparison, table 1 shows no significant changes in the pulse rate at 8hrs, 24hrs and 48hrs in post operative period of all three groups after giving diclofenac suppository, intravenous tramadol and placebo

**Table 2:** comparison of systolic blood pressure between the groups

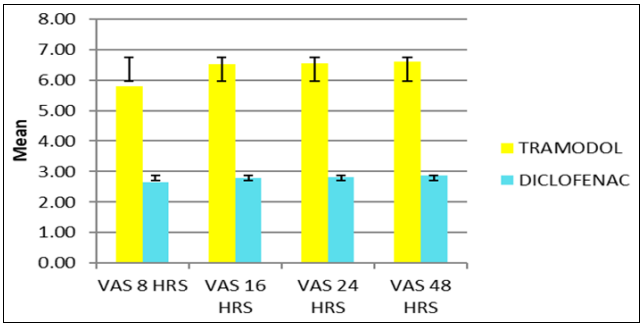
| Groups (n=150) | P value at 8hours | P value at 24 hours | P value at 48 hours |
|---|---|---|---|
| A v/s B | 0.234 | 0.167 | 0.100 |
| A v/s C | 0.453 | 0.819 | 0.789 |
| B v/s C | 0.890 | 0.345 | 0.521 |

On intergroup comparison, table 2 shows no significant changes in the systolic blood pressure at 8hrs, 24hrs and 48hrs in post operative period of all three groups after giving diclofenac suppository, intravenous tramadol and placebo.

**Table 3:** Comparison of diastolic blood pressure between the group

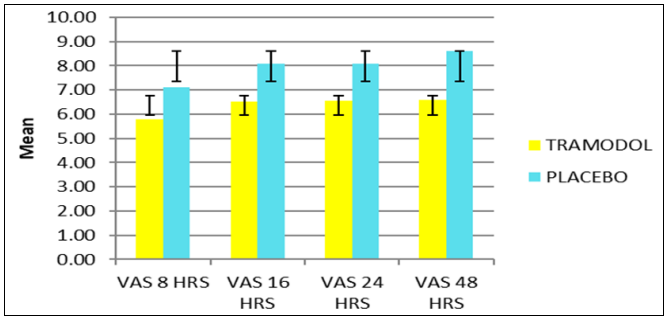
| Groups (n=150) | P value at 8hours | P value at 24 hours | P value at 48 hours |
|---|---|---|---|
| A v/s B | 0.123 | 0.123 | 0.671 |
| A v/s C | 0.210 | 0.512 | 0.819 |
| B v/s C | 0.800 | 0.541 | 0.224 |

On intergroup comparison, table 3 shows no significant changes in the diastolic blood pressure at 8hrs, 24hrs and 48hrs in post operative period of all three groups after giving diclofenac suppository, intravenous tramadol and placebo.



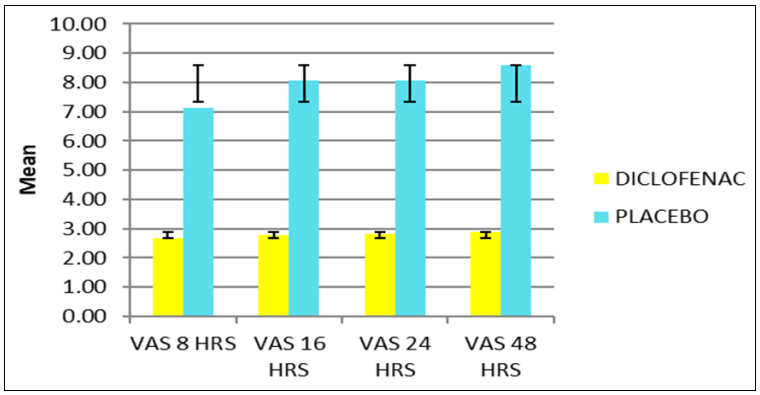

**Graph 1:** Bar graph showing the comparison of visual analog scale between two groups

On intergroup comparison, graph 1 shows significant changes in the visual analog scale at 8hrs,16hrs, 24hrs and 48hrs in post operative period after giving diclofenac suppository, intravenous tramadol



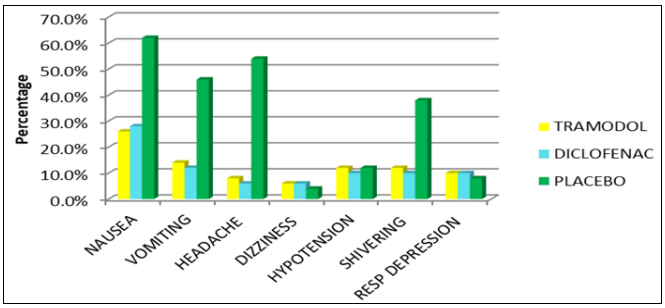

**Graph 2:** Bar graph showing the comparison of visual analog scale between two groups

On intergroup comparison, graph 2 show significant changes in the visual analog scale at 8hrs, 16hrs, 24hrs and 48hrs in post operative period after giving Injection tramadol and placebo.




**Graph 3:** Bar graph showing the comparison of visual analog scale between two group

On intergroup comparison, graph 3 shows significant changes in the visual analog scale at 8hrs, 16hrs, 24hrs and 48hrs in post operative period after giving Diclofenac suppository and placebo.




**Graph 4:** Comparison of Post operative complications between group

On intergroup comparison, graph 4 show comparatively less side effects with diclofenac suppository when compared with that of injection Tramadol and placebo

**Discussion**

This study showed that Diclofenac suppository provided a better analgesic effect when compared to that of Injection Tramadol and with longer pain relief after gynecological surgeries.

Moreover, total excess analgesic consumption was lower in patients who had received Diclofenac suppository compared with those who had received intravenous injection Tramadol.

Nausea, Vomiting and hypotension were the major aside effects of Diclofenac suppository used for post operative analgesia; however in our study these side effects were not more pronounced with Diclofenac suppository as compared with Injection Tramadol.

In our study, we observed, diclofenac suppository was more efficacious up to 48hrs postoperatively as per VAS scale. Shukla AK et all in their study observed that the analgesic effect of diclofenac in 1st 24hrs is significantly greater than tramadol for postoperative pain

To strengthen our study we have also used the ASSIST score at 24hrs which was an objective scale, according to this questionnaire pain at movement was comparatively less in the diclofenac group.

According to the cost-effective analysis, diclofenac is more cost-effective compared to tramadol. Merrikhihaghi S *et al*., in their study, has demonstrated the analgesic effect of diclofenac is 3.21 times more cost-effective than tramadol with the same efficiency and for post-cesarean pain.

Sahil S *et al*. concluded that the diclofenac suppository provides a better quality of postoperative analgesia as compared to tramadol when used as pre-emptive analgesia.

Diclofenac is a peripherally acting analgesic agent, so the adverse effects were also relatively fewer as compared to tramadol which is a centrally acting agent.

As we had conducted the study in our hospital, and we considered the cost of the drug as per hospital formulary. We found that diclofenac is more cost-effective than tramadol in postoperative conditions, the reason behind it is that the efficacy of diclofenac is more than tramadol as mentioned above.

The other probable reason being the better compliance of the patient due to twice a day administration of diclofenac.

As the study was conducted for research work, immediate adverse drug reaction are identified, the long term adverse drug reactions could be elicited.

**Conclusion**

In our present study Diclofenac rectal suppository provides effective and better analgesia in acute post operative pain than intravenous tramadol. The side effect were more pronounced in patient with intravenous tramadol which requires more frequent administration in pain relief than diclofenac suppository

**References**


1. Essentials of medical Pharmacology; K D Tripathi, 8th edition.
2. Miller's Textbook of Anesthesiology, 9th Edition.
3. Al Waili NS. Efficacy and safety of repeated postoperative administration of intramuscular diclofenac sodium in the treatment of post-cesarean section pain: a double blind study. Archieves of Med Res. 2001;32(2):148-54. 19.
4. Dahl V, Hagen IE, Sveen AM, Norseng H, Koss KS. High dose of diclofenac for postoperative analgesia after elective cesarean section in regional anaesthesia. Inter J Obstetric Anaesthesia. 2002;11(2):91-4.
5. Shukla AK, Srivastav AK. Comparative study of tramadol and diclofenac as analgesic for postoperative pain. Int J Med Res Rev. 2015;3(11):1311-1316. DOI: 10.17511/ijmrr.2015.i11.238.
6. Merrikhihaji S, Farshchi A, Farshchi B, Farshchi S, Dorkoosh FA. Tramadol versus diclofenac in pain management after caesarean section: a cost analysis study. J Pharmacoeconomics and pharmaceutical management. 2015;1(1):22-4. 12.
7. Sahil S, Mane M, Paranjape J. Comparison of diclofenac suppository with tramadol suppository for postoperative analgesia in abdominal hysterectomy patients. Med pulse-International medical J. 2017;4(5):606-9.
8. Rud U, Fischer MV, Mewes R, Paravicini D. Postoperative analgesia with tramadol, continuous infusion versus repetitive bolus administration. Anaesthetist. 1994;43(5):316-21.
9. Sachs CJ. Oral analgesics for acute nonspecific pain. American family physician, 2005 Mar 1, 71(5).
10. Kumar PR, Soumya S, Kumar PS, Kumar JS. The effectiveness of intravenous tramadol hydrochloride and diclofenac sodium as postoperative analgesia – A comparative study. International Journal of Pharmaceutical Sciences Review and Research. 2016;36:260-263. 16.
11. Paudel, Rama Deka, Anjali Gupta, Hemant Nepal, Hari. Comparative evaluation of analgesic efficacy of tramadol and diclofenac-sodium in postoperative orthopedic patients. International Journal of Basic & Clinical Pharmacology. 2017;6:2676.