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Effectiveness of wound site infiltration for parturients undergoing elective cesarean section in an Ethiopian hospital: A prospective cohort study

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ABSTRACT

Background: Cesarean delivery (CD) is a commonly performed obstetric surgical procedure and causes moderate to severe postoperative pain. Wound site infiltration (WSI) is becoming a technique to provide postoperative analgesia in a limited-resource setting in regardless of controversy on its effectiveness. The current study is to assess its effectiveness as a part of postoperative analgesia for parturients undergoing elective Cesarean section.
Methods: A Hospital-based prospective cohort study was employed on 58 parturients that underwent elective Cesarean section. Study participants were allocated into the Wound site infiltration and Control group based on planned postoperative pain management. A student t-test was used for normally distributed data while non-normally distributed data were analyzed by Mann Whitney *U* test. Pearson Chi-squared or Fisher's exact test were used to analyzing categorical data as appropriate. A p-value < 0.05 considered as statistically significant.
Results: The median time to request the first analgesia was significantly prolonged within Wound site infiltration 314.31 $\pm$ 47.71 in minutes compared to control group 216.9 $\pm$ 43.18 with a P-value of <0.001. The post-operative verbal NRS score was significantly reduced in Wound site infiltration compared to the control group at 4th and 6th hours with p values of <0.001 and 0.04 respectively.
Conclusion: Wound site infiltration performed following elective cesarean section under spinal anesthesia significantly prolonged time to request the first analgesia, decreases verbal NRS score, and total analgesic consumption within 24 h in postoperative period compared to control group.

1. Introduction

Cesarean delivery is a commonly performed obstetric surgical procedure [1]. Nowadays, the rate of CD is dramatically increasing across the world [2]. Based on the 2011 national review done in Ethiopia, the overall institutional CD rate has been 18% [3].

The severity of postoperative pain following CD is usually rated as moderate to severe [4]. In low-income countries, provision of adequate pain management following cesarean section remains a challenge in routine clinical practice [5].

The provision of effective postoperative analgesia in parturient helps to facilitate early ambulation, breastfeeding, maternal-infant bonding, and prevention of postoperative morbidity and even mortality [6].

Alternatives to provide post-CD pain relief is to use epidural analgesia, patient-controlled analgesia (PCA) and ultrasound-guided nerve block are known techniques to provide effective analgesia. But developing countries face another challenge of limited supply related to medical equipments [7].

In another way, systemic opioids remain a mainstay of management for acute postoperative pain [8] but are associated with complications such as nausea, vomiting, Pruritis, drowsiness, and urinary retention [9]. Beside complications, considering the effects of the opioid on breastfeeding is vital to determine the option of post CD analgesia management [10] Because of opioids passes into breast milk and lead to infant mortality secondary to CNS depression [11].

Wound site infiltration is affordable and easy to perform with high safety of margin. So that, this technique has been used in limited-resource areas as a multi-modal analgesia approach to control post-operative pain. Different published studies indicated conflicting findings in reducing postoperative opioid requirement and pain severity with various ranges of analgesic effectiveness [12–16]. The current study aimed to assess analgesic efficacy WSI for parturients who underwent

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elective CD under spinal anesthesia.

2. Methods

2.1. Study design, area, and patients

A hospital-based Prospective Cohort study was conducted from October 2020 to December 2020 at XX University Teaching Specialized Hospital. This hospital is located in the Gurage zone, about 150 km away from the capital city of the country Addis Ababa and the detailed geographical location of the study area has been stated in the literature [17].

Written informed consent was taken from study participants after clearly explaining the aim of the study, benefit, harm of participating in the study and they have been told as they can withdraw from the study at any step if they feel so. This study was reported in line with STROCSS criteria [18] and registered on www.researchregistry with research registry6510 which is available at https://www.researchregistry.com/register-now#home/registrationdetails/60180bd7626028001cf0f8ce/

2.2. Sample size and sampling procedures

Sample size estimation was calculated by using the pilot study which was done on six patients with a ratio of one to one in exposure and control groups. The time to request the first analgesia was taken to determine the sample size since it gave us the largest sample size. The calculated sample means and standard deviations of time to request the first analgesia in the WSI and Control group were 5.85 h + 2.23 and 4.25 hr+ 1.81 respectively.

Two independent sample size formula between two groups were used to determine the sample size using an alpha = 0.05, a power of 0.80. Accordingly, with added 10% of attrition rate a total of 58 ASA I and ASA II parturients were allocated into two groups. Based on Situational analysis done on previous elective CD within 3 months, 121 parturients have proceeded with surgery under spinal anesthesia.

A systematic random sampling technique was employed to select study participants. The sampling interval k was calculated using the formula: k = N/n; where, N = population per 3 months, n = total sample size. Therefore, 58 study participants were recruited with a probability of 47.93%. So that, the sampling interval is 2 and the first study participant was selected using the lottery method. Based on their exposure status parturients were assigned to WSI or control group.

2.3. Inclusion criteria

All ASA physical status I and II Parturients who were undergoing elective C/S under spinal anesthesia were enrolled in the study and assigned to either wound site infiltration or control group.

2.4. Exclusion criteria

Parturients who received adjuvant with intrathecal local anesthetics, Partial/Failed block, Parturients who received IV Opioids, Sedatives, and Parturients who receive other than 20 ml of 0.25% bupivacaine dose and concentration for the proposed infiltration were excluded from the study.

2.5. Anesthesia care

In the study setting, post CD pain management is done either with wound site infiltration or with systemic analgesia by using parenteral tramadol or diclofenac injection when requested. Based on this, we formed two groups Group I: those who received wound site infiltration (WSI) and Group II systemic analgesia (SA) which is considered in our study as a control group.

On arrival of the parturients to the operation theater, standard monitoring protocols have been applied. Per the perioperative anesthesia management protocol of the study area, parturients were received 10 mg IV metoclopramide before 30 min and spinal anesthesia was administered following aseptic techniques by using 2.5 ml of 0.5% isobaric bupivacaine at a sitting position.

The wound site infiltration was performed by the obstetrician in charge at the end of skin closure with 20 ml of 0.25% bupivacaine, 10 ml on each inferior and superior side of the incision. Study participants were classified as WSI group (n = 29) and SA group (n = 29) based on the responsible anesthetist's decision at the end of skin closure.

2.6. Data collection

After preoperative evaluation, parturients who fulfill inclusion criteria and volunteer to take part in the study were instructed on how to self-report pain using verbal NRS score 0–10 on the morning of operation day at the obstetric ward by a trained nurse.

Socio-demographic and intraoperative variables were filled by the anesthetist in charge and severity of postoperative pain in NRS score at 2nd, 4th, 6th, 8th, 12th, 24th hours, time to request the first analgesia, total postoperative analgesic consumption, and adverse effects in all study participants of both groups were documented when it was reported within 24 h post-operative period by trained recovery and obstetric ward nurse who are unaware of group allocation. Data were collected by two trained anesthetists by using preprepared data collection till the planned sample size was achieved while supervision was made throughout the data collection period.

2.7. Data analysis

Data were analyzed using statistical package for social science (SPSS) software version 22. The normality of data was tested using the Shapiro Wilk test. Levene's test was used to check the homogeneity of variance. Numeric data were expressed in forms of mean ± SD for normally distributed data and median (Interquartile range) for non-normally distributed data. Unpaired Student t-test was used for normally distributed data and Manny Whitney test was used for non-normally distributed data. Categorical data were analyzed using Fisher's exact test or Pearson Chi-squared as appropriate. A p-value < 0.05 considered as statistically significant.

2.8. Operational definitions

Postoperative pain: A patient having a pain score greater than zero starting from recovery within 24 h postoperative period.

Verbal numeric rating scale (NRS): A valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0 to 10(11 point scale) with the understanding that 0 is equal to no pain and 10 equal to the worst possible pain.

Total analgesic consumption: The total amount of analgesic medications used in 24 h postoperative period.

Time to request the first analgesia: defined as a time in minutes or hours from the end of surgical procedure to first time analgesia was requested and given.

Post-operative nausea and vomiting: Parturients have experienced at least one episode of either nausea or vomiting within 24 h postoperative period.

3. Results

3.1. Demographic and perioperative characteristics

During the study period, 58 parturients completed the follow-up and analyzed. The study subject's demographic and perioperative characteristics are comparable between the groups with P-value of >0.05

Table 1
Demographic and Perioperative characteristics of study participants.

	SA (n = 29)	WSI (n = 29)	P-value
Age	26.58 ± 4.09	25.51 ± 4.64	0.356
BMI	22.86 ± 2.7	23.14 ± 2.2	0.756
Parity			
Nulliparous	7	5	0.525
Multiparous	22	24	
Indication for CD			
Previous CD	16	14	0.837
Mal presentation	6	7	
Big baby	3	5	
Others	4	3	
Duration of surgery	30.96 ± 3.09	30.17 ± 2.86	0.316

(Table 1).

3.2. Comparison of time to request the first analgesia

There was a statistically significant prolongation of median time to request the first analgesia in WSI (314.31 ± 47.71) in comparison to the SA group (216.9 ± 43.18) in minutes with a p-value of <0.001. With regards to total postoperative analgesic consumption, all parturients were required IV tramadol consumption at least once in both groups within 24 h postoperatively. The Mann-Whitney *U* test revealed higher IV tramadol consumption in the control group compared to the WSI group with a p-value of 0.014 (Table 2).

Values are presented by median (IQR), *: P-values of less than 0.05 statically significant.

3.3. Comparison of postoperative pain severity by using verbal NRS score (0–10)

The Mann-Whitney *U* test showed that a statistically significant reduction in median verbal NRS scores at the 4th and 6th hours postoperatively in WSI compared to the control group with P values of <0.001 and 0.04 respectively (Fig. 1).

4. Discussion

Our study showed that demographic and perioperative characteristics between the groups were statistically comparable. So that, the observed difference in postoperative analgesia effectiveness was likely due to the wound site infiltration effect in the exposed group.

Our study found a significantly prolonged median time to request the first analgesia in WSI 314.31 ± 47.71 compared to the control group 216.9 ± 43.18 with a p value of <0.001.

This result is in line with the study done by Nasir F et al. [19] which found a significantly prolonged median time to request the first analgesia (4.49 ± 1.12) in WSI compared to the control group (2.36 ± 0.58). Another prospective cohort study conducted by H Million et al. [15] also showed the extended median time to request the first analgesia in WSI 5.26 (9.03 ± 4.12) compared to the non-exposed group 3.46 (5.02 _2.46). Other studies also demonstrated longer mean time to request the first analgesia was observed in WSI compared to the control group [13,20,21]. In disagreement with our finding, a study done by Ephrem.et al. [22] found (286 ± 67) minutes median time to request the first analgesia in the WSI group which is lower than our finding. The reason for this dissimilarity might be due to they used only 15 ml volume of bupivacaine while have used 20 ml for wound infiltration.

Table 2
Comparison of time to request the first analgesia in minutes.

	SA Group n = 29	SI Group n = 29	P-value
First analgesic requirement time (minutes)	216.9 ± 43.18	314.31 ± 47.71	0.0001*
Total analgesics consumption			
Tramadol in mg (IV)	100(50–150)	100(50–150)	0.014
Diclofenac in mg (IM)	75(0–150)	75(0–150)	0.602

With regards to the severity of postoperative pain, our study demonstrated a lower NRS score at the 4th, and 6th hours postoperatively in the WSI group compared to the control group with P-values of <0.001 and 0.04 respectively. Similarly, studies reported a significant reduction of Verbal NRS or VAS pain score at 4th and 6th hr postoperative period respectively [15,19].

In comparison to our finding, a study done by N. K. Nguyen.et al. [23] reported a comparable mean VAS pain score between the groups. The possible justification might be due to different infiltration techniques and a less potent ropivacaine local anesthetic agent was used instead of bupivacaine [24].

With regards to total analgesia consumption of tramadol and diclofenac within 24 h postoperative period, our study observed a significantly higher tramadol analgesia consumption in the control group compared to WSI with a P-value of 0.014. In agreement with our result, a study done by Sarwar A, Tasleem S et al. [16], observed significantly less tramadol analgesia consumption in WSI compared to the placebo group.

Furthermore, multiple studies reported a significantly higher postoperative analgesia demand in the control group compared to WSI which is consistent with our finding [13,15,19,25]. In contrary to our study, a comparable postoperative morphine consumption between subcutaneous WSI and control group were observed [26] This disagreement could be explained by the difference in study participants, the difference in the type of anesthesia, and the difference in postoperative follow-up protocol.

5. Conclusion

Wound site infiltration provides a significantly prolonged the first time to request analgesia and reduces the severity of pain score for parturients undergoing elective cesarean delivery. Furthermore, WSI significantly decreases the total postoperative tramadol analgesia requirement compared to the control group. Based on our findings we recommend the use of WSI as a part of postoperative analgesia management in resource-limited settings.

Limitation

Our study is limited to elective cesarean sections only.

Strength

The strength of our work might be, we employed a prospective study design and random sampling technique.

Acronyms and abbreviations

ASA: American Society of Anesthesiology, CD: Cesarean Delivery, NRS: Numeric Rating scale, WSI: Wound Site Infiltration, SA: systemic analgesia.

Availability of data

Data are available from the first author based on reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Ethical approval

Ethical clearance was obtained from Wolkite University, College of

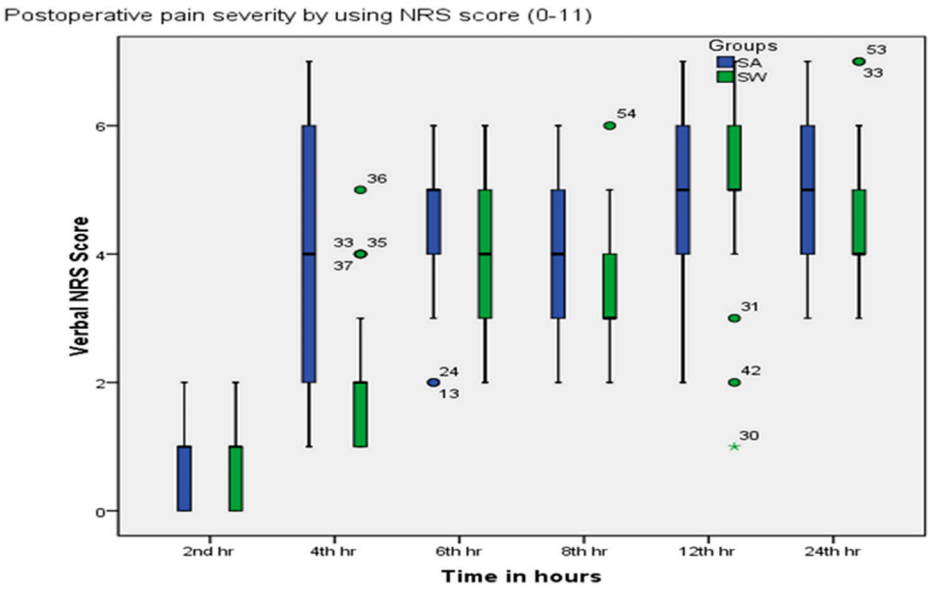

Fig. 1. Pain severity score in NRS.

Medicine and Health Sciences ethical clearance committee.

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Author contribution

All authors equally contributed to the study concept or design, data collection, data analysis or interpretation, writing the paper.

Registration of research studies

1. Name of the registry: http://www.researchregistry.com
2. Unique Identifying number or registration ID: researchregistry6510
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/register-now#home/registrationdetails/60180bd7626028001cf0f8ce/

Guarantor

Mr. Dereje Zewdu.

Consent

Informed consent was taken from a parent of the study participants after telling them the aim of the study, benefit, harm of participating in the study, and they have been told as they can withdraw from the study at any step if they feel so.

Declaration of competing interest

Nothing to declare.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2021.102255.

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