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Intraincisional injection of tramadol versus bupivacaine in post-caesarean pain relief

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Abstract
The aim of this study is to compare the analgesic efficacy of intraincisional infiltration of Inj. Tramadol versus Inj. Bupivacaine for postoperative pain relief in Caesarean section under spinal anaesthesia and to compare postoperative pain scores and total consumption of rescue analgesics.
Materials and Methods: This study was carried out in the Department of Obstetrics and Gynaecology in Rajah Muthiah Medical College and Hospital from 2018 -2020 after getting the approval of Ethical Committee. Sixty Antenatal mothers of age group (18-35 yrs) with BMI (18.5 – 40 Kg/m2) scheduled for caesarean under spinal anaesthesia were included in the study. Patients under exclusion criteria were excluded in this study. Informed written consent was obtained prior to procedure. Under spinal anaesthesia caesarean section was performed. At the time of skin closure patients were randomly divided into two groups. Group A (n=30) – treated with Inj. Tramadol 40 mg. Group B (n= 30) – treated with Inj. Bupivacaine 0.25% 0.7 mg/kg. All drugs were diluted with sterile normal saline to 20 ml solution and administered intraincisionally at the time of skin closure. On arrival in recovery room, pain intensity is assessed by Visual Analogue Scale ranging from 0 to 10 and then 15, 30, 60 minutes, 2 hrs, 6 hrs, 12 hrs, 24 hrs after arrival from recovery. If analgesia is considered inadequate, rescue analgesics Inj. Diclofenac 75 mg intramuscular or Inj. Tramadol 1mg/kg intramuscular was added. The frequency of nausea, vomiting, rigor and mean arterial blood pressure were evaluated.At the end of 24 hours patients were asked about the quality of pain relief using the following score – excellent – 4,very good-3, good -2, poor-1.
Results: Demographic data - age distribution, BMI, gravidity showed no significant difference. Mean age, BMI group A 25.43 ± 3.61, 25.11 ± 3.61 and Group B was 25.03 ± 4.26, 23.37 ± 2.74. Both were homogenous. Mean Pain scores by Visual analogue scale for group A was 0.76 ± 1.16, 1.90 ± 0.92 and 0.97 ± 1.12 and for group B was 0.53 ± 0.68, 1.17 ± 0.74 and 0.30 ± 0.53 at 6, 12 and 24 hours. The pain score was slightly higher in Group B than Group A. The 'f' value of Group B is higher in nature but the Pain score was statistically significant 'P' of 0.001 was obtained for both groups. Group B was more effective in postoperative analgesia but Group A also has significant postoperative analgesic effect. The Mean Systolic and Diastolic BP is higher in Group B. Also the Systolic BP was statistically significant. On comparing complications 2 patients reported nausea in Group A and 6 patients reported rigors in Group B.
Conclusion: In this comparative study, even though Bupivacaine had better analgesic effect, Tramadol also proved to have significance in pain scores and prolonged analgesic effect and less complications. Therefore Intraincisional infiltration of Tramadol and Bupivacaine before skin closure in caesarean sections prolonged the postoperative analgesic effect, reduced consumption of rescue analgesics, better compliance for mother and baby and enhanced patient satisfaction.

Keywords: Caesarean, spinal anaesthesia, intraincisional administration, tramadol, bupivacaine, visual analogue scale

Introduction
The word Caesarean is derived from the Latin word caedare, which means 'to cut'. Caesarean section is otherwise known as C-section. Caesarean section is the delivery of an infant, alive or dead, through an abdominal uterine incision after the period of viability. The term Caesarean section was first used by James Guillimeau. The first Caesarean delivery was documented in 1020 AD. In 1926 Munro Kerr was the first to describe lower segment Caesarean section and popularised the procedure.
In an era of obstetric surgeries, Caesarean is one of the commonest surgeries performed. Pain relief is obtained by multimodal analgesia [1]. Pain relief should be optimum for recovery of the patient, to make the patient mobilize earlier, inturn resulting in faster recovery, initiation of breast feeding, bonding of baby, and preventing thromboembolic complications.

Spinal anaesthesia is the method of choice for Caesarean section. In regional anaesthesia –epidural and spinal, relief of pain is limited to certain anatomical region with minimal side effects and mother is conscious to have skin to skin contact with immediately born baby.

Enhanced recovery after surgery (ERAS) is a concept where evidence based aspects of perioperative care combined to enhance speedy recovery of patient [2]. ERAS protocols recommend multimodal analgesia for early recovery, mobilization, maternal bonding with newborn, reduces thromboembolic events, prevents persistent pain thereby reducing the risk of postpartum depression [3]. Neuraxial anaesthesia along with local anaesthetic wound infiltration reduces the need for additional rescue analgesics [4]. Postoperative pain management is a major task for surgeons on their patients recovery. Local anaesthetic wound infiltration prior to skin closure lessens inflammation of wound, peripheral and central hyperalgesia. It reduces postoperative pain and wound healing process is not impaired [5].

Local anaesthesia – infiltration can be combined with general anaesthesia or spinal anaesthesia so that dosage of analgesic and anaesthetic drugs can be reduced during surgeries thereby providing adequate postoperative pain relief. Local anaesthesia when given as infiltration involves reversible numbing of a specific region of body. It prevents sensation of pain [6]. Local anaesthetic drugs doesn't affect essential body functions. Respiratory depression is least reported in local anaesthetics when used as wound infiltration. Tramadol a selective μ-receptor agonist has local anaesthetic effect on peripheral nerves [7]. Pain inhibition is mediated through opioid and nonopioid system [8]. Tramadol inhibits reuptake of norepinephrine and hydroxytryptamine by displacing stored hydroxytrypatamine from the nerve endings mediated through α2-agonistic and serotonergic activity [9]. Bupivacaine blocks the generation and conduction of nerve impulses. Therefore bupivacaine is used for infiltration of surgical incisions [10]. Thereby in this study, comparative study of Inj. Tramadol and Inj. bupivacaine was done as wound infiltration for postoperative pain relief in Caesarean sections under spinal anaesthesia.

Materials and methods

Study settings

The study was done in The Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College and Hospital.

Study Population

60 patients were assigned for the study and were randomly assigned into two groups – Group A and Group B. Antenatal mothers of age group (18-35 yrs) with BMI (18.5–40 Kg/m2) scheduled for Caesarean under spinal anaesthesia were included in the study.

Exclusion Criteria

1. Patients allergic to drugs
2. Pre- eclampsia and eclampsia
3. Gestational Diabetes
4. Cardiopulmonary diseases
5. Skin infections
6. Renal or Liver diseases
7. Immunocompromised patients
8. Sero positive patients
9. Coagulation disorders
10. Morbid obesity

After getting informed written consent, random numbers were assigned to each patient. Caesarean section was performed under spinal anaesthesia.

At the time of skin closure patients were randomly divided into two groups

Group A (n=30) – treated with Inj. Tramadol 40 mg

Group B (n= 30) – treated with Inj. Bupivacaine 0.25% 0.7 mg/kg.

Both drugs were diluted with sterile normal saline to give 20 ml solution and administered intraincisionally at the time of skin closure. On arrival in recovery room, pain intensity is assessed by Visual Analogue Scale ranging from 0 to 10 and then 15,30,60 minutes,2 hrs, 6 hrs, 12 hrs, 24 hrs after arrival from recovery. If analgesia was considered inadequate rescue analgesics Inj. Diclofenac 75 mg intramuscular or Inj. Tramadol 1mg/kg intramuscular was added. The frequency of nausea, vomiting, rigor and mean arterial blood pressure were evaluated. At the end of 24 hours patients were asked about the quality of pain relief using the following score – excellent – 4, very good-3, good -2, poor-1.

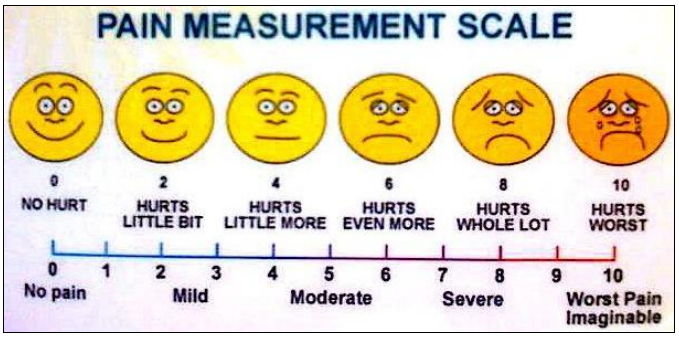

Fig 1: Visual analogue scale

Data analysis and results

In the current study, the analgesic effects of Tramadol and Bupivacaine was compared. Sixty Antenatal mothers posted for Caesarean surgeries were divided randomly into two groups – Group A and Group B. The main outcome was pain score at different times of study period. The comparison of pain score at different times was analysed by ANOVA (Analysis of Variance). Between two group comparison was carried out by Independent sample 't' test. The entire statistical procedure was performed by SPSS 21.

Table 1: Age and BMI distribution

	Tramadol (A)		Bupi vacaine (B)		Independent Sample Test	
	Mean	SD	Mean	SD	'T'	'P'
Age	25.43	3.60	25.03	4.26	0.392	0.69
BMI	25.11	3.61	23.37	2.74	2.10	0.06

The mean age of the group A women was 25.43 ± 3.61, whereas the mean age for group B women was 25.03 ± 4.26 years. The 'P' value was insignificant, 'P'= 0.692, hence the two groups were homogenous with respect to age.

The mean BMI of the group A was 25.11 ± 3.61 the mean BMI of group B was 23.37 ± 2.74. The 'P' Value was insignificant P= 0.060 and therefore the two groups were homogeneous with reference to BMI.

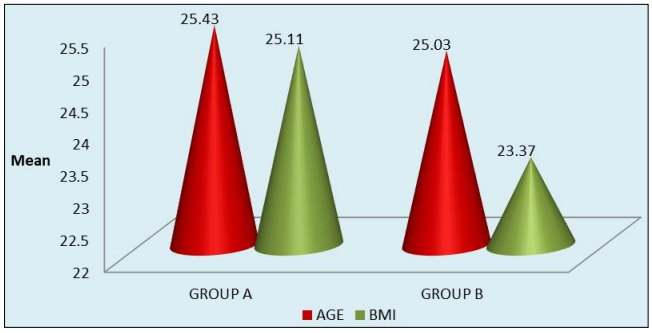

Fig 2: Age and BMI distribution

Table 2: Gravida distribution

	Group A		Group B		Chi square test	
	Mean	**SD**	**Mean**	**SD**	**'T'**	**'P'**
Primi	12	40	16	5303	0.089	0.769
Multi	18	60	14	46.7		
Total	30	100	30	100		

The primi gravida was 40% in Group A whereas 53.3% in group B. the frequency of multi gravida was 60% in group A and 46.7% in group B. The chi – square test of independence was insignificant P= 0.769. Therefore the gravid status was homogenous between the groups.

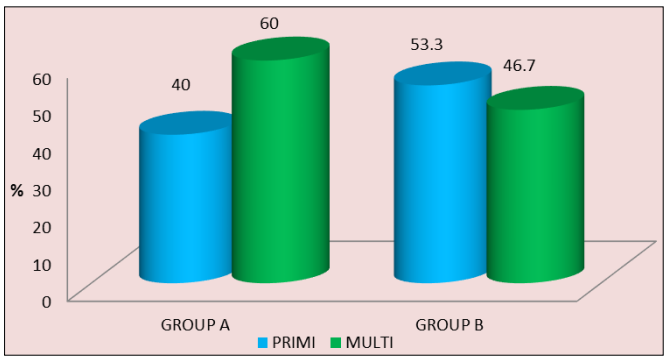

Fig 3: Gravida distribution

Table 3: Pain score analysis for various hours - visual analogue scale

	Group A		Group B	
	Mean	SD	Mean	SD
6 Hours	0.76	1.16	0.53	0.68
12 Hours	1.90	0.92	1.17	0.74
24 Hours	0.97	1.12	0.30	0.53
One way ANOVA				
'F'	9.43		13.84	
'P'	0.001		0.001	

The mean pain score for group A at 6 hours, 12 hours and 24 hours was 0.76±1.16, 1.90±0.92 and 0.97±1.12 respectively. The one way ANOVA was used to study the difference in the pain score at different periods of the study. The 'F' value was 9.43 with the corresponding of 0.001, which is statistically significant. Therefore the pain score for group A was statistically significant at different times of measurement.

The pain score was 0.53±0.68, 1.17±0.74 and 0.30±0.53 at 6 hours, 12 hours and 24 hours respectively for group B women's. The 'F' value was 13.84 with the corresponding 'P' of 0.001 which is statistically significant. Therefore the pain score were different at the various times of the study periods.

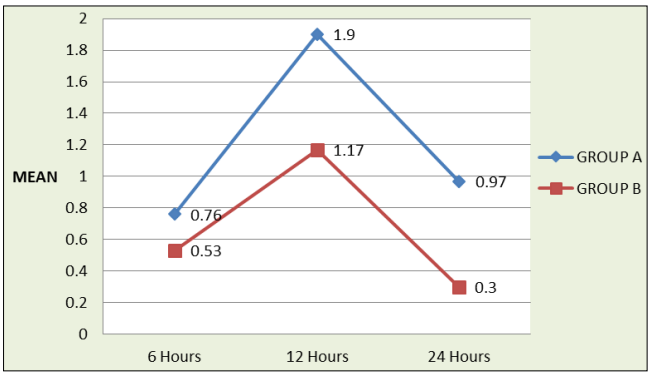

Fig 4: Pain score analysis for various hours - visual analogue scale

Table 4: Post HOC method (Mean difference)

Pain score	Group A		Group B	
	Mean Difference	**Significant**	**Mean Difference**	**'P' Value**
6 hrs 12 hrs 24 hrs	-1.13 -0.20	0.001 0.474	-0.633 0.230	0.001 0.175
12 hrs 24 hrs	-933	0.001	0.867	0.001

The difference in the pain scores between 6th hours and 12th hours was statistically significant in both the groups. As the mean pain score was improved in 12th hours, there was significant increasing level of pain at 12th hours, compared to 6th hour.

The mean difference in the pain score between 6 hours and 24 hours was statistically insignificant in both the groups. The difference in the pain score between 12th and 24th hours was statistically significant in both groups. Therefore pain score was significantly lower at the 24th hour compared to 12th hour.

Table 5: Analysis of pain score in different times

Difference	Group (A)		Group (B)		Independent Sample Test	
	Mean	SD	Mean	SD	'T'	'P'
6 Hours Vs 12 Hours	1.13	1.63	0.63	0.71	1.53	0.130
6 Hours Vs 24 Hours	0.20	1.29	-0.23	0.89	1.50	0.138

The mean increase in the pain level between 6 hours to 12 hours in group A 1.13 ± 1.63. The mean increase in the pain level between 6 to 12 hours for group B was 0.63 ± 0.71. Therefore the increase in the pain level was higher in group B than in group A but the difference was statistically insignificant (P=130).

The mean increase in pain for group A between 6 and 24 hours was 20±1.29. In group B the reduction in pain intensity was meagre and was 0.23±0.89. The difference between the group was statistically insignificant (B= 138).

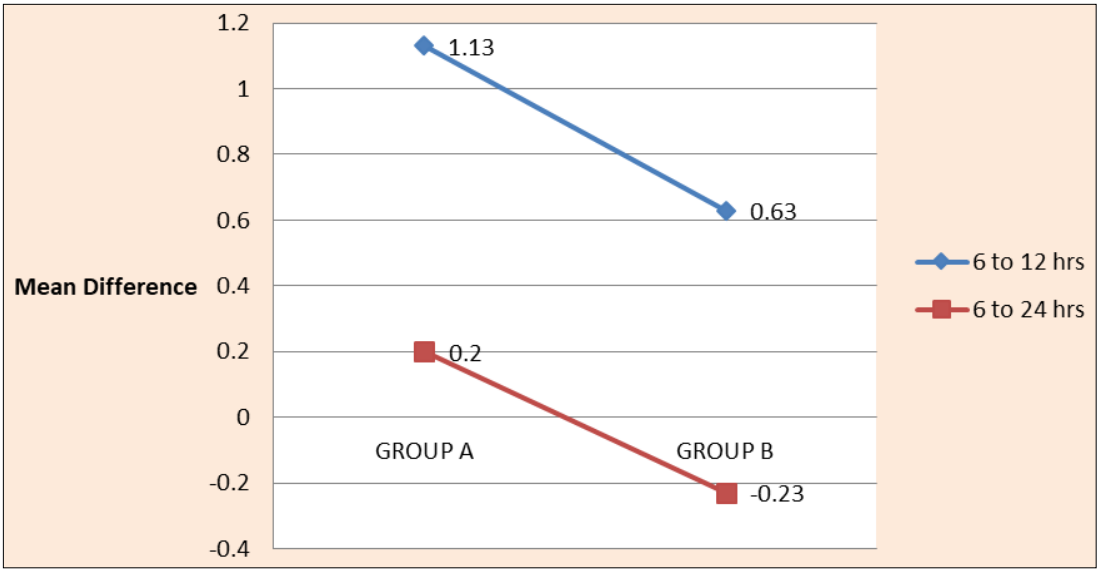

Fig 5: Analysis of pain score in different times

Table 6: Over all pain score (Scale)

Over all Pain Score	Group (A)		Group (B)	
	Mean	SD	Mean	SD
	2.57	1.10	2.87	0.57

The mean pain score for group A was 2.57 ± 1.10. The mean pain score for group B was 2.87 ±.57.

Table 7: Rescue analgesics distribution

Rescue Analgesics (in mg)	Group (A)		Group (B)	
	Number	Percentage	Number	Percentage
100mg 1 Doses	20	66.7	28	93.3
200mg 2 Doses	9	30.0	2	6.7
300mg 3 Doses	1	3.3	-	-
Total	30	100	30	100

The majority of group A had 1 dose (100) rescue analgesics (66.7%). The most of group B patients were provided with 100mg (1 dose) of rescue analgesics (93.3%). For group A women 200 mg doses of rescue analgesics' was given for 30% even 3.3% women in group A required 300 mg of rescue Analgesics.

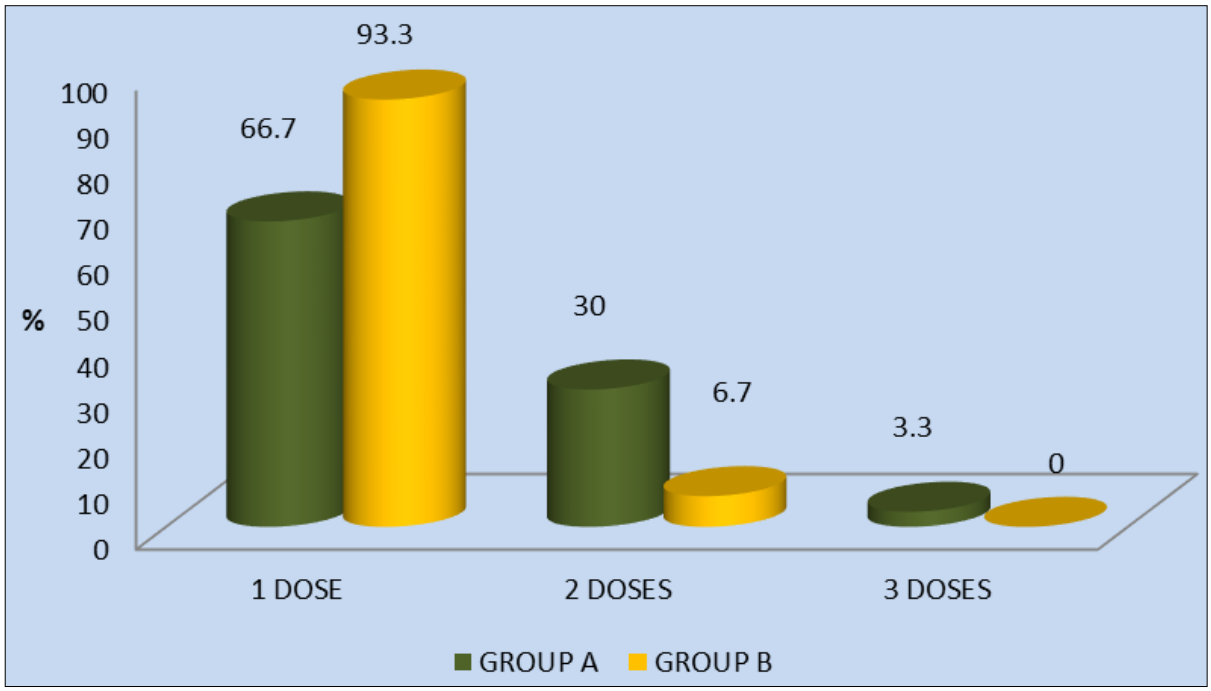

Fig 6: Rescue analgesics distribution

Table 8: Blood pressure analysis and distribution

	Group A		Group B		Independent Sample Test	
	Mean	**S.D**	**Mean**	**S.D**	**'t'**	**'P'**
Systolic BP	108.33	7.47	113.00	8.77	2.22	0.030
Diastolic BP	73.33	6.61	75.67	6.26	1.40	0.166

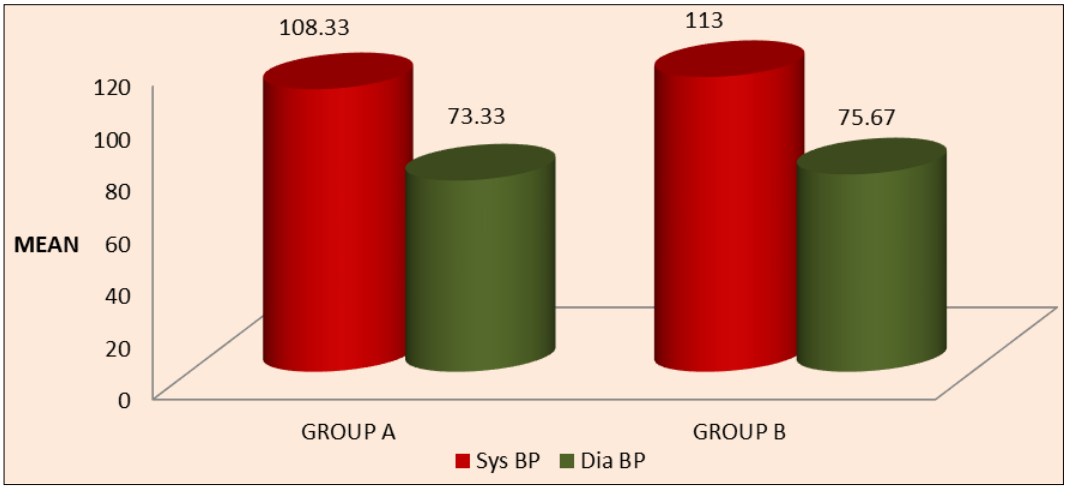

Fig 7: Blood pressure analysis and distribution

The Mean Systolic BP for Group A was 108.33 ± 7.47 whereas it was 113.00 ± 8.77 for Group B. The Mean Diastolic BP for Group A was 73.33 ± 6.61 where as it was 75.67 ± 6.26 for Group B. It is inferred that there was significant variation in Systolic BP between groups whereas the Diastolic BP variation was statistically insignificant.

Discussion

Caesarean sections both elective or emergency surgeries were done under anaesthesia. General or Spinal anaesthesia can be used. Spinal anaesthesia is one of the widely used techniques for Caesarean sections [11]. Meticulously among various anaesthesia techniques used, multimodal analgesia is effective for postoperative pain relief. Wound infiltration with local anaesthetics reduces dosage of analgesia [12, 13]. Tramadol is a synthetic analogue of codeine. It has local anaesthetic, anti-inflammatory, antinociceptive action and unlike other opioids respiratory depression is least reported [14, 15]. Among various studies, Jou *et al*. suggested similar mechanism of action of tramadol with lidocaine [16].

Bupivacaine, a local anaesthetic reduces the levels of interleukin 10 and increases substance P in the wound when used as infiltration for postoperative pain relief in caesarean sections [17].

Demographic data - age distribution, BMI, gravidity showed no significant difference. Mean age, BMI group A 25.43 ± 3.61, 25.11 ± 3.61 and Group B was 25.03 ± 4.26, 23.37 ± 2.74. Both were homogenous. Mean Pain scores by Visual analogue scale for group A was 0.76 ± 1.16, 1.90 ± 0.92 and 0.97 ± 1.12 and for group B was 0.53 ± 0.68, 1.17 ± 0.74 and 0.30 ± 0.53 at 6, 12 and 24 hours. The pain score was slightly higher in Group B than Group A. The 'f' value of Group B is higher in nature but the Pain score was statistically significant 'P' of 0.001 was obtained for both groups. Group B was more effective in postoperative analgesia but Group A also has significant postoperative analgesic effect.

The cumulative rescue analgesics needed was decreased in group B 6.7% when compared to Group A 30%. The Mean Systolic and Diastolic BP is higher in Group B. Also the Systolic BP was statistically significant. On comparing complications 2 patients reported nausea in Group A and 6 patients reported rigors in Group B.

In our study Mean age, BMI were homogenous and comparable with other studies.

Table 9: Comparison of mean age distribution in various studies

	Our study	**Amin [2010]**	**Sachidananda *et al*. [2017]**	**Sarwar [2016]**
Mean age	25.43	25.06	23.43	26.52

The Mean pain score in our study was statistically significant and 'P' of 0.001 was obtained. Pain score for Group A and B were statistically significant at various times of measurement. Pain relief was good enough as compared to other studies mentioned below.

Table 10: Comparison of pain scores distribution in various studies

	Our study	**Jabalameli *et al*. [2012]**	**Amin [2010]**	**Sarwar [2016]**	**Sachidananda *et al*. [2017]**
Group A Mean score	1.90	2.5	3.84	2.8	3.13
P value	0.001	<0.001	0.020	0.00026	0.1907
Group B Mean score	1.17	3.6	3.48	1.98	2.77
P value	0.001	<0.001	0.020	0.00026	0.1907

Jabalamelli *et al*. studied there was no significant difference in nausea among both groups, similarly in our study only 2 patients had nausea in Group A.

The rescue analgesics needed were also minimum. There was also no significant change in the vital parameters like pulse rate, saturation and blood pressure, thus providing safety of usage of both Tramadol and Bupivacaine as intraincisional infiltration for post-operative pain relief in Caesarean sections.

Conclusion

In this comparative study, eventhough Bupivacaine had better analgesic effect, Tramadol also proved to have significance in pain scores and prolonged analgesic effect and less complications. Therefore Intraincisional infiltration of Tramadol and Bupivacaine before skin closure in caesarean sections prolonged the postoperative analgesic effect, reduced consumption of rescue analgesics, better compliance for mother and baby and enhanced patient satisfaction.

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