
A prospective comparative study between tramadol, lidocaine and placebo in subcutaneous wound infiltration for postoperative pain relief in cesarean section

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Abstract

Background: As the rate of cesarean section (CS) is increasing rapidly, the need of postoperative analgesia is increasingly required. Aim: to evaluate the effect of tramadol injection at incision site before closure of the skin in patients undergoing cesarean section on post-operative pain and the need of analgesics in comparison to lidocaine.

Methods: this study was conducted in 2 hospitals in kingdom of Saudi Arabia in period of January 2021 till June 2021, ninety women undergoing cesarean section delivery were divided into 3 groups to receive tramadol, lidocaine or placebo subcutaneously before closing of skin in CS. using visual analogue scale (VAS), Pain was assessed at 6, 12 and 24 h post-operative.

Results: Pain (VAS scores) were significantly lower in the tramadol group in comparison to the other two groups at 6 h ($p < 0.001$), and 12 h ($p < 0.01$). VAS score at 24 h was significantly lower in the Tramadol group compared with Placebo group ($p < 0.01$) and was comparable to Lidocaine group. Non statistically significant difference between VAS scores in Lidocaine group and Placebo was. Time to first analgesic demand was significantly longer in Tramadol group; 2.58 ± 0.93 versus 2.47 ± 0.82 versus 5.97 ± 3.19 hours in the Placebo, Lidocaine and Tramadol group respectively, $p < 0.001$.

Conclusion : local wound injection with tramadol resulted in significantly lower pain scores, But longer time to first analgesic request and lower overall cumulative 24-hour consumption of analgesics. Lidocaine didn't add any analgesic effect over placebo. tramadol wound injection in CS is a good choice for post-operative analgesia.

Keywords: Lidocaine, post cesarean section analgesia, post operative pain, tramadol.

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Introduction

Caesarean section (CS) is a major surgical procedure and it has been one of the most frequently performed operations nowadays. Although CS has some benefits, such as lowering the risk of birth injuries (e.g., asphyxia,

shoulder dystocia, fractures), it can cause moderate to severe postoperative pain. (1)

So, controlling of pain post-Cesarean section may help in rapid recovery, reduction of hospital stay and early bonding between mother and her newborn, while inadequate pain relief may prolong duration of hospitalization beside comorbidities (2)

The term “local infiltration analgesia” is used to describe the application of “high volume of diluted, long-acting local anesthetic” in tissue structures to provide analgesia. Wound infiltration with local anesthetics is used as the main anesthetic for minor surgeries, such as repair of lacerations, skin surgery and treatment of painful oral or genital lesions, but can also be used as supplement to general anesthesia in several types of surgical procedures. (3)

The aim of the current work is to evaluate the impact of tramadol infiltration at incision site before closure of the skin in patients undergoing cesarean section on post operative pain and analgesic requirements in comparison to lidocaine.

Materials and methods

This study is a prospective comparative control trial which was carried in 2 hospitals in kingdom of Saudia Arabia in period of January 2021 till June 2021. We included 90 women pregnant at term who were scheduled to deliver with elective cesarean section through Pfannenstiel incision. Women with major medical problem, bleeding disorder, drug addiction or with allergy to the drug used in the study were excluded. All women included in this study gave an informed consent after proper counseling. The study was approved by appropriate ethical committee .

Sample Size Justification

The study included all women fulfilling the inclusion and exclusion criteria who were

admitted between January 2021 till June 2021 at the 2 hospitals, so 90 women were included in study.

The Ninety women undergoing cesarean section delivery under spinal anesthesia were divided into 3 groups to receive tramadol (group A), lidocaine (group B) or placebo (group C) subcutaneously before closing of skin in CS All patients had routine cesarean section then at time of skin closure, the wound was infiltrated during skin closure with 20 ml of 0.9% saline in group C (n=30), 20 ml of 1% lidocaine hydrochloride in group B (n=30) or 50mg tramadol hydrochloride diluted in 20 ml of 0.9 saline in group A (n=30).

Pain assessment was done using VAS after 6, 12 and 24 hours post-operatively. VAS is considered the gold standard tool for assessment of pain for research purpose. A paper with a 100mm horizontal straight line with 2 ends one end represents no pain and the other represents the worst pain. The patient was asked to mark on the line the pain she feels. Patients received post-operative analgesia of Diclofenac sodium 75mg intramuscular injection on demand.

Statistical analysis

Data are presented as mean, standard deviation (SD), median and range values. For parametric data, A one-way analysis of variance (ANOVA) when comparing between more than two means. Chi-square (χ^2) test of significance was used in order to compare proportions between qualitative parameters. The significance level will be set at $P \leq 0.05$. Statistical analysis were performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY:IBM Corp.

Results

The general characteristics, obstetric history and past medical and surgical history of the included women were comparable between the Placebo, Lidocaine and Tramadol

group. As shown in table (1), there was no statistically significant difference between the three groups as regards age, body mass index (BMI) and gestational age at delivery.

In the Placebo, Lidocaine and Tramadol group, 5 women (16.7%), 6 women (20%) and 4 women (13.3%) respectively were primigravid ($p=0.691$). History of previous one or more cesarean section was found in 19 women (63.3%), 17 women (56.7%) and 19 women (63.3%) among women in the Placebo, Lidocaine and Tramadol group respectively ($p=0.688$). (Data not tabulated).

We found that the VAS scores were significantly lower in the Tramadol group compared with the other two groups at 6 h and 12 h. While at 24 h, we found that the VAS score was significantly lower in the Tramadol group compared with the Placebo group ($p<0.001$) but was comparable to Lidocaine group. The difference in VAS scores between Lidocaine group and Placebo was statistically not significant (table 2).

We also found that time to first analgesic request was significantly longer in the Tramadol group compared with the other two groups (table 2, figure 1). While the mean time of first analgesic request in Lidocaine group compared with Placebo group revealed no statistically significant difference.

As regard the Comparison between the three groups about postoperative analgesic consumption; there were significantly fewer patients requiring diclofenac at 24 h in the Tramadol group compared with Placebo and Lidocaine group. The number of women requiring analgesia at 6h and 12 h was comparable between the three study groups (table 3). Likewise, the cumulative 24-hour consumption of diclofenac was significantly lower in the Tramadol group compared with the other two groups (figure 2).

Discussion

Our Results Interpretation and their comparison to other studies

The current study showed that VAS scores were significantly reduced with subcutaneous infiltration of tramadol compared to lidocaine and placebo at 6, 12 and 24 hours, the time to first analgesic request was significantly longer and total consumption of analgesic in 24 hours was significantly reduced with tramadol.

We also found that lidocaine did not provide good analgesic effect as the VAS scores were comparable to that of placebo throughout the postoperative period. The time to first analgesic request and total analgesic consumption of analgesics in 24 hours were comparable between lidocaine and placebo. These results disagree with Ghenaee et al. (2015) results where they studied 100 cases randomized to lidocaine 2% (4 mg/kg diluted in 30 mL of normal saline), they concluded that lidocaine 2% injection in wound of cesarean section incision has reduced the postoperative pain and decreased the need of any additional analgesia [4]

Our Results were supported by Kessous et al in their RCT which evaluated injection of 1% lidocaine solution in the incision site at cesarean deliveries and reported that there was no significant difference between lidocaine and placebo in postoperative pain scores or analgesic request. (5)

This finding is further supported in a RCT which assessed analgesic effects of tramadol versus saline infiltration subcutaneously in lower abdomen surgeries and it was reported that tramadol significantly reduces pain and opioid consumption. (6)

In our study, tramadol wound infiltration was superior to lidocaine wound infiltration, which was supported by the study of

Jabalameli et al. (2012). They compared pethidine, tramadol, bupivacaine, and placebo in the wound infiltration in total of 120 patients undergoing cesarean section [7]. They found that pethidine and tramadol were superior to other compared groups in reducing postoperative pain and the need for additional analgesia in the pethidine group and tramadol group were significantly lower. These results may be explained by the long duration of action of tramadol. Sachidananda et al. (2017) found that tramadol augmented the action of bupivacaine and prolonged the pain free period and decreased the need of any extra analgesia [8].

The results of the current study disagreed with results of Jayashree et al. (2019), their study included 60 women undergoing CS under spinal anesthesia. Tramadol was compared to bupivacaine, they found that bupivacaine was better in its analgesic effect than tramadol. However, in their study, tramadol had significant pain-relieving effect and prolonged duration.[9].

Clinical Implication of our study

As Evidence revealed the high incidence of postoperative pain and its strong influence on the mother, family and medical practitioners. [10] We conclude that local wound infiltration with tramadol resulted in significantly low pain scores, longer time to first analgesic request and overall lower cumulative 24-hour consumption of analgesics. Lidocaine did not add any additional analgesic effect over placebo. Tramadol wound infiltration in cesarean section is a good choice for post-operative analgesia

Weakness and strength points of study

Main limitation of this study is inadequate number of patients as Arab women backward Islamic culture limits their participation in clinical trials, also lack of randomization in this study because there are no RCT units in

private hospitals, the private patients refuse the idea of randomization and ask for best option and the hospital administration were not encouraging the idea stating that we are not a governmental hospital while strength point is that it is a multicenter trial that decreases the publication bias.

Recommendation for future research

Further studies are needed to evaluate the effect of bupivacaine and other narcotics injection in CS wound.

Conclusion

local wound injection with tramadol resulted in significantly lower pain scores, But longer time to first analgesic request and lower overall cumulative 24-hour consumption of analgesics. Lidocaine didn't add any analgesic effect over placebo. tramadol wound injection in CS is a good choice for post-operative analgesia.

Ethics approval

Study approved by appropriate ethical Committee .

Consent for publication

Non applicable.

Availability and data material

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors report there are no competing interests to declare.

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Table (1): Patients’ characteristics.

	Placebo (n=30)	Lidocaine (n=30)	Tramadol (n=30)	p-value
Age (years)	31.11±4.43	30.39±4.53	30.80±4.02	0.812
BMI (kg/m ²)	28.94±4.02	27.30±3.91	28.63±3.19	0.200
Gestational age (weeks)	39.66±1.65	39.55±1.85	39.86±1.55	0.772

p-value >0.05 is insignificant

Data presented as mean ± standard deviation, analysis done using one-way analysis of variance (ANOVA), kg= kilogram, m= meter

Table (2): comparison between the studied groups as regards pain scores and time to first analgesic request

	Placebo (n=30)	Lidocaine (n=30)	Tramadol (n=30)	p-value
VAS at 6 h	3.09±1.24	3.30±1.03	2.27±0.82*	<0.001
VAS at 12 h	4.94±1.55	4.94±1.13	3.71±1.85†	0.003
VAS at 24 h	4.22±0.82	3.71±0.93	3.09±1.34‡	<0.001
TFA request, h	2.58±0.93	2.47±0.82	5.97±3.19*	<0.001

p-value <0.001 is highly significant; p-value <0.05 is significant; p-value >0.05 is insignificant

Data presented as mean ± standard deviation, analysis done using one-way analysis of variance (ANOVA), VAS= visual analogue scale, h= hour, TFA= time to first analgesic request, *P<0.001 versus Placebo group & Lidocaine group, †P<0.01 versus Placebo group & Lidocaine group, ‡P<0.001 versus Placebo group only.

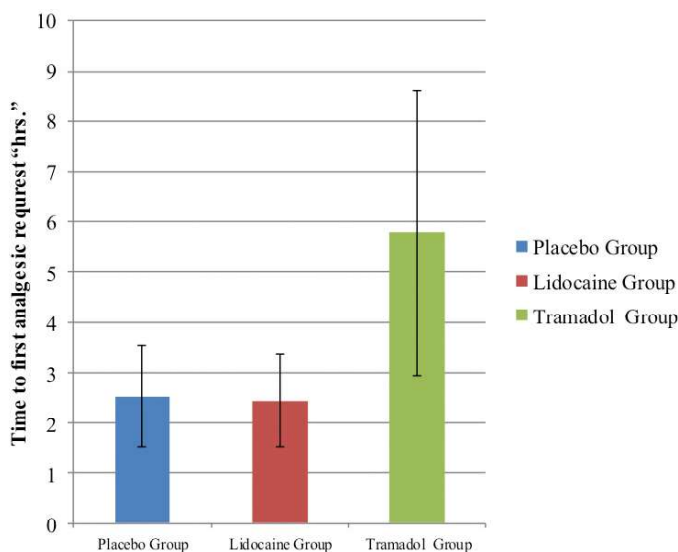


Figure (1): Mean time to first analgesic request in the three study groups. Error bars represent standard error of the mean.

Table (3): Comparison of analgesic consumption between the study groups

Diclofenac consumption	Placebo (n=30)	Lidocaine (n=30)	Tramadol (n=30)	p-value
at 6 h	6 (20.0%)	3 (10.0%)	2 (6.7%)	0.260
at 12 h	25 (83.3%)	29 (96.7%)	24 (80.0%)	0.133
at 24 h	28 (93.3%)	25 (83.3%)	15 (50.0%)	<0.001

p-value <0.001 is highly significant; p-value >0.05 is insignificant

Data presented as number (percentage), analysis done using Chi square test.

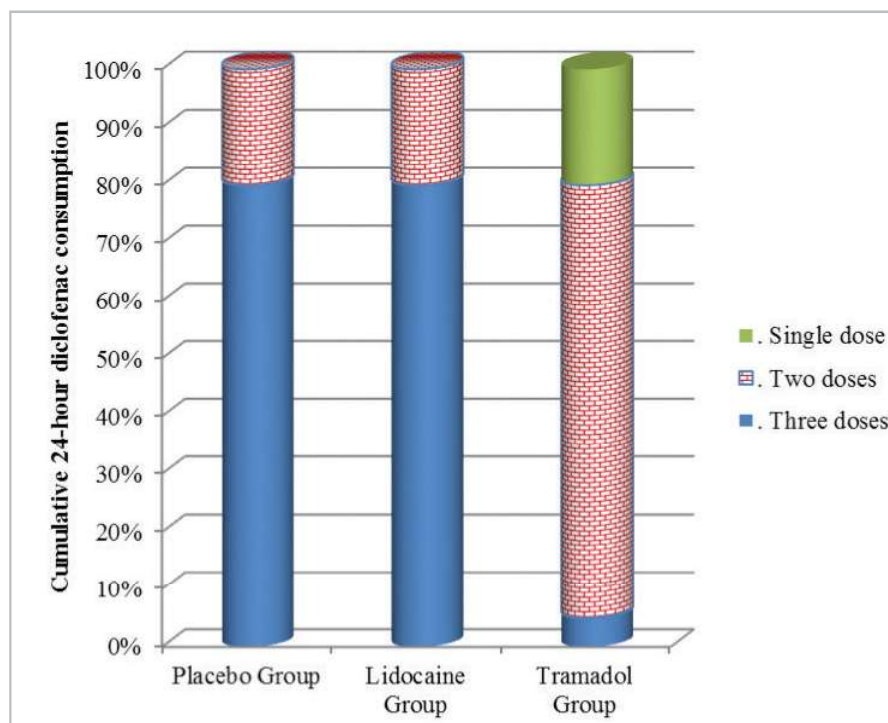


Figure (2): Cumulative 24-hour diclofenac consumption in the three study groups.