

Analgesic Efficacy of Bilateral Ilioinguinal and Iliohypogastric Nerve Block for Post Caesarean Delivery Under Spinal Anaesthesia, 2016. Double blind randomized Study

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Abstract

Background: Pain after cesarean section is a common phenomenon. Optimal postoperative pain control is paramount as it facilitates early mobilization of the mother, decrease patient morbidity, improve mother –new born bonding and patient satisfaction. This study was designed to determine the analgesic efficacy of bilateral ilioinguinal and iliohypogastric nerve block for caesareans delivery under spinal anaesthesia in the first 24 post-operative hours, Gondar University hospital, Northwest Ethiopia.

Methods: A total of 80 parturients undergoing caesarean delivery via Pfannenstiel incision under spinal anaesthesia were randomly allocated to receive either bilateral II-IH block with 16 ml of 0.25% bupivacaine per side or no II-IH nerve block. Both groups received scheduled IM diclofenac 75 mg every 8 h and intravenous tramadol for breakthrough pain. Pain was assessed at 0, 4, 6, 8, 12, and 24 h after operation both at rest and on movement using numeric rating scale. Time for first analgesia request and total postoperative analgesia consumption were assessed.

Results: Pain severity was decreased both at rest and on movement at all time intervals for 24 h of operation in the treatment group ($P < 0.001$) except at 0 h. Tramadol consumption was decreased by more than 50% in the treatment group compared to the controls for 24 h following surgery ($P < 0.001$). The first analgesia request time was also significantly prolonged in the intervention group than to the control group ($P < 0.001$).

Conclusion and recommendation: Compared to no intervention, bilateral II-IH blocks in patients undergoing caesarean delivery with Pfannenstiel incision had significantly improved pain relief at rest and with movement and resulted in significantly less tramadol consumption in the first 24 h after surgery. These results support the use of bilateral II-IH blocks as part of a multimodal analgesic regimen.

Keywords: Cesarean delivery; Ilioinguinal/iliohypogastric nerve block; Postoperative pain; Postoperative total analgesia consumption; First analgesia request time

Background

Caesarean delivery via a Pfannenstiel incision is one of the main surgical approaches [1,2]. Caesarean delivery (CD) and subsequent manipulation performed through Pfannenstiel incision is commonly associated with severe pain in the postoperative period that may last for several months [3]. Under treatment of postoperative pain is the main reason for patient dissatisfaction [3,4].

Child delivery is accompanied with emotional stress that could be worsened by pain. Under treatment of pain after Caesarean delivery can negatively affect ambulation, breastfeeding, and even maternal bonding [2,5]. Optimal postoperative analgesia is crucial to facilitate early maternal ambulation, improve infant care, decrease postoperative morbidity and mortality, decrease length of hospital stay and improve patient experience with hospital services [6,7].

No single optimal postoperative pain treatment method after caesarean delivery under spinal anaesthesia has been reported. But

different techniques such as spinal, systemic, or both opioids as part of multimodal analgesia during the postoperative period are being practiced [4,7]. However, opioids in both routes are commonly associated with side effects such as nausea, vomiting, sedation, itching, risk of delayed maternal respiratory depression, delayed initiation of breastfeeding and impairment of mother-infant bonding [2-4,8]. In addition, there is also inadequate supply of opioids particularly in resource limited settings, lack of patient monitoring equipments such as pulseoximetry and lack of skill of care givers in the postoperative period [9].

Furthermore, recent studies reported that caesarean delivery which is performed via Pfannenstiel incision is a major source for both acute and chronic pain [10] and both systemic (single bolus/patient controlled) and neuraxial (spinal/epidural) opioids are effective against both visceral and somatic components of pain. Nevertheless, the adverse effects of opioids hinder their use in the clinical settings [11].

The practice of regional nerve block techniques by health professionals for postoperative pain management is rising, and demonstrated a decrease requirement of supplementary analgesia [12,13] Moreover, abdominal field nerve blocks as part of multimodal analgesia with parenteral analgesics are becoming popular for

postoperative pain management after caesarean delivery [5,14,15]. Furthermore, ilioinguinal and iliohypogastric (II-IH) nerve blocks are widely practiced for the treatment of postoperative pain after caesarean delivery [2] and for analgesia for different age groups of patients undergoing hernia repair [16,17]. Bilateral II-IH nerve block found to be effective to provide analgesia after low transverse caesarean delivery as the Pfannenstiel incision has both a somatic and a visceral component, and the somatic pain generated at the incision site is innervated by the II-IH nerve, that innervate the L1-2 dermatome distribution (3k) [18].

Previous studies revealed different outcomes regarding the analgesic efficacy of II-IH nerve block for post caesarean pain, inguinal repair and surgery involving the female genital tract. Moreover, exploring the efficacy of II-IH nerve block could help to tackle sever postoperative pain after cesarean delivery particularly in settings where there is shortage of epidural kit supply and availability of strong opioids for pain management. We aimed to assess the analgesic efficacy of bilateral ilioinguinal and iliohypogastric nerve block for post caesareans delivery under spinal anaesthesia, Gondar University hospital, Northwest Ethiopia, 2016.

Methods

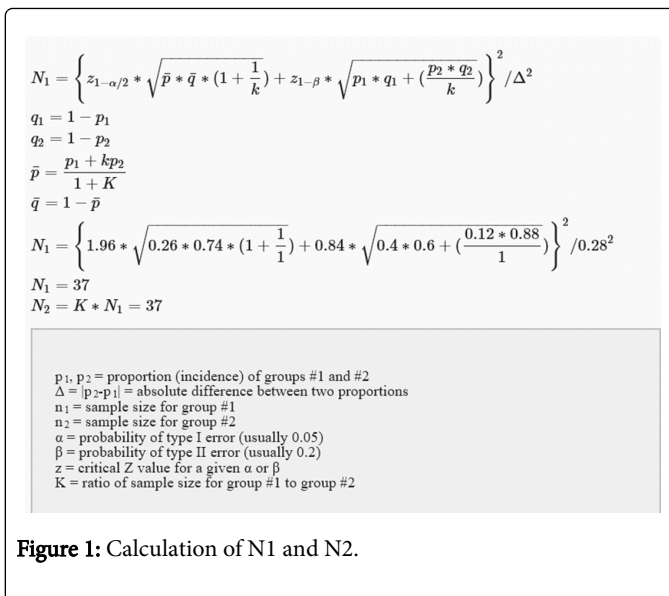
Ethical clearance was obtained from School of Medicine ethics committee, University of Gondar. Eighty two ASA I and II parturients who underwent non emergent caesarean delivery requiring spinal anaesthesia were included in this study. Parturients with severe preeclampsia, eclampsia, history of substance abuse, infection at needle insertion site, or allergy to local anaesthetics and declined to participate were excluded from the study.

Sampling procedure

The recruited parturients were given spinal anaesthesia under strict aseptic technique and they were randomly allocated to: either the "Group B" or "Group C" by simple random sampling method (i.e. lottery method using leveled piece of paper) just after spinal anaesthesia given, by the investigator. Those who received II-IH nerve block with 0.25% bupivacaine were the "Group B" and those who received no block were "Group C". Immediately after skin closure Group B participants were received the nerve block by one of the investigator and then they transferred to the obstetric ward after the procedure.

Sample size determination

There was no documented study that shows the incidence of postoperative pain following CD under spinal anaesthesia in the study area. But from the previous studies abroad, the incidence of moderate to severe post caesarean pain without treatment is about 40% [1]. In the previous research the block showed 70% reduction immediate VAS score in postoperative period. Sample size was determined on the basis of pain severity scores (using NRS) of the "block group" and the "Control Group" as calculated from previous research, with the power of 80% and the level of significance=5%, (as I calculated online using <http://clincalc.com/stats/samplesize.aspx> and checked manually) the sample size N1 becomes 74 and by considering a potential drop rate of 10%, we took a total of 82 participants (Figure 1).



Major independent variables were sociodemographic (age, height, weight and body mass index), duration of surgery, hemodynamic variables (Heart rate, blood pressure), parity and number of previous caesarean delivery.

Operational definition

Verbal numerical rating scale: A pain assessment tool in which the number assigned from 0-10 to represent severity of pain.

0=no pain, 1-3=mild pain, 4-6=moderate pain, 7-10=severe pain.

Total opioid analgesic consumption: The amount of opioid analgesic drugs given for the patient in the first 24 h.

Non urgent caesarean delivery: A caesarean delivery in which, there are no maternal and fetal compromises existed, like fetal distress, cord prolapse, uterine rupture, obstructed labour Hypotension: If SBP <20% of the preoperative value.

Bradycardia: Defined as a heart rate less than 50 beats/min

Parity: Number of births she has given to a fetus with a gestational age of >24 weeks regardless of whether the child was born alive or was stillborn.

Nulliparous: Has not given birth previously.

Primiparous: Has given birth once.

Multiparous woman: Has given birth more than once.

Data collection procedures

All voluntary parturients who underwent non urgent caesarean delivery via Pfannenstiel incision under spinal anaesthesia were included in the study. All parturients were given cimetidine 200 mg IV and metoclopramide 10 mg 10-20 min before the operation according to the institution protocol and written informed consent was obtained just before anaesthesia given by the investigator. After obtaining written informed consent, standard monitoring like NIBP, pulseoximeter, electrocardiogram(ECG) were attached, while co-loading with 10-15 mg/kg of crystalloid, each patient received spinal anesthesia between L3-L4 level with 2-2.5 ml of 0.5% heavy

bupivacaine (according to the height of the patient) using 22-26-Gauge spinal needle. After the spinal needle withdrawn the patients were repositioned in supine position with slight elevation of the head for comfort and level of sensory block was assessed and tested using pinprick sensation at 5 min intervals by one of the investigators who were unaware of the group allocation. The maximum level of sensory block was the highest level of disappearance of pinprick sensation and operations were started when the spinal block with sensory level reaches at T4. Maternal blood pressure was measured every 1 min for the first 15 min and every 2-5 min throughout the procedure.

After the spinal anaesthesia given, the study population were randomly assigned into two groups by using lottery method, Group B: those who received ilioinguinal and iliohypogastric nerve block with 0.25% bupivacaine (Block group) and Group C: those who not received the block (control group). In the study group, the nerve block was performed by one of the investigator using the technique described by bell et al. [3] immediately after skin closure while they were screened with drape. In the control groups, the block was not performed. After the procedure all patient were transferred to the ward. All participants received diclofenac sodium 75 mg IM 8 hourly and the first dose was given at the end of operation. Patients and personnel who were involved in the data collection were not informed on the group type of patients.

Sociodemographic variables were filled by one of the investigator and the remaining postoperative outcome variables and hemodynamic variables were filled by the data collectors who were unaware of the group allocation. After the patient transferred to the ward, the data collectors were assessed the pain intensity within the given time interval using NRS. Assessment of the presence and intensity of pain was done immediately after transfer to the ward (0 h) and at 4 h, 6 h, 8 h, 12 h and 24 h after surgery both at rest and with movement (turning from side to side) by using verbally administered Numerical rating scale pain assessment tools.

At the same time the HR and BP were also assessed and the patients' opioid consumption was recorded. Each participant was treated for pain according to the pain management protocol. All data were coded by the investigator to identify patients on the questionnaire and the completed questionnaires were kept in a secured location.

Data quality management

Three anaesthetists and two midwives were trained on post-operative pain scoring using pain assessment tools, post-operative pain management protocol and data collection process.

Statistical analysis

Data were cleaned and checked for completeness before entered in to database by the Investigator. The data were entered to SPSS version 20.0 statistical package. Distribution of data was checked using Shapiro-Wilk normality test. Normally distributed demographic data were analyzed using independent student t-test. Not -normally distributed data were analyzed using Mann Whitney U test. Means was compared by using Student's t or Mann Whitney U test. Normally distributed data were presented as mean ± Standard deviation. Not-normally distributed data were presented as median (IQR). A p value less than 0.05 was considered as statistically significant.

Result

Sociodemographic characteristics of study participants

Eighty two participants were recruited in this study. Two patients were excluded from the study because of inadequate spinal anaesthesia leaving 80 participants, 39 in Group B and 41 in Group C. The two groups were not statistically different regarding demographic variables (Tables 1 and 2).

Demographic data	Group B(n=39)	Group C(n=41)	P-value
Age (year)	28.74 ± 5.59	27.85 ± 5.35	P=0.469
Weight (kg)	64.35 ± 6.36	64.21 ± 5.02	P=0.913
Height (cm)	158.23 ± 2.42	158.85 ± 2.90	P=0.302
BMI (kg/m)	25.46 ± 2.71	26.11 ± 1.96	P=0.219
Duration of surgery	60.3846 ± 10.02	62.4390 ± 9.56	P=0.351

Key: SD: Standard Deviation; sociodemographic and other data (Mean ± SD), p>0.05

Table 1: Sociodemographic and other data of each group of patients who underwent non emergent caesarean delivery at the University of Gondar Hospital, Northwest Ethiopia, 2016.

Data	Group B(n=39)	Group C(n=41)
Parity=n (%)		
Nulliparous	23 (59.0)	23 (56.1)
Primi parous	12 (30.8)	11 (26.8)
Multiparous	4 (10.3)	7 (17.1)
Number of previous CD=n (%)		
1	27 (69.2)	29 (70.7)
2	10 (25.6)	11 (26.8)
3	2 (5.1)	1 (2.4)

Key: Data are expressed as number and percentage (%)

Table 2: Data on parity and number of previous caesarean delivery.

There was normal distribution sociodemographic data as checked using Shapiro-Wilk Test and homogeneity of variance as assessed by Levene's Test for Equality of Variances. An independent t-test was run on the data with 95% CI for the mean comparison of age, weight, height, BMI and duration of surgery. The number of previous caesarean delivery and parity were comparable across the group (Table 2).

Hemodynamic parameters

According to independent sample t-test, in both groups, mean changes in SBP, DBP and h were not significantly different (P>0.05) (Tables 3-5).

Group	Mean SBP at various time intervals (mmHg)					
	Time	4 h	6 h	8 h	12 h	24 h
Group B	Mean ± SD	112.92 ± 11.31	114.89 ± 10.98	113.23 ± 11.54	113.35 ± 9.47	114.53 ± 8.39
Group C	Mean ± SD	115.02 ± 13.09	115.12 ± 10.09	113.02 ± 9.45	114.95 ± 9.71	114.19 ± 8.35

Key: mmHg: millimeter of mercury; Value are expressed using mean ± SD, P>0.05

Table 3: Mean systolic blood pressure (SBP) at various time intervals.

Group	Mean diastolic blood pressure at various time intervals (mmHg)					
	Time intervals	4 h	6 h	8 h	12 h	24 h
Group B	Mean ± SD	70.00 ± 8.14	70.49 ± 5.95	70.08 ± 6.37	70.33 ± 6.075	70.74 ± 5.91
Group C	Mean ± SD	70.70 ± 8.72	72.12 ± 7.66	69.20 ± 5.92	70.12 ± 7.08	71.51 ± 6.15

Key: mmHg: millimeter of mercury; Values are expressed using mean ± SD, P>0.05

Table 4: Mean diastolic pressure at various time interval.

Group	Mean HR at various time intervals(bpm)					
	Time	4 h	6 h	8 h	12 h	24 h
Group B	Mean ± SD	87.58 ± 7.48	86.82 ± 7.63	87.53 ± 7.47	87.56 ± 7.47	79.02 ± 4.96
Group C	Mean ± SD	86.24 ± 8.38	86.29 ± 8.53	86.00 ± 8.14	85.80 ± 8.01	80.43 ± 5.80

Key: Values are expressed using mean±SD P>0.05; bpm= beats per minute

Table 5: Mean heart rate (HR) at various time intervals.

Postoperative pain severity score using NRS

Since the numeric rating pain score was not normally distributed, Mann Whitney U test was used to test the NRS. The median pain score both at rest and movement is shown in (Tables 6 and 7). Pain severity scores were similar on arrival in the ward in both groups but were significantly decreased at 4 h, 6 h, 8 h, 12 h and 24 h in II-IH block group compared to a control group both at rest and on movement (P<0.001).

Time intervals	Median numeric rating scale at rest					
	0 h	4 h	6 h	8 h	12 h	24 h
Group B	0 (0)*	1 (1)**	2 (1)**	2 (1)**	2 (2)**	2 (1)**
Group C	0 (0)*	3 (2)**	4 (2)**	3 (1)**	4 (0)**	4 (0)**

Key: Data are expressed using median (IQR); **= statistically significant

Table 6: Postoperative pain severity using numeric rating scale at rest.

Time intervals	Median numeric rating scale on movement					
	0 h	4 h	6 h	8 h	12 h	24 h
Group B	0 (0)*	1 (1)**	2 (1)**	2 (1)**	2 (2)**	2 (1)**

Group C	0 (0)*	5 (3)**	6 (1)**	5 (2)**	6 (1)**	5 (1)**
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Key: Data are expressed using median(IQR); **= statistically significant

Table 7: Postoperative pain severity using numeric rating scale on movement.

Postoperative total tramadol consumption

Tramadol consumption was tasted using independent sample t-test. The mean tramadol use was significantly lower in the II-IH block than the control group at all time intervals throughout the study period (p<0.05) (Figure 2).

The mean total tramadol consumption over 24 h was reduced by more than 50% in II-IH block group compared to control group (71.157 ± 37.4 vs. 219.51 ± 39.73) mg in II-IH block group and control group respectively, (p<0.001) (Table 8).

Postoperative first opioid analgesics request time

The first opioid analgesics request time between the two groups was compared using Mann Whitney U test. Time of first opioid analgesia request was shorter in the control group than in II-IH block group. The median time elapsed before first opioid analgesia request was 4 h (IQR: 4-6 h) in control group and 12 h (IQR 6-24 h) in II-IH block group (P<0.001) (Table 8).

Observation	Group B	Group C	P value
Time elapsed before the first request of opioid analgesia (h)	12 (18)**	4 (2)**	P<0.0001
Total tramadol consumption in 24 h (mg)	71.153 ± 37.4*	219.51 ± 39.73*	P<0.0001

Key: IQR=interquartile range; Mean ± SD*; Median ± IQR**

Table 8: The time elapsed before the first request of opioid analgesia and total tramadol consumption.

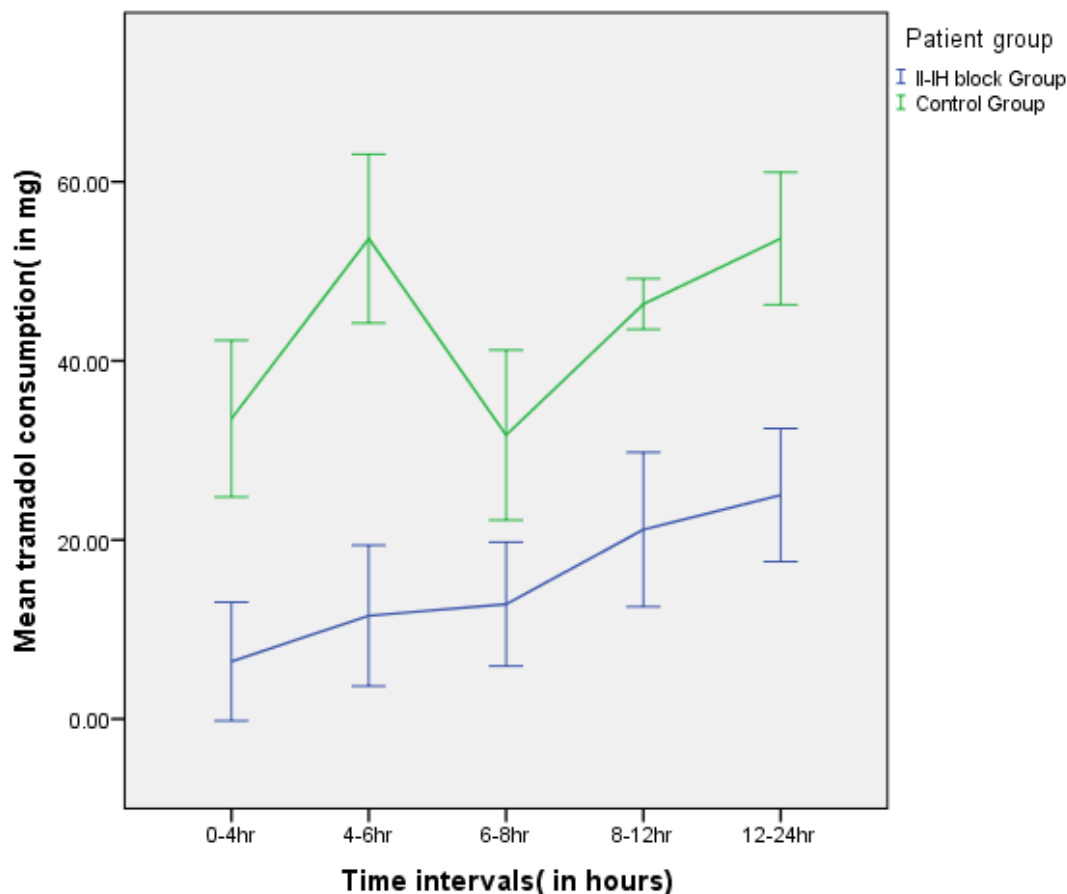


Figure 2: The line trend showed the mean tramadol consumption at estimated time interval between the block and the control group.

Discussion

This study depicted that ilioinguinal- iliohypogastric (II-IH) nerve block remarkably reduced postoperative pain and total tramadol consumption after caesarean delivery under spinal anaesthesia compared to no block group.

In this study, hemodynamic parameters such as heart rate, systolic and diastolic blood pressure were comparable between the two groups. We have found that II-IH nerve block with intramuscular diclofenac remarkably decreased the severity of pain both at rest and on movement, delayed postoperative first opioid analgesia request time and decreased total postoperative tramadol consumption during the first 24 h of operation in parturients underwent CD under spinal anaesthesia.

A previous study revealed a good analgesic effect of II-IH nerve block for parturients undergoing cesarean delivery under spinal [3,19,20] or general anaesthesia [2,12,21]. In our study, the pain was assessed using numeric rating scale and additional tramadol on request was given when the NRS ≥ 4 . The median NRS was low in the II-IH block group than the control group at all time intervals both at rest and on movement. The median NRS was found to be highly significant at all estimated time interval except at 0 h ($P<0.001$).

The NRS pain severity scores were similar between II-IH block group and the control group immediately after the patient transferred to the ward. This could attribute to prolonged analgesic effects of spinal anaesthesia. Even though, pain severity in the II-IH block group and the control group were different at 4hr and 8 hour at rest, it was not clinically significant. This finding was supported a study carried out by

Sakallı et al. the mean VAS was remarkably decreased in the intervention group than the control group at 6 h, 8 h, 12 h, 16 h and 24 h [2]. However, in their study, there was no difference in the mean VAS score at 0 h, 2 h. This could be due to the procedure was performed under GA and in fact the block may take time to produce analgesia.

Similarly, a study done in Jordan showed a significantly reduced mean VAS score by this nerve block using local anaesthetics when compared with placebo group in parturients underwent caesarean delivery under general anaesthesia [21]. Moreover, our finding was also consistent with a study conducted by Bunting et al. Bell et al. and Ganta et al., where the mean VAS score was low in those who received II-IH block compared with the placebo group in parturients underwent caesarean delivery [12,22]. In addition, in another study, VAS pain scores were decreased both at rest and upon coughing in block group compared to the placebo group [3]. These might be due to the use of the same dose of local anaesthetics and techniques employed.

However, a study conducted in USA, nerve block did not produce a significant reduction in pain after cesarean delivery under spinal anaesthesia with intrathecal morphine (ITM) compared to ITM alone [2] ($P > 0.05$). This could be due to neuraxial morphine produces analgesia by binding to opioid receptors in the dorsal horn of the spinal cord. In addition, unlike that of peripheral nerve blocks, subarachnoid morphine is effective in the treatment of both somatic and visceral pain. This finding was also in concordance with another study conducted in USA on 60 patients undergoing laparotomy under general anaesthesia [1].

This discrepancy could be due to the use of different nerve block techniques as they used single injection technique which may not be possible to block the nerve completely as there may be variation of nerve distribution among individuals. Moreover, multi-level injection technique has a success rate of greater than 90 percent as reported by Bell et al. [3]. In addition, the block was carried out by different people that could be affected by inter-person skill variability.

Moreover, the mean total opioid analgesics requirements in the first 24 h were significantly lower in treatment group (71.153 ± 37.4) than control group (219.51 ± 39.73) respectively ($P < 0.001$). This finding was in agreement with a study performed by Sakali et al., where the mean patient controlled analgesia tramadol consumption was decreased by 50% in the intervention group using local anaesthetics compared with the placebo group [2]. In their study, the mean PCA tramadol consumption in the innervation group was (331 ± 82 mg vs. 622 ± 107 mg) respectively. The difference in mean total opioid consumption compared with the current study, might be due to a difference in anaesthesia technique and analgesic administration technique. In the previous study, general anaesthesia and patient controlled analgesic administration technique were used whereas spinal anaesthesia and nurse/anaesthetist controlled analgesic administration techniques were used in the present study.

Similarly, Bell et al. also reported PCA morphine use was remarkably lower in the intervention group than the placebo group during the first 24 h postnatal period in patients underwent caesarean delivery under spinal anaesthesia [3]. Furthermore, our finding was comparable with trials conducted by Yucel E et al. and Naghshineh et al., where postoperative analgesics consumption was significantly lower in the nerve block group compared with the control group [23-25]. This might be because Pfannenstiel incision is principally

conducted by L1 and L2 dermatomes and depositing a local anaesthetic on the target nerves gives prolonged pain relief.

Moreover, a study conducted by Oriola et al. on 70 female patients undergoing gynaecologic surgery via suprapubic laparotomy under GA, revealed that total PCA morphine consumption in the intervention group was decreased by greater than 50% compared to the placebo group ($P < 0.001$) [26]. This finding was in agreement with our study which might be due to the use of the same nerve block technique and the incision site is principally conducted by these nerves.

Furthermore, Sakallı et al. reported that, there was a significantly reduced pain score and amount of PCA tramadol consumption by the ilioinguinal- iliohypogastric nerve block group during the 24 h following caesarean delivery when performed after wound closure ($P < 0.05$) [2]. In addition, Bell et al. found that pain score and PCA morphine use were significantly lower in the intervention group than the placebo group within 24 h of postnatal period when its performed after surgical intervention ($P < 0.05$) [3].

In this study, the median first analgesia request time was significantly delayed in the block group than the control group ($P < 0.0001$). This finding was in accordance with a study conducted by Yucel et al. that in II-IH block group, the first analgesia request time was longer than the counter parts [27]. This finding was also similar with a study conducted by Wolfson et al. that the mean time to first analgesics request were significantly prolonged in the block group than the control group ($P < 0.01$) [3]. This might be because of the prolonged effect of nerve block.

Anatomic landmark technique was employed for nerve block in the current study. It is believed that ultrasound guidance could improve the certainty and safety of the block by confirming the position of the needle. However, the merits of landmark technique using “double pop” method regarding safety and certainty have been reported [2,3,12,27]. However; ultrasound guidance for regional anaesthesia has not been decisively established to improve safety [28,29].

Limitations of the study

The ilioinguinal and iliohypogastric nerve block produces sensory analgesia of the lower abdominal wall. We avoided testing for sensory loss for blinding issue though it could help to confirm whether the block is successful or not. In addition, most scholars used patient controlled morphine for postoperative pain management. However, we used nurse/anaesthetist controlled analgesia technique as morphine and patient controlled analgesia pumps were not available our hospital during the study period.

Conclusion and Recommendation

Compared to no intervention, bilateral II-IH blocks in patients undergoing caesarean delivery with Pfannenstiel incision had significantly improved pain relief at rest and with movement and resulted in significantly less tramadol consumption in the first 24 h after surgery. These results support the use of bilateral II-IH blocks as part of a multimodal analgesic regimen.

Conflict of Interest

The authors declare no conflict of interest.

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