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ORIGINAL RESEARCH

Comparative Study Of Preventive Analgesia Using Diclofenac Suppository, Tramadol Suppository And Paracetamol Infusion In Post-Caesarean Pain Relief

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ABSTRACT

Aim: To see and compare tramadol suppository, intra-venous paracetamol and diclofenac suppository for post-caesarean pain relief, side effects, time of starting breastfeeding, uterine retraction, vaginal bleeding, the time between caesarean section and ambulation and duration of first rescue analgesic requirement among the three groups. **Material and Methods:** A randomized controlled prospective study was done over 90 postpartum women who underwent caesarean section under spinal anaesthesia. Randomization was done using a computer-generated random number table (before caesarean section) in groups A, B, and C; each group consisted of 30 pregnant women. Group A- The patient received a tramadol suppository of 100 mg per rectally within 30 minutes of skin closure after caesarean section. Group B- patient received a paracetamol injection of 1 gm in 100 ml normal saline by intravenous route over 15 minutes within 30 minutes of skin closure after caesarean section, and group C- patient was given diclofenac suppository 100 mg per rectally within 30 minutes of skin closure after caesarean section. All patients of group A and group C received paracetamol infusion 1 gm in 100 ml normal saline routinely within 30 minutes of caesarean section. Pain was assessed using Visual Analogue Scale at 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours after caesarean section. **Results:** VAS score was found to be least in Diclofenac suppository with paracetamol infusion followed by combination analgesia of tramadol suppository plus paracetamol infusion and monotherapy of paracetamol infusion alone**.** In group A, B and C; 20%, 70% and 6.7% of subjects required rescue analgesia respectively. Out of all subjects among all three groups, 33.3 % of subjects from Group A, 23.3 % from Group B, and 6.7 % of subjects from Group C had adverse effects, with a p-value of 0.038. **Conclusion:** It can be concluded from the results that combination analgesia of Diclofenac suppository with paracetamol infusion is a better preventive analgesic than combination analgesia of tramadol suppository plus paracetamol infusion and monotherapy of paracetamol infusion alone with a lesser number of subjects requiring rescue analgesia.

Keywords: Preventive Analgesia, Diclofenac Suppository, Tramadol Suppository, Paracetamol Infusion, Post-Caesarean Pain

INTRODUCTION

One of the most common surgical procedures in women is caesarean section. (1) The rate of caesarean section in the Indian public health sector is around 12 per cent, and around 28 per cent in the Indian private sector. (2) Pain is one of the most undesirable outcomes of a caesarean section. (3) Pain after a caesarean section has two components: visceral and somatic. Visceral pain is due to uterine wound and its contractions, while surgical site nociceptors cause somatic pain. (4)

Pain management after a caesarean section is necessary for the relaxation of the mother to communicate with the infant and to start breastfeeding as early as possible. (5) It is required for early ambulation, reducing the unpleasant feeling and early ambulation, decreasing hospital stay duration, reducing complications associated with immobility like atelectasis, deep vein thrombosis and constipation and reducing the chances of chronic pain syndromes. (6, 7, 8)

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Various methods are recommended for pain management after caesarean section, including systemic opioids and neuraxial opioids. (9) But opioids have side effects like vomiting, nausea, respiratory depression, sedation and risk for infants from breastmilk exposure to opioids. (9,10) Nowadays, preventive analgesic agents are used to centrally control pain-induced sensitization, thus decreasing the development and persistence of pain sensations. (9)

Tramadol is an opioid analgesic which acts centrally. It can be administered orally, intravenously or rectally. (11) It acts on μ receptors. (12) After a single dose of tramadol by the oral route of administration, only 68 % of the drug is bioavailable due to high first-pass metabolism. (13) After the oral and intravenous route of administration, the peak concentration of tramadol in plasma is reached rapidly, causing systemic side effects like nausea, vomiting, dryness of mouth, and sedation. (11) Tramadol use for pain management after delivery for a short duration is useful in patients who tolerate opioids poorly. Tramadol administration during early lactation and breastfeeding causes negligible harm to healthy-term infants. (14)

Paracetamol is a non-steroidal anti-inflammatory drug and is devoid of opioid side effects. Postoperative administration of paracetamol reduces acute pain. (9) It is a non-opioid analgesic inhibiting prostaglandin synthesis in the central nervous system. It reaches cerebrospinal fluid by crossing the blood-brain barrier and has an antinociceptive effect on the central nervous system. Intravenous administration of paracetamol relieves the pain within 5-10 minutes. After administration, its peak analgesic effect is seen in 1 hour, lasting 4-6 hours. (5)

Diclofenac is a non-steroidal anti-inflammatory drug administered orally, intravenously, intramuscularly, intra-colonically, subcutaneously, topically and rectally. Diclofenac administration after surgery reduces narcotic demand for pain relief. (15) After intravenous administration, plasma levels of diclofenac were below detection limits at 5.5 hours. (16) Sometimes, a small dose of morphine is given intrathecally along with diclofenac for pain management after caesarean section. (17)

VAS is commonly used to assess the severity of pain. Paper VAS consists of a 10 cm length line with endpoints defining no pain to pain as bad as possible. Paper VAS showed a significant correlation with electronic VAS, and paper VAS is a valid and time-saving method for assessing pain severity. (18) The present study was conducted to compare pain relief (using VAS Score) of tramadol suppository (in combination with paracetamol infusion), diclofenac suppository (in combination with paracetamol infusion) and intra-venous paracetamol (monotherapy) in post-caesarean patients.

MATERIALS AND METHODS

The present single blinded randomised controlled trial was conducted at Department of Obstetrics and Gynaecology, General Hospital, Sector 6, Panchkula, Haryana among 90 postpartum women after primary caesarean section for a period of one and a half years.

Sample Size: 90 pregnant women

$N = (Z_{\alpha/2})^2\ 2s^2/d^2$

Where N denotes sample size, s is the standard deviation obtained from a previous study, and d is the accuracy of the estimate or how close to the true mean. Zα/2 is normal deviate for two-tailed alternative hypothesis at a significance level. Power design is assumed to be 80%.

S– Standard deviation = 0.35 (2)

$Z_{\alpha/2} = Z_{0.05/2} = Z_{0.025} = 1.96$ at type 1 error of 5%

d = 0.24

$N= (1.96)^2\ 2*0.35^2/0.24^2= 16.31$

Considering the error and dropout, the sample size was increased to 30. In the present study, we had taken three groups. Therefore, the minimum sample size required per group was 30.

Subjects were divided into three groups by computer-generated random number tables. Group A- The patient received a tramadol suppository of 100 mg per rectally (Supridol-100) within 30 minutes of skin closure after caesarean section. Group B- The patient received a paracetamol injection of 1 gm (Paracap Paracetamol infusion IP 1000mg/100ml) in 100 ml normal saline by intravenous route over 15 minutes within 30 minutes of skin closure after caesarean section. Group C- The patient received a diclofenac suppository of 100 mg per rectally [generic supply of 50mg (2 suppositories used) from the hospital drug store] within 30 minutes of skin closure after caesarean section.

Inclusion Criteria

1. 18-40 years of age
2. Term Pregnancy ≥37 weeks of gestation
3. Live singleton pregnancy
4. Women undergoing primary caesarean section including elective and emergency caesarean section
5. Pregnant women giving consent for the study.

Exclusion Criteria

1. History of bleeding
2. History of allergy to Tramadol, or Paracetamol or Diclofenac
3. History of hepatic or renal disease
4. Pregnancy associated with medical disorders like diabetes, gestational hypertension, eclampsia
5. Intrauterine foetal death
6. Emergency caesarean section done during the second stage of labour
7. Women who refused to participate in the trial.

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Methods

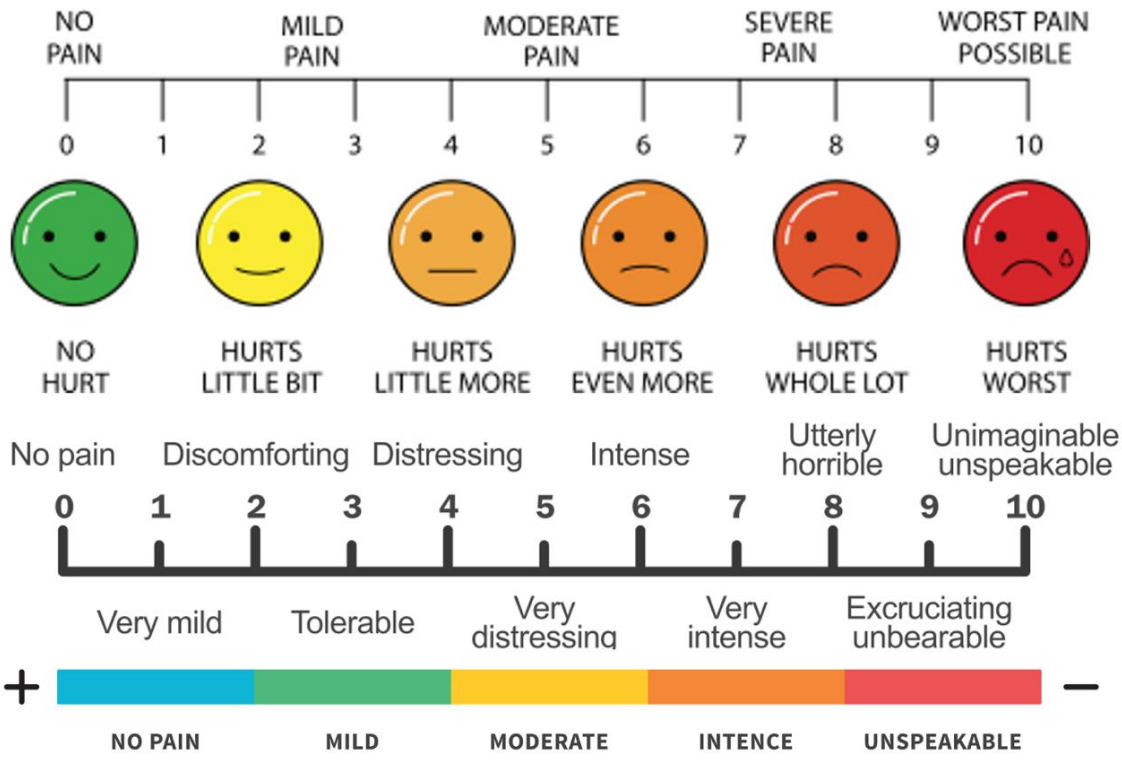
The selected cases were subjected to written informed consent about the study. Then, history was taken, and a complete general examination was done. An abdominal examination was done. Routine laboratory investigations, such as CBC, LFT, KFT, coagulation profile, viral markers, and blood group, were sent. Trans abdominal sonography was done to assess foetal well-being.

Eligible patients underwent randomization by computer-generated random number tables and were allocated to one of the three groups. We have taken 90 envelopes using computer-generated random number tables: 30 envelopes had tramadol suppository, 30 envelopes had diclofenac suppository, and 30 envelopes had paracetamol infusion. All the drugs were indented from the hospital pharmacy. Pregnant women did not know anything about the group assignment.

Blood was sent for cross-matching. Injection of Ceftriaxone 1gm intravenously after sensitivity testing was given half an hour before skin incision. Injection Rantac 50 mg intravenously and injection of Perinorm 10 mg intravenously were given before the caesarean section. Catheterization and foetal heart rate were done before shifting the patient to the operation theatre.

On arrival of the patient at the operation theatre, an intravenous line was initiated with an 18 gauge cannula. Preoperative recording of heart rate, non-invasive blood pressure (SBP, DBP and MAP) and arterial oxygen saturation were carried out. Foetal heart sound was checked. Spinal anaesthesia was given using 0.5 per cent bupivacaine (heavy) by 25 gauge spinal needle. The patient was laid in the supine position, and the table was tilted to 15 degrees to prevent aortocaval compression. After a caesarean section, analgesics were given according to the randomized group given as Group A and Group C also got additional injections of paracetamol 1gm in 100 ml of normal saline over 15 minutes within 1 hour of skin closure. So, Group A and Group C had combination analgesia (suppository with paracetamol infusion) and Group B had monotherapy of paracetamol infusion only. All patients got paracetamol infusion intravenously after caesarean section every 8 hours till 24 hours.

Then pain was assessed using the Visual Analogue Scale at 1, 2, 3, 4, 6, 8, 10, 12 and 24 hours after caesarean section by the Principal investigator. Pain was assessed at the surgical site. Side effects and vitals were watched for, and the time between caesarean section and ambulation was monitored.



VAS score < or =3 was considered an adequate level of analgesia. Rescue analgesia as 50 mg intravenous tramadol injection in 100 ml 0.9% normal saline over 30 minutes was given at VAS score > or = 4. Rescue analgesia was given in addition to paracetamol infusion which was given regularly at 8 hourly duration post caesarean section. Rescue analgesia was given at the time of hourly reassessment when VAS score > or = 4 or when the patient demanded in between reassessment times and assessed with VAS score > or = 4 and charting of rescue analgesia was done at the time of nearest reassessment.

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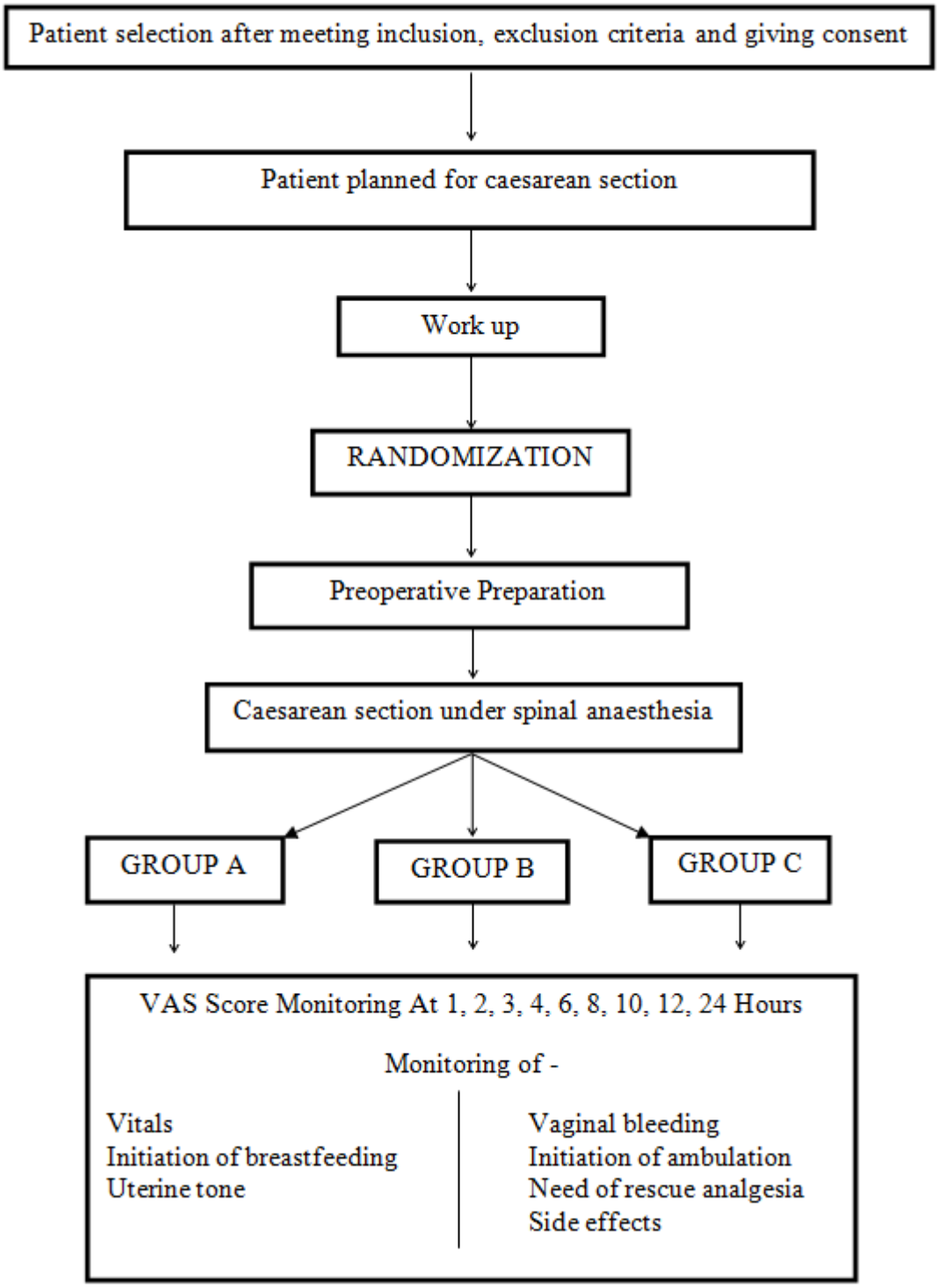

Statistical analysis

The quantitative variables were evaluated using an unpaired t-test. The qualitative variables were compared using the Chi-square test. A p-value < 0.05 was assumed to be statistically significant. Statistical Package for Social Sciences (SPSS) version 22.0 was used for analysis.

RESULTS

Most of the pregnant women belonged to the age group of 26-30 years in all three groups, with mean maternal age of 28.60± 2.88 years in group A, 27.50± 2.64 years in group B and 28.47± 3.24 years in group C (p=0.291). In group A, 63.3% of subjects underwent elective caesarean section while 36.7% underwent emergency caesarean section; in group B, 56.7% of subjects underwent elective caesarean section while 43.3 % underwent emergency caesarean

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section whereas in group C 66.7% subjects underwent elective caesarean section and 33.3% underwent emergency caesarean section (p=0.718), which is statistically non-significant (table 1).

Table 1: Distribution of subjects according to baseline characteristics

Age groups (years)	Group A		Group B		Group C	
	N	%	N	%	N	%
≤25	3	10.0	7	23.3	5	16.7
26-30	22	73.3	20	66.7	20	66.7
>30	5	16.7	3	10	5	16.7
Gravida						
Primigravida	14	46.7	19	63.3	16	53.3
Multigravida	16	53.3	11	36.7	14	46.7
Total	30	100	30	100	30	100
Type of Caesarean section						
Elective	19	63.3	17	56.7	20	66.7
Emergency	11	36.7	13	43.3	10	33.3
Total	30	100	30	100	30	100

At 1 hour, the mean VAS score in group A, group B, and group C was 1.67±0.66, 2.50±0.57 and 2.40±0.49 respectively (p <0.001), which is statistically significant, showing tramadol suppository to be a better analgesic than diclofenac suppository or paracetamol infusion for post caesarean pain relief. At 2-hour mean VAS score in group A, group B and group C was 2.27±1.14, 2.50±0.77 and 2.10±0.30 respectively (p =0.015), which is statistically significant, showing diclofenac suppository to be better analgesia than tramadol suppository or paracetamol infusion as a preventive analgesia at 2 hours for post caesarean pain relief. At 3 hours, 4 hours and 6 hours, tramadol suppository, diclofenac suppository and paracetamol infusion were comparable preventive analgesics for post-caesarean pain. At 8 hours, the mean VAS score in Groups A, B, and C was 1.47±0.50, 1.17±0.37 and 1.67±0.47, respectively (p <0.001), which is statistically significant. At 10 hours, the mean VAS score in group A, group B, and group C was 1.3±0.46, 1.10±0.30 and 1.47±0.50 respectively (p =0.008), which is statistically significant, suggesting paracetamol infusion to be a better analgesic than diclofenac suppository and tramadol suppository for post caesarean pain (table 2).

Table 2: Mean VAS score among three groups at different time intervals

Time interval (in hours)	Group A	Group B	Group C	p value*
1	1.67±0.66	2.50±0.57	2.40±0.49	<0.001
2	2.27±1.14	2.50±0.77	2.10±0.30	0.015
3	2.37±1.29	2.40±1.03	2.23±0.93	.358
4	2.07±0.86	2.93±1.89	1.93±0.45	.225
6	1.77±0.67	2.50±1.92	1.87±0.34	.662
8	1.47±0.50	1.17±0.37	1.67±0.47	<0.001
10	1.30±0.46	1.10±0.30	1.47±0.50	0.008
12	1.07±0.25	1.07±0.25	1.13±0.34	0.581
24	1.00±0.00	1.00±0.00	1.00±0.00	1.00

*Kruskal-Wallis test

No significant difference was found between the groups w.r.t. type of CS (table 3).

Table 3: Mean VAS score among three groups at different time intervals in elective and emergency caesarean section

Time interval (in hour)	Group A			Group B			Group C		
	Elective CS	Emergency CS	p value *	Elective CS	Emergency CS	p value*	Elective CS	Emergency CS	p value*
1	1.79±0.63	1.45±0.68	0.14	2.29±0.58	2.77±0.43	0.02	2.40±0.50	2.40±0.51	1.00
2	2.00±0.74	2.73±1.55	0.23	2.24±0.83	2.85±0.55	0.01	2.05±0.22	2.20±0.42	0.20
3	2.26±1.32	2.55±1.29	0.35	2.12±1.16	2.77±0.72	0.05	2.00±0.32	2.70±1.49	0.13
4	2.11±0.99	2.00±0.63	0.96	2.29±1.57	3.77±2.00	0.02	1.95±0.22	1.90±0.73	0.70
6	1.79±0.71	1.73±0.64	0.85	2.06±1.47	3.08±2.32	0.21	1.95±0.22	1.70±0.48	0.06
8	1.37±0.49	1.64±0.50	0.16	1.18±0.39	1.15±0.37	0.87	1.75±0.44	1.50±0.52	0.17
10	1.32±0.47	1.27±0.46	0.80	1.06±0.24	1.15±0.37	0.39	1.55±0.51	1.30±0.48	0.20

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12	1.05±0.22	1.09±0.30	0.69	1.06±0.24	1.08±0.27	0.84	1.15±0.36	1.10±0.31	0.70
24	1.00±0.00	1.00±0.00	1.00	1.00±0.00	1.00±0.00	1.00	1.00±0.00	1.00±0.00	1.00

*Mann Whitney Test

Out of 30 subjects of group A, six subjects (20%) required rescue analgesia, while in 24 subjects (80%), rescue analgesia was not needed. Of the 30 subjects in group B, 21 (70%) required rescue analgesia. In comparison, rescue analgesia was not needed in 9 subjects (30%). In contrast, out of 30 subjects of group C, two subjects (6.7 %) required rescue analgesia, while in 28 subjects (93.3%), rescue analgesia was not needed (p <0.001), which is statistically significant, as shown in table 4 showing more patients who received paracetamol infusion required rescue analgesia than the patients who got either tramadol suppository or diclofenac suppository.

Table 4: Distribution of subjects according to the requirement of rescue analgesia in different groups

Rescue analgesia requirement	Group A		Group B		Group C		p value
	N	%	N	%	N	%	
Yes	6	20	21	70	2	6.7	<0.001*
No	24	80	9	30	28	93.3	
Total	30	100	30	100	30	100	

*Chi-Square test

In group A, out of 30 subjects, 93.3% of subjects initiated breastfeeding within 2 hours after the caesarean section, while 6.7 % of subjects initiated breastfeeding after 2 hours of the caesarean section. In group B, out of 30 subjects, 96.7% of subjects initiated breastfeeding within 2 hours after caesarean section, while 3.3 % of subjects initiated breastfeeding after 2 hours of caesarean section while in group C, out of 30 subjects, 100 % of subjects initiated breastfeeding within 2 hours after caesarean section (p=0.355) which is statistically non-significant. In Group A 66.7% (n=20) did not have any adverse effects while 33.3% (n=10) had adverse effects. In Group B 76.7% (n=23) did not have any adverse effects while 23.3% (n=7) had adverse effects. In Group C 93.3% (n=28) did not have any adverse effects while 6.7% (n=2) had adverse effects with p value 0.038 which is statistically significant as shown in table 5.

Table 5: Distribution of subjects according to time of initiating breastfeeding and adverse events in different groups

Initiation of breastfeeding	Group A		Group B		Group C		p value
	N	%	N	%	N	%	
Within 2 hour	28	93.3	29	96.7	30	100	0.355
More than 2 hour	2	6.7	1	3.3	0	0	
Adverse effects							
No	20	66.7	23	76.7	28	93.3	0.033
Dizziness	2	6.7	0	0	0	0	
Gastritis	0	0	5	16.7	0	0	
Nausea	7	23.3	1	3.3	1	3.3	
Vomiting	1	3.3	1	3.3	1	3.3	
Total	30	100	30	100	30	100	

The mean time of initiating ambulation in Group A, group B and Group C was 11.3±3.37, 14.37±3.27, and 10.2±2.21 respectively (p<0.001), which is statistically significant as shown in table 6 showing patients who got paracetamol infusion started ambulation later than the patients who got tramadol suppository or diclofenac suppository.

Table 6: Mean time of stating ambulation among three groups

	Group A	Group B	Group C	p value
Mean time of starting ambulation(hour)±2SD	11.30± 3.37	14.37± 3.2	10.20± 2.21	<0.001*
Range	8-20	8-20	8-18	

*Kruskal Wallis Test

DISCUSSION

Our study population comprised 90 women undergoing primary caesarean section at ≥37 weeks of gestation with singleton live pregnancy with an equal number of subjects (30) in group A (tramadol suppository with paracetamol infusion), group B

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(paracetamol infusion) and group C (diclofenac suppository with paracetamol infusion). There was no statistical difference between the demographic, medical, or surgical history. The age distribution of the three groups was similar, with a p-value of 0.291. Similar results were found in a study by Hooda R et al. (2) with p-value>0.05. Another study done by Shetty LD et al. (19) also showed similar results with p-value>0.05. Hence, the three groups were comparable in terms of age.

There was no difference in the distribution of the study population according to gravida, with a p-value of 0.476. Similar results were found in a study by Hooda R et al. (2) with p-value>0.05. Another study done by Shetty LD et al. (19) also showed similar results with p-value>0.05. A similar survey by Rani KU et al. (5) showed a p-value >0.05 among the groups based on parity. Hence, the three groups were comparable in terms of gravida.

At 1 hour, the mean VAS score in group A, group B, and group C was 1.67±0.66, 2.50±0.57 and 2.40±0.49 respectively (p <0.001), which is statistically significant, showing that tramadol suppository is better than diclofenac suppository and paracetamol infusion for pain relief at 1 hour. Similar results were shown in the study conducted by Hooda R et al. (2) with p-value <0.001, which was statistically significant, suggesting the paracetamol group had more VAS score than tramadol suppository or diclofenac suppository group as mean VAS of paracetamol infusion group was 7.90 compared to mean VAS score of diclofenac suppository or tramadol suppository which was 5.6 and 5.4 respectively. The study was also comparable to the survey conducted by Rani KU et al. (5) with a value of 0.000, which is statistically significant. Another study by Akhavanakbari G. et al. (20) also showed similar results with a p-value <0.001. Hence, it is concluded that tramadol suppository has a lower mean VAS score at 1 hour compared to diclofenac suppository and paracetamol infusion.

At 2 hours, out of 30 subjects of Group A, 2 (6.6%) subjects required rescue analgesia, while in Group B and Group C, none of the subjects required rescue analgesia. So at 2-hour mean VAS score in groups A, B, and C was 2.27±1.14, 2.50±0.77 and 2.10±0.30 respectively (p =0.015), which is statistically significant, indicating diclofenac suppository to be better analgesia than tramadol suppository and paracetamol infusion. The study was comparable to the study conducted by Vyankatesh J et al. (21) with a p-value <0.0001, which is statistically significant, showing diclofenac suppository as better preventive analgesia than tramadol suppository as a mean VAS of diclofenac suppository and tramadol suppository at 2 hours was 0.6 and 2.20 respectively. A similar study conducted by Rani KU et al. (5) also showed a significant difference in mean VAS score at 2 hours with a p-value of 0.000. Another study conducted by Reddy MS et al. (22) also showed similar results with a lower mean VAS score with diclofenac suppository than with paracetamol infusion, measuring mean VAS score 2 and 2.5, respectively, with p-value <0.001, which was statistically significant. Hence, it is concluded that diclofenac suppository had a lower mean VAS score at 2 hours as compared to tramadol suppository and paracetamol infusion.

At 4 hours out of 30 subjects of group A, only 1 (3.3%) subject required rescue analgesia; in group B, 10 (33%) subjects out of 30 required rescue analgesia, while no subject in group C required rescue analgesia. But the mean VAS scores in Groups A, B and C were 2.07±0.86, 2.93±1.89 and 1.93±0.45, respectively (p =0.225), which is statistically non-significant. Similar results were found in a study done by Mitra S et al. (23) with p-value of 0.469, which was statistically non-significant. Hence, it is concluded that the three preventive analgesics used were comparable in providing pain relief at 4 hours after caesarean section.

At 6 hours, no subjects in Group A and Group C required rescue analgesia, while 9 (30%) subjects in Group B required rescue analgesia. But the mean VAS scores in Groups A, B and C were 1.77±0.67, 2.50±1.92 and 1.87±0.34, respectively (p =0.662), which is statistically non-significant. A study done by Bakhsha F et al. (24) showed comparable mean VAS scores between intravenous paracetamol (5.13±1.4) and diclofenac suppository (6.67±1.18) that were statistically non-significant. So, it is concluded that at 6 hours, diclofenac suppository and intravenous paracetamol were comparable analgesics for pain relief.

At 8 hours, all subjects of the three groups received an injection of paracetamol 1000 mg in 100 ml 0.9 % normal saline intravenously—no subject of any group required rescue analgesia. The mean VAS scores in Groups A, B and C were 1.47±0.50, 1.17±0.37 and 1.67±0.47, respectively (p <0.001), which is statistically significant. A study conducted by Reddy MS et al. (22) showed statistically significant results with p-value <0.001 at 8 hours. Another study was conducted by Vyankatesh J et al. (21) with p-value <0.0001.

At 10 hours, the mean VAS score in groups A, B and C was 1.3±0.46, 1.10±0.30 and 1.47±0.50, respectively (p =0.008), which is statistically significant. In a study conducted by Vyankatesh J et al. (21), the mean VAS score of subjects who were given a diclofenac suppository was 2.57±0.73 while in subjects who were given a tramadol suppository, the mean VAS was 3.40±0.56, with p-value <0.0001. Another study by Shetty LD et al. (19) showed that the mean VAS score of the diclofenac group and tramadol group was 2.88±1.37 and 4.13±1.89, respectively, with a p-value of 0.01, which is statistically significant. So it is concluded that subjects with combination analgesia (as given in the study in the form of injection paracetamol at 8 hours in combination with either diclofenac suppository or

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tramadol suppository just after caesarean section) have lower mean VAS scores than monotherapy.

The mean VAS score in groups A, B and C at 12 hours was 1.07±0.25, 1.07±0.25 and 1.13±0.34, respectively (p =0.581), which is statistically non-significant. At 16 hours, another dose of injection paracetamol 1000 mg in 100 ml 0.9% normal saline was given to all 30 subjects of all three groups.

At 24 hours, the mean VAS score in Groups A, B, and C was 1.00±0.00, 1.00±0.00 and 1.00±0.00, respectively (p =1.0), which is statistically non-significant. A similar study was conducted by Hooda R et al. (2), which showed similar results with mean VAS score at 24 hours in groups with diclofenac suppository, tramadol suppository and placebo suppository to be 0.00±0.00, 0.02±0.20 and 0.00±0.00 respectively with p value 0.159 which was statistically non-significant. Another study was conducted by Mitra S et al. (23), which showed similar results with a p-value of 0.119, which is statistically non-significant. Hence, it is concluded that tramadol suppository, diclofenac suppository and paracetamol infusion are comparable preventive analgesics 24 hours after a caesarean section.

In our study, it was found that at most of the time there was no significant difference between the mean VAS score in three groups at different time intervals based on the type of caesarean section (elective or emergency). The results were similar to the study conducted by Hooda R et al. (2) with a p-value>0.05, which is statistically non-significant. Another study conducted by Rani KU et al. (5) also showed similar results with p-value>0.05. So, it is concluded that the type of caesarean section does not affect the mean VAS score.

Out of all subjects among all three groups, 33.3 % subjects (n=10) from group A, 23.3% subjects (n=7) from group B and 6.7 % subjects (n=2) from group C had adverse effects with p value 0.038, which is statistically significant showing more side effects associated with tramadol suppository than diclofenac suppository or paracetamol infusion. A similar study was done by Rani KU et al. (5), which showed similar results with a p-value of 0.001, which is statistically significant. Another study was conducted by Reddy MS et al. (22) that showed more adverse effects in subjects who were given a diclofenac suppository (7.7%) as compared to subjects who were administered paracetamol infusion (2.2%). So, it is concluded that tramadol suppository is associated with more maternal adverse effects as compared to diclofenac suppository and paracetamol infusion.

In our study, out of 30 subjects of group A, six subjects (20%) required rescue analgesia, while in 24 subjects (80 %), rescue analgesia was not needed. Out of 30 subjects in group B, 21 subjects (70 %) required rescue analgesia, while in 9 subjects (30 %), rescue analgesia was not needed. In contrast, out of 30 subjects in group C, two subjects (6.7 %) required rescue analgesia, while in 28 subjects (93.3 %), rescue analgesia was not needed with a p-value <0.001, which is statistically significant, showing more requirement of rescue analgesia in patients receiving paracetamol infusion than in patients receiving either tramadol suppository or diclofenac suppository. A similar study was conducted by Shetty LD et al. (19) that showed more subjects of the tramadol suppository group (80.4% subjects at 8 hours and 98.2% at 10 hours) required rescue analgesia as compared to the diclofenac suppository group (4.2% subjects at 8 hours and 6.3% at 10 hours). Another study was conducted by Hooda R et al. (2) that showed only 2 % of subjects who received a diclofenac suppository required rescue analgesia, 2% of subjects of tramadol suppository required rescue analgesia, while 95 % of subjects of placebo suppository with paracetamol infusion required rescue analgesia with p-value <0.001 which is statistically significant. So, it is concluded that diclofenac suppository is a better preventive analgesic than tramadol suppository and paracetamol infusion. After a caesarean section, patients receiving diclofenac suppository required less rescue analgesia as compared to patients who got either tramadol suppository or paracetamol infusion.

Limitations

1. Small study populations, as only primary caesarean sections, were considered.
2. Pain relief was not assessed in correlation with the stage of labour in which emergency caesarean section was done.
3. Other post-operative complications of elective and emergency caesarean section were not studied.
4. Other factors affecting ambulation (like body mass index, intra-operative complication and others) were not considered.

CONCLUSION

1. Combination analgesia (Diclofenac suppository plus paracetamol infusion or Tramadol suppository plus paracetamol infusion) is better than monotherapy (paracetamol infusion) for prevention of pain after caesarean section.
2. Diclofenac suppository plus paracetamol infusion is a better preventive analgesia combination than tramadol suppository plus paracetamol infusion.
3. There is less need for rescue analgesia in subjects receiving diclofenac suppository (with paracetamol infusion) as compared to subjects receiving tramadol suppository (with paracetamol infusion) and subjects receiving paracetamol infusion monotherapy.
4. Adverse effects (nausea, vomiting, gastritis and dizziness) were more common in subjects receiving Tramadol suppository (with paracetamol infusion) than subjects receiving diclofenac suppository (with paracetamol infusion) and paracetamol infusion monotherapy.

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5. No significant difference was noted in initiating breastfeeding, vitals and postpartum complications (postpartum haemorrhage) among the three groups.
6. Early ambulation was observed in subjects receiving diclofenac suppository (with paracetamol infusion) as compared to subjects receiving tramadol suppository (with paracetamol infusion) and subjects receiving paracetamol infusion monotherapy.

Thus, the study concluded that combination analgesia of Diclofenac suppository with paracetamol infusion is a better preventive analgesic than combination analgesia of tramadol suppository plus paracetamol infusion and monotherapy of paracetamol infusion alone with a lesser number of subjects requiring rescue analgesia.

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