

RECTAL PREOPERATIVE TRAMADOL AND INTRAOPERATIVE BUPIVACAINE WOUND INFILTRATION AT CESAREAN DELIVERY FOR POSTOPERATIVE ANALGESIA

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ABSTRACT

Background: Delivery by CS is increased and is one of the most common great operative procedures done worldwide. Prompt and adequate postoperative pain relief is an important issue of caesarean delivery. Pain relief may cause good psychological and physical effects in patients, lead to better recovery from surgical procedures and early mobilization of patients to prevent complications. Pain after operations is usually managed with opioids. These agents exert their analgesic effects through μ -receptors in the CNS. The effect of opioids is limited by the occurrence of tolerance or side effects such as vomiting, nausea, sedation, or respiratory depression. Tramadol, is analgesic with weak μ -opioid receptor agonist and activity at serotonergic, noradrenergic and GABAergic systems, is another alternative parenteral, oral and rectal analgesic for post caesarean pain. The local anesthetic may be used before or after abdominal nerve block, absorbed by systemic route and secreted in breast milk, but their effects on breast fed babies have not yet been demonstrated. This is in contrast to morphine or pethidine, both of which have significant transfer to breast milk and may have a sedative effect on the baby. **Objectives:** Of our study was to measure the effect of rectal tramadol and bupivacaine infiltration on pain relief after CS and on opioids requirement. **Patients and methods:** 312 parturient, scheduled for CS under general anesthesia, participated in this study, 156 parturient received placebo rectally and saline infiltration and the other 156 received Tramadol 100mg rectally and Bupivacaine 0.25% infiltration in the wound. **Results:** Rectal Tramadol and local Bupivacaine infiltration is effective in decreasing intensity of postoperative pain and the amount of the opioids consumption. **Conclusion:** Combination of the rectal Tramadol suppository and Bupivacaine infiltration of surgery wound cause longer duration of analgesia and decrease consumption of opioids. so can be a good choice for pain relief after cesarean delivery.

Key Words: Tramadol, bupivacaine, wound infiltration, cesarean delivery, postoperative analgesia.

INTRODUCTION

Cesarean delivery is one of most commonly operated surgeries. It is calculated that about 15% of births worldwide and 21.1% of those in western countries occur through a cesarean section⁽¹⁾.

The 2008 demographic and health survey in Egypt also expressed that the cesarean delivery rate in the five years before the survey was about 25% of deliveries nationwide and 37% of labours in urban areas⁽²⁾.

Post cesarean pain composed of visceral and somatic component. Visceral pain comes from uterine wound and contractions. The somatic component arises from nociceptors in the surgical wound. Nerves from the anterior abdominal wall are derived from T6 to L1 and pass through the plane between the layers of the transversus abdominis and internal oblique muscles⁽³⁾.

The variability between individual in the increase amplitude of postsurgery pain is affected by many factors, such as individual

allergy to pain, psychological events (e.g., irritability and somatization), age and genetic factors⁽⁴⁾.

The severity of post cesarean pain would be predicted as to use analgesia. However the multifactorial predictive system for post surgery pain and analgesic need is still in the start, recent research has evidenced many important items, contain the mother predictions anxiety, thermal and electrical pain threshold in the lower back beside the dermatomes of the surgical wound⁽⁴⁾.

Uncontrolled pain well in the immediate postoperative period may lead to the occurrence of chronic pain. The use of different multimodal analgesia has great fasted the management of postsurgery pain⁽⁵⁾.

Pethidine and morphine, are the most widely consumed and cost-effective agents. Increasing of intravenous analgesia has been achieved with regional nerve blockade, especially for patients done hysterectomy or caesarean delivery⁽⁶⁾.

The aim from administration of preoperative analgesia is to prevent sense of pain from beginning by blocking the most response of nervous system to pain. The local anaesthesia is used to protect the central nervous system from the effects of noxious stimuli. According to some neural pain pathway theories, the sensitization of superficial pain receptors may further sensitize the nervous system to painful sensation⁽⁷⁾.

Cesarean delivery is a great surgical operation, after whichl postosurgery discomfort and pain can be occure It is documented that when pain inadequately relieved can lead to number of complications in the postoperative period⁽⁸⁾.

Local anesthesia is a agood and safe anesthetic object for most surgical operation.when added with general anesthesia, local anesthetic infiltration lower the need for systemic analgesics⁽⁹⁾.

Local anaesthetics act by reversible block of impulse distribution along the nerve fibres by stoping the entry of sodium ions through the cell membrane of the fibres. Treatment of postoperative pain after cesarean delivery under general anesthesia is mostly multimodal. Local anaesthetics comunely absorbed systemically and secreted in breastmilk, but their effects on breastfed newly born have not yet been in contrast to morphine or pethidine, both of which have transfer to breastmilk ,cause sedation of the baby and impair the early bonding between newborn and his mother⁽¹⁰⁾.

Tramadol is an analgesic with mixed non Opioid and Opioid properties. used for the treatment of acute post operative and chronic pain of intermediate or severe intensity. So tramadol may be suitable to treat post operative pain in LSCS; however after intravenous and oral routes , peak concentrations are reached rapidly and this has been accompanied by post operative nausea and vomiting, so rectal aroute of tramadol may be usefull in this situation. It is the established treatment for postoperative pain in adults⁽¹¹⁾.

The goal of this study is to find out the effect of combination of rectal tramadol suppository and local “Bupivacaine” wound

infiltration in the subcutaneous tissue at the end of operation on postoperative pain and use of “Pethidine” after cesarean delivery.

PATIENTS AND METHODS

This trial is a rondomized,double-blind placebo-controlled study which was conducted at obstetrics & gynecology department of Zagazig general hospital. Three hundred and twelve (312) pregnant women who scheduled for elective cesarean section under general anesthesia,fulfilled the inclusion criteria and agreed to participate in this study.

Inclusion data:

- Women aged 18-40 years
- Women scheduled for elective LSCS

Exclusion data:

- History of bleeding
- History of allergy to tramadol or Bupovacaine
- History of hepatic or renal disease
- History of previous local anasthetic agent at the previous CS wound
- Pregnancy medical disorders eg; diabetes,essential hypertention,pre eclampsia, heart diseases,renal and others disorders.
- Women who refused to participate in the trial.

Methods:

The selected cases subjected to the following:

- A written informed consent.
- Proper full history taking.
- Full general examination with especial concern to vital signs, chest examination and heart examination.
- Abdominal examination.
- Routine laboratory investigations in the form of complete blood count, liver function tests, kidney function tests, prothrombin time and prothrombin concentration.
- Trans-abdominal ultrasound study.

Randomization:

The patients were randomly allocated to one of the two groups: the study group (group I) and the placebo group (group II).

1- Group I (n=156 women) had received:

- Tramadol suppository rectally immediately after general anesthesia.
- Infiltration with 20 milliliter (ml) of 0.25% Bupivacaine using 20 ml syringe before closure of the skin 10ml subcutaneously on each of the upper and lower edges of the incision.
- Patient received declofenac sodium 75ml IM during the immediate postoperative period, additional rescue analgesia in form of pethidine 50mg IM upon patient request and when $VAS > 3$

2- Group II (n=156 women) had received :

- The placebo rectally immediately after general anesthesia.
- Infiltration with 20 ml of 0.9% saline in both sites as group I.
- Patient received declofenac sodium 75ml IM during the immediate postoperative period, additional rescue analgesia in form of pethidine 50mg IM upon patient request and when $VAS > 3$

Pain assessment:

The main outcome is postoperative pain scores (VAS) evaluated by a staff blinded to the patients' group, evaluation of the intensity of pain with the visual analogue scale (VAS) as soon as they responded to verbal stimuli in the recovery room (30 min) and at postoperative 2, 4, 6, 8, 12, and 24 h. $VAS = 3$ was considered to be an adequate level of analgesia.

Visual analogue scale (VAS) is most common used as a pain assessment instruments, and is considered the gold standard in research and clinical practice.

Primary outcome:

- Reduction of postoperative pain qualitative measurement by (VAS).
- 24 hrs total pethidine consumption.

Secondary outcome:

- Decrease need for postoperative opioid.
- Percentage of side effects as Fever, pruritis, vomiting and wound infection.

Statistical analysis:

Collected data were presented on suitable tables and figures. Quantitative data were summarized as mean, SD while Qualitative as frequency and percentage.

Data were analyzed by the aid of software package of SPSS version 16 using (student t test) for quantitative data and (chi square test) for qualitative data.

The clinical data were recorded on a report form. These data were tabulated and analyzed using the computer program SPSS (Statistical package for social science) version 16 to obtain :

Descriptive statistics were calculated for the data in the form of : Mean and standard deviation for quantitative data and frequency and distribution for qualitative data.

RESULTS

There was no significant difference in patient demographics between the 2 groups with respect to age, weight, height, gravidity, parity, number of previous sections and gestational age as shown in tables 1, 2.

There was statistical highly significant difference in time of ambulation and Time interval for first analgesic request as comparing group I to group II as in table (3)

There was statistical highly significant difference in visual analogue scale values through the first 24hours postoperative as comparing group I to group II. There was statistical highly significant difference in Pethidine consumption /24h between two group as in table (4).

Table (1): Comparison between group I &II according to patient epidemiological data

Variable	Group I		Group II		Student t test	P value
	Mean± (Range)	SD	Mean± (Range)	SD		
Age	26.25±5.19 (19-37)		25.65±5.81 (17-40)		0.966	0.335 NS
Weight	80.04±7.53 (64-96)		79.03±5.3 (65-90)		1.37	0.173 NS
Height	159.22±4.34 (150-167)		159.08±3.29 (153-170)		0.338	0.735 NS
GA	38.31±1.12 (36-40)		38.09±1.18 (36-41)		1.67	0.095 NS

Data were shown as mean ± standard deviation.

p> 0.05= not significant.

Table(2): Comparison between group I &II according to gravidity, parity and no of previous section.

	Group I		Group II		Total		Fisher exact test (FET)	P value	
	No	%	No	%	No	%			
Gravidity	1	28	17.9	29	18.6	57	18.3	6.4	0.17 NS
	2	62	39.7	73	46.8	135	43.3		
	3	40	25.6	38	24.4	78	25.0		
	4	24	15.4	15	9.6	39	12.5		
	5	2	1.6	1	0.6	3	1.0		
Parity	0	32	20.5	42	26.9	74	23.7	8.71	0.057 NS
	1	67	42.9	73	46.8	140	44.9		
	2	40	25.6	34	21.8	74	23.7		
	3	15	9.6	6	3.8	21	6.7		
No of previous section	0	30	19.2	42	26.9	72	23.1	6.37	0.158 NS
	1	72	43.5	73	46.5	145	46.5		
	2	44	28.2	35	22.4	79	25.3		
	3	8	5.1	5	3.2	13	4.2		
	4	2	1.6	1	0.6	3	1.0		

Table (3): Comparison between the two groups according to Surgery time , Anesthetic time , Ambulation time, Time interval for 1st analgesic request

Variable	Group I Mean± SD (Range)	Group II Mean± SD (Range)	Student t test	P value
Surgery time /min	41.94±6.37 (30-70)	40.87±6.49 (30-70)	1.46	0.145 NS
Anesthetic time /min	52.12±5.99 (40-80)	51.03±6.49 (40-80)	1.54	0.124 NS
Incision length /cm	11.1±1.21 (10-13)	10.87±1.0 (10-13)	1.84	0.067 NS
Ambulation time	3.97±0.71 (3.0-7.0)	6.49±0.86 (4.0-9.0)	28.17	0.001 HS
Time interval for 1 st analgesic request	7.04±1.06 (6-9)	1.45±0.16 (0-1)	88.1	0.001 HS

Table(4): Visual analogue score (VAS) and Bethidine consumption 24h of the two studied groups

Variable	Group I Mean± (Range)	SD	Group II Mean± (Range)	SD	Student test	t	P value
VAS 30 min	1.81±1.13 (0-6)		5.76±1.2 (4-9)		45.19		<0.001 HS
VAS 2h	01.19±0.41(0-2)		2.24±0.49 (1-3)		20.6		<0.001 HS
VAS 4h	2.19±0.48 (1-5)		3.26±0.61 (2-6)		17.23		<0.001 HS
VAS 6h	2.25±0.45 (1-3)		3.37±1.02 (1-7)		12.47		<0.001 HS
VAS 8h	3.03±1.29 (2-7)		4.08±1.33 (1-7)		7.09		<0.001 HS
VAS 12h	2.57±2.33 (1-6)		2.12±0.59 (1-6)		12.75		<0.001 HS
VAS 24h	1.77±0.97 (1-4)		3.12±1.09 (2-7)		11.53		<0.001 HS
Pethidine consumption 24h	68.33±24.12 (50- 100)		130.77±24.4 (100-150)		22.73		<0.001 HS

Data were shown as mean ± standard deviation.

**p< 0.001= highly significant.

Tab. (5): Comparison between the two studied groups as regard side effects

		Group I (156)		Group II (156)		Total		FET	P value
		No	%	No	%	No	%		
Vomiting	Yes	5	3.2	8	5.1	13	4.2	x ² = 0.722	0.395 NS
	No	151	96.8	148	94.9	299	95.8		
Pruritis	Yes	3	1.9	3	1.9	6	1.9	0.0	1.0 NS
	No	153	98.1	153	98.1	306	98.1		
Temp>38	Yes	4	2.6	3	1.9	7	2.2	0.146	0.724 NS
	No	152	97.4	153	98.1	305	97.8		
Wound infection	Yes	6	3.8	4	2.6	10	3.2	0.516	0.750 NS
	No	150	96.2	152	97.4	302	96.8		

Data are expressed as percentage %

p> 0.05= not significant.

DISCUSSION

Post-cesarean delivery pain is an important object in obstetrics. many reserches have expesed the need of a good postoperative analgesia on movement, rehabilitation, and decreasing the time of stay at the hospital ⁽¹²⁾. And also it enhances bonding between the newborn and the mother .

Large amounts of opioid analgesic drugs are often required in the treatment of intense post-surgical operation pain. However this option is associated with a lot of side effects, including evident disruption of mother/newborn bonding⁽¹³⁾.

Thinking of reducing post-operative pain and enhancement of early ambulation and mother-newborn relationship we decided to conduct the current study in which we use tramadol rectal suppository and ifiltration of surgery wound by bupovacaine to reduce post-operative pain after the cesarean section and reduce opioids consumption to avoid their adverse effects.

We have found that combination of effect of tramadol suppository after general anesthesia with bupovacaine wound infiltration had lowered the post surgery pain and pethidine consumption in the post surgery period. Our aim was to obtain maximum pain relieve and decrease morphia use because they are associated with sedation, decrease of bowel motility, and secreted into breast milk can lead to sedation of the baby .

Some participant may be uncomfortable from adminstation of the suppository rectally,so in our study we introduced suppositories after induction of general anesthesia.

There was no available studies showing the duration of analgesia after combination of rectal tramadol suppository and infiltration of wound by bupovacaine 0.25%.so we conduct our study.

In this study, there were no significant differences between the two studied groups as regard patient weight ,age ,icisional length, gestational age, height, anesthetic time, surgery time ,parity and number of previous cesarean section.

The results of our study revealed that combination of tramadol suppository and

infiltration of surgery wound by20ml 0.25% bupovacaine after performance of cesarean section provided a significant degree of reducing post-operative pain as shown by decrease in pain scores of visual analogue scale in the study group through the 1st.24h post-operative when compared to group of mothers in placebo group.

At 6 hours mean VAS score 2.25 in comparison to VAS in placebo group 3.37 and at 8 hours it was 3.03 in comparison to 4.08 , after that rescue analgesia was given.

the duration of analgesia was prolonged at the study group which was observed by time needed for 1st analgesic request and the percentage of mothers requirered it at both group.

In comparing group of mothers who undergo tramadol suppository and ifiltration of surgery wound by bupovacaine to group of mothers in placebo group there was marked reduction in total pethidine consumption mg/24h,(the study group 68.33,the control group130.77).

There was earlier onset of ambulation in group of mothers who had the combination of tramadol suppository and infiltration of surgery wound by bupovacaine 3.97 ± 0.71 (3.0-7.0 hours after surgery) as compared to group of mothers in placebo group as 6.49 ± 0.86 (4.0-9.0 hours after surgery).

In our study only 5 from 156 patients had vomiting. This low incidence contributed to the administration of tramadol by rectal route.

The results of others researchers who conducted similar studies regarding to analgesia consumption and decrease of postoperative pain the following was found:

Vyankatesh et al.⁽¹⁴⁾ done comparison between the analgesic efficacy of tramadol and diclofenac sodium used as a rectal suppository in suppressing postoperative pain after Cesarean section.concluded that rectal suppository of diclofenac and tramadol had a good effect on postoperative analgesia after cesarian delivery.and decrease postoperative pethidine consumption.

Demiraran et al.⁽¹⁵⁾ investigated whether levobupivacaine and tramadol wound infiltration lowered postoperative pain after Cesarean delivery under general anesthesia

and reduce the need for analgesics immediately postoperative. They documented that postoperative analgesia was significantly prolonged and fewer analgesics were required after wound infiltration with tramadol or levobupivacaine at Cesarean section under general anesthesia. They concluded that this technique may be a good choice for postoperative analgesia in patients having Cesarean section under general anesthesia..

Anees⁽¹⁶⁾ investigated Local skin infiltration using Bupivacaine 0.5% was not successful in controlling post CS somatic pain.

Amin and Tahir⁽¹⁷⁾ revealed that direct local wound infiltration of Bupivacaine provided good pain relief after CS and reduced the requirements of parenteral narcotic analgesia with no major side effects.

CONCLUSION

Combination of the rectal tramadol suppository and bupivacaine 20 ml 0.25% infiltration of surgery wound cause longer duration of analgesia and decrease consumption of opioids so can be a good choice for pain relief after cesarean delivery.

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