Original Research Article

Comparison of intramuscular diclofenac sodium, diclofenac sodium suppository and intravenous tramadol for postoperative analgesia in gynaecological surgeries done under spinal anaesthesia

Sonali Mahendra Khobragade*

Department of Anaesthesiology, Indira Gandhi Government Medical College, Nagpur, Maharashtra, India

Received: 25 June 2018
Accepted: 26 July 2018

*Correspondence:
Dr. Sonali Mahendra Khobragade,
E-mail: drsonalibhagat@yahoo.in

ABSTRACT

Background: Postoperative pain management is a vital factor contributing towards speedy recovery of the patient in the perioperative period without significant morbidity. The purpose of this study was to compare the analgesic efficacy and safety of three most frequently used analgesic drugs-intramuscular diclofenac sodium, diclofenac suppository and intravenous tramadol hydrochloride in patients undergoing gynaecological surgeries.

Methods: A hospital based, prospective, randomized, comparative study was undertaken in tertiary care hospital for a period of two years. The study included 90 adult patients undergoing gynaecological surgeries in spinal anaesthesia. Postoperative pain intensity was assessed by visual analogue scale. Level of sedation was assessed by four point scale along with haemodynamics.

Results: There were no significant changes in the pulse rate, systolic blood pressure and diastolic blood pressure after giving I.M. diclofenac, diclofenac suppository and I.V. tramadol. The mean VAS scores were comparable in all three groups (p>0.05). The level of sedation was more in tramadol group than in diclofenac intramuscular and rectal group which was statistically significant (p=0.001).

Conclusions: Diclofenac suppository provides effective postoperative analgesia when compared with Inj. Diclofenac I.M. and Inj. tramadol I.V. in patients undergoing infraumbilical gynaecological surgeries with stable vitals and no side effects.

Keywords: Diclofenac sodium intramuscular, Diclofenac suppository, Postoperative analgesia, Tramadol

INTRODUCTION

Pain is by far the most distressing effect of the disease. All medical persons regard its relief as one of their main duties specially the anaesthesiologists. Acute pain services must act as a vehicle, while the anaesthesiologists remain crucial contributors in the fascinating field of pain management. If pain is agony, relieving pain is an ecstasy. Pain is classified as acute or chronic; it is the acute pain category that has to be dealt with in the immediate postoperative period. Painful incision impairs deep breathing, reduces pulmonary compliance, increases muscle tone and increase oxygen consumption. Stress response to pain may results in the state of negative nitrogen balance. Pain causes sympathetic nervous system stimulation causing increase risk of myocardial ischemia and infarction, also the limitation of physical activity causing deep vein thrombosis. More distressing is the psychological aspect leading to fear, anxiety and resentment towards hospital causing patient discomfort, long hospital stay, poor patient outcome, greater use of healthcare resources and increase in the total cost of health care services. The present day concept of postoperative pain relief is
regarded as time dependant maximization of comfort of the patient with safer and cheaper analgesics. Gynaecological surgeries are major contributors of the total surgeries performed in our hospital. Usually opioids are the mainstay in the treatment of postoperative pain. Opioids however, produce side effects like nausea, vomiting, sedation, pruritis and respiratory depression. Non steroidal anti inflammatory drugs are attractive alternative to opioids as they are devoid of opioid related side effects yet providing effective analgesia along with antipyretic and anti-inflammatory action. Diclofenac is non selective NSAID belonging to acetic acid group. NSAIDs inhibit the biosynthesis of prostaglandins by preventing the substrate arachidonic acid from binding to the COX enzyme active site. The COX enzyme are COX-1 and COX-2 isoenzymes. COX-1 catalyzes the production of prostaglandins that are involved in various physiologic functions like maintenance of normal renal function in the kidneys, mucosal protection in gastrointestinal tract and production of proaggregatory thromboxane A2 in the platelets. COX-2 expression can be induced by inflammatory mediators in many tissues and has a role in the mediation of pain, inflammation and fever. Peripheral blocking of prostaglandin synthesis and central inhibition of COX-2 play a very important role in nociception. Diclofenac with greater peak analgesia seems to be an attractive cheaper package. This is specially of great concern in developing country like India. Tramadol is a centrally acting analgesic that has moderate affinity for \( \mu \) receptors and weak kappa and delta opioid receptor affinity.\(^2\) It is 5 to 10 times less potent than morphine as an analgesic. In addition to \( \mu \) receptor agonist, tramadol enhances the function of the spinal descending inhibitory pathway by inhibiting neuronal reuptake of 5-hydroxytryptamine and norepinephrine also the release of 5-hydroxytryptamine. Tramadol is a racemic mixture of two enantiomers. Tramadol causes analgesia without depression in ventilation and has low potential for development of tolerance, dependence and abuse along with marked decrease in postoperative shivering. Keeping all this in mind we decided to study the efficacy of more commonly used analgesic I.M. diclofenac, diclofenac suppository and I.V. tramadol in postoperative analgesia of intraubrnabial gynaecological surgeries done under spinal anaesthesia.

**METHODS**

After approval from institutional ethics committee, this randomized, comparative study was conducted in the tertiary care hospital. Total 90 patients were included in the study after written informed consent.

**Inclusion criteria**

It includes following parameter.

- Age 20-40 years.
- ASA grade I and II.
- Weight 40-80 kg.
- Height 150-170cm.
- Patient willing to undergo surgery under regional anaesthesia.

Patients who had contraindications to regional anaesthesia like bleeding diathesis, local or generalized sepsis and patients on anticoagulants, patients with acid peptic disease, patients with known allergy to NSAIDs, opioids and bupivacaine, patients with neurological lesions, psychiatric illness, cardiovascular diseases like arrhythmias, IHD and valvular heart disease, Liver, Respiratory, Kidney disease and hemodynamically unstable patients were excluded from the study.

Detailed pre-anesthetic evaluation of the patients was performed by an anaesthesiologist a day before surgery. Preliminary Investigations in the form of CBC, RBS, Coagulation profile, Liver function tests, KFT, Electrocardiography, Chest x ray (PA) view were noted. All patients were kept nil by mouth for 8 hrs. All patients were given overnight sedation in the form of Tab. Alprazolam 0.5 mg orally a day prior to surgery. In operation theatre, multipara monitoring device with ECG, pulse rate, non-invasive blood pressure, SpO2 was attached to the patient and baseline parameters were noted. Ringer lactate was started after establishing intravenous line with 18 G cannula. Thereafter, intravenous fluids were calculated and given as per body weight and operative loss. Patients also received Inj. Ranitidine 50 mg and Inj. Ondansetron 4 mg IV slowly as a premedication. Subarachnoid block was given in left lateral position with 25G spinal needle and bupivacaine was given according to height and weight of the patient. Oxygen was administered to all the patients at 5L/min. sensory analgesia was checked till the start of surgery by pin prick at 1 min interval and later at 5 min interval. Surgery was allowed to start when level of sensory blockade was T4. Blood pressure, heart rate, SPO2, and urine output was monitored intra and post operatively.

Patients were sedated with Inj. Midazolam 1 mg in titrated doses. Intraoperatively and postoperatively, bradycardia (heart rate<60 beats per minute) was to be treated with 0.6 mg injection Atropine and hypotension (systolic blood pressure falling more than 20% basal value or less than 80 mmHg) with 3-6 mg injection Mephentermine as bolus along with necessary fluid replacement. Respiratory depression (SpO2 <90% or respiratory rate < 10 breaths per minute) if any, was to be treated by administering 100% O2 with face mask or ventilation with IPPV accordingly. Duration of surgery was noted. Postoperatively immediately after surgery, patients were randomly allocated to any of the three groups.

- Group A- Inj. diclofenac sodium I.M. 1.5mg/kg TDS for 2 days.
- Group B-diclofenac sodium suppository 100mg BD for 2 days.
• Group C- Inj. tramadol 2mg/kg in NS TDS 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 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.

![Figure 1: VAS score.](image)

Pain score, sedation and vitals were observed at 2hrs, 4hrs, 8hrs, 16hrs, 24hrs on first postoperative day and 8 hourly on second postoperative day. Complications like nausea, vomiting, headache and dizziness were assessed simultaneously. If patients complained of nausea or vomiting, inj. Ondanestron 4mg I.V given for treatment. Rescue analgesia was given with Inj. Pentazocine 0.5mg/kg I.M. if VAS was 5 or more. Pain at injection site in group A and discomfort for rectal route in group B were particularly enquired in each visit.

**Statistical analysis**

Data were collected, tabulated, coded then analysed using SPSS computer software version 20.0 and Microsoft word and Excel have been used to generate graphs and tables etc. Numerical variables were presented as mean and standard deviation (SD). Tests applied-Student unpaired t-test, student paired t-test, chi-square test, ANOVA test. Analysis of quantitative data between the two groups was done using student unpaired t-test. Qualitative data was represented in form of frequency and percentage Association between qualitative variables was assessed by Chi-Square test.

| Value  | Significance          |
|--------|-----------------------|
| >0.05  | Non-Significant       |
| <0.05  | Significant           |
| <0.001 | Highly Significant    |

**RESULTS**

The present study was carried out to evaluate the safety and efficacy of I.M. diclofenac, diclofenac suppository and I.V. tramadol for post-operative analgesia in infraumbilical gynaecological surgeries. Total 90 patients were enrolled in the study in the group of 30 each. Patients were comparable with respect to demographic characteristics such as age, weight, height, ASA grading and duration of surgery (Table 2).

**Table 1: Interpretation of p-value.**

**Table 2: Mean (SD) basal and postoperative pulse rate alterations.**

| Group | Basal | 8 hours | 24 hours | 48 hours | P value |
|-------|-------|---------|----------|----------|---------|
| Group A | 85.06±7.85 | 84.80±9.24 | 82.8±6.88 | 81.93±4.16 | 0.2699(NS) |
| Group B | 87.3±8.5 | 88.56±4.03 | 86.86±4.45 | 84.93±4.16 | 0.2688(NS) |
| Group C | 85.6±5.73 | 84.86±9.83 | 82.73±5.86 | 82.06±5.36 | 0.1573(NS) |

**Table 3: Mean pulse rate changes between the groups.**

| Groups (n=30) | P value at 8 hours | P value at 24 hours | P value at 48 hours |
|---------------|-------------------|---------------------|---------------------|
| A Vs B        | 0.5982(NS)        | 0.7248(NS)          | 0.7102(NS)          |
| A Vs C        | 0.8626(NS)        | 0.7846(NS)          | 0.8376(NS)          |
| B Vs C        | 0.4118(NS)        | 0.4374(NS)          | 0.5471(NS)          |
When compared with basal pulse rate, there was no statistically significant change in pulse rate at 8 Hrs, 24 Hrs and 48 Hrs in postoperative period of all three groups (p>0.05) suggesting that there were no significant changes in the pulse rate after giving I.M. diclofenac, diclofenac suppository and I.V. tramadol (Table 3).

On intergroup comparison, there were no significant changes in the pulse rate (p>0.05) (Table 4).

When compared with basal SBP, there was no statistically significant change in blood pressure at 8 Hrs, 24 Hrs and 48 Hrs in postoperative period of all three groups (p>0.05) suggesting that there were no significant changes in the SBP after giving I.M. diclofenac, diclofenac suppository and I.V. tramadol (Table 5).

On intergroup comparison, there were no significant changes in the SBP (p>0.05) (Table 6).

When compared with basal DBP, there was no statistically significant change in blood pressure at 8 Hrs, 24 Hrs and 48 Hrs in postoperative period of all three groups (p>0.05) suggesting that there were no significant changes in the DBP after giving I.M. diclofenac, diclofenac suppository and I.V. tramadol (Table 7).

On intergroup comparison, there were no significant changes in the DBP (p>0.05) (Table 8).

The mean pain score in I.M diclofenac Group was 3.13±0.89 at 8 hours, 2.46±0.63 at 24 hours and 1.36±0.49 at 48 hours. In diclofenac suppository group, mean pain score was 3.56±0.73 at 8 hours, 2.53±0.62 at 24 hours and 1.33±0.61 at 48 hours. In tramadol group, mean pain score was 2.93±0.64 at 8 hours, 2.43±0.56 at 24 hours and 1.26±0.50 at 48 hours. Bar diagrammatic representation in Figure 1.

| Group   | Basal | 8 hours | 24 hours | 48 hours | P value  |
|---------|-------|---------|----------|----------|----------|
| Group A | 114.33±6.78 | 115.86±9.24 | 112.33±6.12 | 112.13±4.69 | 0.1224(NS) |
| Group B | 113.46±5.89 | 117.13±6.63 | 113.8±5.33   | 114.3±5.14 | 0.0624(NS) |
| Group C | 114.2±7.34  | 113.4±9.68  | 114.1±5.63   | 111.4±6.53 | 0.3591(NS) |

### Table 4: Mean (SD) basal and postoperative SBP alterations.

| Groups (n=30) | P value at 8 hours | P value at 24 hours | P value at 48 hours |
|---------------|--------------------|---------------------|---------------------|
| A Vs B        | 0.3942(NS)         | 0.2694(NS)          | 0.1527(NS)          |
| A Vs C        | 0.3307(NS)         | 0.3396(NS)          | 0.7894(NS)          |
| B Vs C        | 0.0521(NS)         | 0.8209(NS)          | 0.0604(NS)          |

### Table 5: Mean SBP changes between the groups.

| Group   | Basal | 8 hours | 24 hours | 48 hours | P value  |
|---------|-------|---------|----------|----------|----------|
| Group A | 73.33±4.34 | 74.86±5.0 | 73.67±4.20 | 72.40±3.61 | 0.1773(NS) |
| Group B | 71.2±3.34  | 72.46±3.88 | 71.53±2.38 | 71.73±2.55 | 0.4461(NS) |
| Group C | 73.06±3.43 | 73.0±3.77  | 72.4±4.11  | 71.8±3.53  | 0.2536(NS) |

### Table 6: Mean (SD) basal and postoperative DBP alterations.

| Groups (n=30) | P value at 8 hours | P value at 24 hours | P value at 48 hours |
|---------------|--------------------|---------------------|---------------------|
| A Vs B        | 0.8268(NS)         | 1.00(NS)            | 0.7371(NS)          |
| A Vs C        | 0.1714(NS)         | 0.4812(NS)          | 0.1709(NS)          |
| B Vs C        | 0.2577(NS)         | 0.4343(NS)          | 0.1135(NS)          |

### Table 7: Mean DBP changes between the groups.

| Duration | Group A (n=30) | Group B (n=30) | Group C (n=30) |
|----------|----------------|----------------|----------------|
| 8 hours  | 3.13±0.89      | 3.56±0.73      | 2.93±0.64      |
| 24 hours | 2.46±0.63      | 2.53±0.62      | 2.43±0.56      |
| 48 hours | 1.36±0.49      | 1.33±0.61      | 1.26±0.50      |

### Table 8: Mean (SD) pain score in postoperative period.
On intergroup comparison, there was statistically insignificant difference in the pain scores in all the three groups (p>0.05). All three drugs are equally effective in postoperative pain relief (Table 9).

In Group A and Group B all patients were alert. Sedation was not seen in any patient. However, in Group C the patients were sedated. The level of sedation was more in Group C than in Group A and Group B which was statistically significant (Table 10).

About 13.33% patients of Group A, 20% patients of Group B and 6.66% patients of Group C required rescue analgesia (Table 11).

Nausea was noted in 10% patients and vomiting was seen in 3.3% patients in intramuscular diclofenac group. In Tramadol group, 23.3% patients had nausea and 10% patients had vomiting. Whereas no patient in diclofenac suppository group had any of the complications. SPO2 was maintained in all the patients (Table 12).

DISCUSSION

The proper treatment of postoperative pain is vital and important for care of the patients. Optimal pain treatment after gynaecological surgeries should guarantee patient comfort, allow early ambulation and postoperative recovery. Opioids have been the cornerstone in the management of the postoperative pain relief since centuries. But side effects like respiratory depression, nausea, vomiting, sedation, pruritis and urinary retention have proved to be the main obstacle in the use of opioids for the postoperative analgesia. NSAIDs are used to control the inflammatory response that usually follows tissue disruption and help to decrease the pain associated with it. It is the inhibition of prostaglandin synthesis that

Table 9: Comparison of mean VAS scores between the groups in the postoperative period.

| Groups (n=30) | P value at 8 hours | P value at 24 hours | P value at 48 hours |
|--------------|--------------------|---------------------|---------------------|
| A Vs B       | 0.0855(NS)         | 0.9109(NS)          | 0.8394(NS)          |
| A Vs C       | 0.7713(NS)         | 0.8423(NS)          | 0.4760(NS)          |
| B Vs C       | 0.1303(NS)         | 0.7219(NS)          | 0.2046(NS)          |

Table 10: Mean (SD) sedation score in the postoperative period.

| Group         | Basal | 8 Hours | 24 Hours | 48 Hours | P Value     |
|---------------|-------|---------|----------|----------|-------------|
| Group A       | 0     | 0       | 0        | 0        |             |
| Group B       | 0     | 0       | 0        | 0        |             |
| Group C       | 0     | 0.1±1.18| 0.56±0.50| 1.33±0.71| P=0.001(HS) |

Table 11: Patients requiring rescue analgesia.

|                   | Group A (n=30) | Group B (n=30) | Group C (n=30) | P value |
|-------------------|----------------|----------------|----------------|---------|
| Number (%)        | 4 (13.33)      | 6 (20%)        | 2 (6.66%)      | 0.374(ns)|

Table 12: Postoperative complications.

| Postoperative complications | Group A (n=30) | Group B (n=30) | Group C (n=30) |
|------------------------------|----------------|----------------|----------------|
| Nausea                       | 3 (10%)        | 0              | 7 (23.3%)      |
| Vomiting                     | 1 (3.3%)       | 0              | 3 (10%)        |
| Dizziness                    | 0              | 0              | 0              |
| Headache                     | 0              | 0              | 0              |
| Respiratory depression       | 0              | 0              | 0              |
is considered important in the amelioration of pain. Thus, NSAIDs have antipyretic action along with analgesic action without causing sedation. Tramadol has analgesic efficacy due to weak µ agonistic action also the inhibition of reuptake of both 5-HT and noradrenaline together with presynaptic stimulation of 5-HT release. Taking all this into consideration the present study was designed to assess safety and efficacy of most commonly used analgesics in postoperative pain management that is I.M. diclofenac, diclofenac suppository and I.V. tramadol. All the patients in our study were comparable with respect to age, height, weight and duration of surgery.

**Haemodynamics alterations**

In our study, there were no significant changes in the pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate after giving I.M. diclofenac, diclofenac suppository and I.V. tramadol. Canepa G et al, observed that haemodynamic parameters like pulse rate, blood pressure and respiratory rate did not undergo significant change after administering Inj. tramadol. In the study by Rud et al, the haemodynamic parameters like pulse rate, respiratory rate remained normal after administering Inj. tramadol. In the study by Sachs CJ et al, the haemodynamic parameters like pulse rate, blood pressure and respiratory rate did not undergo significant change after administering Inj. Tramadol and Inj. Diclofenac. The findings of the above study were similar to the findings from our study.

**Mean VAS scores**

In our study, The mean pain score in diclofenac I.M. group was 3.13±0.89 at 8 hours, 2.46±0.63 at 24 hours and 1.36±0.49 at 48 hours. In diclofenac suppository group, mean pain score was 3.56±0.73 at 8 hours, 2.53±0.62 at 24 hours and 1.33±0.61 at 48 hours. In tramadol group, mean pain score was 2.93±0.64 at 8 hours, 2.43±0.56 at 24 hours and 1.26±0.50 at 48 hours. On intergroup comparison, the mean VAS scores in all three groups were statistically non-significant (p>0.05) denoting that intramuscular diclofenac, diclofenac suppository and intravenous tramadol were equally effective analgesic in postoperative pain relief. Canepa G et al, noted that mean vas score in tramadol group was 3.20±1.8 at 8 hours and 2.5±0.8 at 48 hours. Sachs CJ et al, noted that Mean VAS score at 8 hours was 3.68±1.2 in diclofenac group, 4.02±0.8 in valdecoxib group and 3.42±1.4 in tramadol group. Mean VAS score at 24 hours was 2.6±0.29 in diclofenac group, 3.1±0.21 in valdecoxib group and 2.2±0.42 in tramadol group. Mean VAS score at 48 hours was 1.33±0.9 in diclofenac group, 1.46±1.07 in valdecoxib group and 1.26±1.11 in tramadol group. They concluded that Inj. diclofenac, Inj. valdecoxib and Inj. tramadol gives effective postoperative analgesia and are equianalgesic. Lars et al, observed that mean VAS score in diclofenac group was 2.5 at 8 hours, 1.8 at 12 hours and 1.0 at 24 hours. Cabrera et al, observed that Mean VAS score was 2.75±1.25 at 8 hours and 2.2±0.40 at 24 hours. Scott RM et al, noted that Mean VAS score in diclofenac group was 3.96 at 8 hours and 2.43 at 24 hours. Chen D et al, observed that mean VAS scores at 2, 8 and 12 hours in I.M diclofenac were 3.32, 3.02 and 2.84 and in suppository were 3.76, 3.28 and 2.76 (p>0.05). They concluded that diclofenac I.M and suppository provided equivalent analgesia. Boulert A et al, noted that Mean VAS score at 8 hours in diclofenac group was 2.3±0.3. Karamen S et al, noted the Mean VAS score in tramadol group was 2.2±0.4. Surakarn J et al, observed that Median VAS score was 1 (0-6) at 6 hours, 1.5 (0-4) at 24 hours and 3 (0-4) at 48 hours in diclofenac group. Patil RK et al, noted that mean pain score by verbal rating scale at 6 hours was 2.18±0.35 in tramadol group and 2.37±0.32 in diclofenac group (p=0.351) (NS). They concluded that both iv tramadol and diclofenac sodium appears to have equipotent effect as postoperative analgesic. Merrikkihaghi S et al, noted that mean VAS score at 12 hours was 3.5±0.7 in tramadol group and 3.3±0.3 in diclofenac group. The mean VAS score at 24 hours was 1.5±0.6 in tramadol group and 1.2±0.5 in diclofenac group which was statistically insignificant (p>0.05). They concluded that tramadol and diclofenac are equally effective in postoperative pain relief. Diclofenac being cost effective than tramadol. Sahil S et al, observed that mean VAS scores were lower in diclofenac suppository group (2.6±0.57 at 4 hours, 2.83±0.88 at 6 hours) than tramadol suppository group (3.12±0.54 at 4 hours, 3.36±0.65 at 6 hours) which were statistically significant (p<0.05). They concluded that diclofenac suppository provide better quality of postoperative analgesia as compared to tramadol when used as preemptive analgesic. Gupta M et al noted that mean VAS score was 2.60±0.96 at 8 hours and 2.30±0.71 at 24 hours in intramuscular diclofenac group. Shukla AK et al, noted that mean VAS score was 2.45±0.25 at 24 hours and 1.59±0.14 at 48 hours in tramadol group whereas 2.01±0.11 at 24 hours and 1.51±0.16 at 48 hours in diclofenac group in hydrocoele patients. The mean VAS score at 24 and 48 hours in diclofenac group (2.01±0.20, 1.59±0.49) were significantly lower than tramadol group (2.5±0.04, 2.0±0.27) in hernia surgery patients (p<0.001). They concluded that diclofenac provides effective and better analgesia in acute postoperative pain than tramadol.

**Degree of sedation**

In our study, mean sedation score in tramadol group was 0.1±1.18 at 8 hours, 0.56±0.50 at 24 hours and 1.33±0.71 at 48 hours. The sedation score in Inj. tramadol increased from 8 hours to 48 hours. Whereas no sedation was noted in diclofenac I.M and suppository group. These suggested that level of sedation was more in Inj. Tramadol group than IM diclofenac and diclofenac suppository group which was statistically significant (p=0.001) (HS). Sedation score in the present study were similar to the various studies done by different researchers. Sachs CJ, observed moderate sedation with Inj. Tramadol. Al Waili
NS et al, noted lower sedation (0-1) with IM diclofenac. 18 Scott RM et al and Dahl V et al observed no sedation with diclofenac suppository. 8, 19 Rud U et al, Karamen S et al, and Karaca M et al noted good sedation with Inj. tramadol. 5, 11, 20 Paudel R observed that patients were more sedated in tramadol group than diclofenac group (p<0.05). 21

Postoperative complications

In our study, nausea was noted in 10% patients in IM diclofenac group and 23.3% patients in IV tramadol group (p=0.299) (NS). Vomiting was noted in 3.3% patients of IM diclofenac and 10% patients in tramadol group (p=0.612) (NS). There was no nausea and vomiting noted in diclofenac suppository group. Thus, incidence of nausea and vomiting was more in tramadol group. None of the patient experienced dizziness, headache and respiratory depression in any group. Chen D et al, observed that 12% patients had nausea and 8% patients had vomiting in Inj. diclofenac group whereas no patient experienced nausea and vomiting in diclofenac suppository group. 9

In a study of Patil RK et al, noted that 7 patients (23.33%) had nausea and 3 patients (10%) had vomiting in intravenous tramadol group and in diclofenac group, 5 patients (16.6%) had nausea and 2 patients (6.66%) had vomiting. 13 Searles JA et al, observed that no patient had nausea and vomiting in diclofenac suppository group. 22

In our study, 6 patients (20%) in Inj. diclofenac group complaint of pain at the injection site. None of the patient in the diclofenac suppository group complaint of discomfort due to suppository. Surgeons were satisfied with pain relief by diclofenac suppository. Diclofenac suppository had various advantages. Diclofenac suppository was devoid of gastritis, nausea, vomiting hence suitable in nil by mouth patients without respiratory depression yet providing equipotent analgesia in comparison to intramuscular diclofenac and intravenous tramadol. Also, diclofenac suppository was cheaper providing cost effective alternative to these most commonly used drugs for postoperative analgesia. It requires no special technique for suppository insertion and hence can be safely administered by paramedical works and ANMs without any need for continuous monitoring of the patient. Hence, Diclofenac sodium suppository can be used at remote places where expert medical personnel and advance monitoring equipment’s are not available.

CONCLUSION

Diclofenac suppository provides a cost effective, equipotent analgesia when compared with Inj. diclofenac I.M. and Inj. tramadol I.V. in patients undergoing gynaecological surgeries with stable vitals and no side effects.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Elsharkawy H, Naguib Mohamed A. Stoelting’s textbook of pharmacology and physiology in anaesthetic practice: 5th edition; Peripherally acting analgesics. 2014:269-275.
2. Cummings K, Naguib Mohamed A. Stoelting’s textbook of pharmacology and physiology in anaesthetic practice: 5th edition; Opioid agonists and antagonists. 2015:217-241.
3. Canepa G, Di CS, Ghia M, Vadala A, Reali M, Cerruti S, et al. Post-operative analgesia with tramadol: a controlled study compared with an analgesic combination. Int J Clin Pharmacol Res. 1993;13(1):43-51.
4. Rud U, Fischer MV, Mewes R, Paravicini D. Postoperative analgesia with tramadol, continuous infusion versus repetitive bolus administration. Anaesthetist. 1994;43(5):316-21.
5. Sachs CJ. Oral analgesics for acute nonspecific pain. American family physician. 2005 Mar 1;71(5).
6. Gillberg LE, Harsten AS, Stahl LB. Preoperative diclofenac sodium reduces postlaparoscopy pain. Canadian J anaesthesia. 1993 May 1;40(5):406-8.
7. Cabrera Magana EN, Solis EJ, Lopes RC. Tramadol in the management of gyneco-obstetric pain. Ginecolobstet Mex. 1997;65:152-4.
8. Scott RM, Jennings PN. Rectal diclofenac analgesia after abdominal hysterectomy. Aust NZ J Obs Gynaecol. 1997;37(1):112-4.
9. Chen D, Clement Y, Simeon D, Pinto PLM. Analgesic effects of diclofenac suppository and injection after preoperative administration. Int J Clin Pharm Res. 1999;19;2(4):47-51.
10. Boulert A. Diclofenac intramuscular single dose to decrease pain in postoperative cesarean section: a double blind randomized control trial. J of Med Asso Thai. 2005;88(1);9-15.
11. Karamen S, Uysaller E, Firat V. the use of tramadol for pain relief after abdominal hysterectomy. Clin Exp Obs Gyn. 2005;32(1):45-8.
12. Surakaran J, Yeun T. Intramuscular diclofenac for analgesia after cesarean delivery: a randomized control trial. J Med Asso Thai. 2009;92(6):733-8.
13. Patil RK, Samal S, Pattnaik SK, Jena SK. The effectiveness of intravenous tramadol hydrochloride and diclofenac sodium as postoperative analgesia:a comparative study. Int J Pharm Sci Rev Res. 2016;36(1):260-3.
14. Merrikhihi J, Farshchi A, Farshchi B, Farshchi S, Dorkoosh FA. Tramadol versus diclofenac in pain management after cesarean section: a cost nalysis study. J pharmacoconomics and pharmaceutical management. 2015;1(1):22-4.
15. Sahil S, Mane M, Paranjape J. Comparison of diclofenac suppository with tramadol suppository for postoperative analgesia in abdominal hysterectomy patients. Medpulse-International medical J. 2017;4(5):606-9.

16. Gupta M, Trivadi LH, Tripathi DC, Chavda P. Comparison of diclofenac patch and intramuscular diclofenac for postoperative analgesia in abdominal hysterectomy under spinal anaesthesia: A prospective randomized clinical study. J recent advances in pain. 2017;3(3):113-8.

17. Shukla AK, Srivastava AK. Comparative study of tramadol and diclofenac as analgesic for postoperative pain. Int. J Med Res Rev. 2015;3(11):1311-6.

18. 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. Archives of Med Res. 2001;32(2):148-54.

19. 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.

20. Karaca M, Kocoglu H, Gocman A. Comparison of tramadol with lornoxicam in patient controlled analgesia after gynecological surgery. Euro J Gynecol Oncol. 2006;27(1):78-80.

21. Paudel R, Deka A, Gupta HK, Nepal HP. Comparative evaluation of analgesic efficacy of tramadol and diclofenac sodium in postoperative orthopedic patients. Int J Basic Clin Pharm. 2017;6(11):2676-83.

22. Searles JA, Prings DW. Effective analgesia following perineal injury during childbirth: a placebo controlled trial of prophylactic rectal diclofenac. British J Obs Gyn. 1998;105(6):627-31.

Cite this article as: Khobragade SM. Comparison of intramuscular diclofenac sodium, diclofenac sodium suppository and intravenous tramadol for postoperative analgesia in gynaecological surgeries done under spinal anaesthesia. Int J Res Med Sci 2018;6:3034-41.