



Research Article

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**Transversus Abdominis Plane Block versus Wound Infiltration
for Analgesia after Cesarean Delivery: A Randomized Controlled
Double-Blinded Clinical Trial**

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Abstract

Background: Adequate pain control after cesarean delivery is a significant concern both for parturients and obstetric anesthesiologists. Transversus Abdominis Plane (TAP) block and local Wound infiltration with anesthetics are alternatives for reducing the severity of pain, total analgesic consumption, and opioid side effects. Both the TAP block and wound infiltration are superior to placebo; however, it is unknown which provides better analgesia after cesarean delivery because of a scarcity of randomized clinical trials. So, we hypothesized that the TAP block would decrease postoperative pain and postoperative cumulative opioid consumption at 24 hours.

Objective: To compare analgesic effectiveness of Transversus Abdominis Plane block (TAP) versus Wound site Infiltration (WI) after cesarean delivery under spinal anesthesia.

Patients and Methods: The process of US-guided TAP block or local wound infiltration was explained to all patients, and they were taught how to use the visual analog scale (VAS). After receiving approval from the medical ethical council, the study was done on 198 randomly selected patients aged 19 to 40 years old in hospital's university. They were divided into three groups.

Results: Compared to patients with wound infiltration, patients with TAP block had significantly lower pain scores for 12-16 hours following surgery and had lower total demand for analgesia in the first 24 hours after surgery.

Conclusion: Compared to local wound infiltration, bilateral TAP block effectively reduced postoperative pain and total 24-hour postoperative opioid and analgesic consumption after Cesarean section under spinal anesthesia.

Key words: TAP; transversus abdominis plane. VAS; visual analogue score; wound infiltration; cesarean section; postoperative pain; analgesia

Introduction

Since its relationship with improved fetal prognosis was revealed, the Cesarean section rate has steadily increased (Nasir, Sohail, Sadiq, & Habib, 2019). Around 15 percent to 20 percent of deliveries worldwide are Cesarean sections, and the rate is significantly higher in developing nations, where it is estimated to be around 40%. (Nasir et al., 2019). Postoperative pain is one of the most avoidable complications of the surgery. It is caused by the body's physiological response to tissue injury at the surgical site (Disceken & Kose, 2021). According to a poll conducted in the United States in 2003, there is a 70% likelihood that a patient may have significant pain following surgery (Nirgianakis et al., 2021). Effective postoperative pain management is critical since it has been linked to patient recovery, hospital stay

length, stress response, pneumonia, deep vein thrombosis, poor wound healing, persistent pain, and depression (Nasir et al., 2019). Multimodal analgesia, or a combination of medications for pain treatment with fewer side effects, is now commonplace (Richeb , Brulotte, & Raft, 2019). Opioids are the first-line medicines for reducing postoperative pain after Cesarean sections and are given either intravenously (IV) or intrathecally (IT) prior to surgery (Peene, Le Cacheux, Sauter, Joshi, & Beloeil, 2021). However, their use has been linked to postoperative problems such as respiratory depression, urine retention, pruritis, ileus, nausea, and vomiting. Non-opioid systemic analgesics, on the other hand, have proven ineffective in treating pain, and alternative approaches, such as epidural analgesia, necessitate constant monitoring and surveillance (Nasir et al., 2019). Preventive analgesia, which involves intraoperative or postoperative analgesic intervention, has just been introduced and has the potential to reduce postoperative pain and drug use (Yeung, Irwin, & Cheung, 2021). Transverses-abdominis plane block, IV, and local anesthetic infusion are some options (Tsai et al., 2017). TAP block is a localized anesthetic treatment that inhibits T6-L1 nerve roots and can give analgesia for the lower abdomen procedures. It can be done under ultrasonography (US) guidance or anatomic landmarks (Wahlen & De Gasperi, 2021). Because of its simplicity, safety, and cost-effectiveness, wound infiltration with local anesthetics is becoming more common in clinical practice (Stamenkovic et al., 2021). we hypothesized that the TAP block would decrease postoperative pain and postoperative cumulative opioid consumption at 24 hours.

Patients and Methods

A prospective double-blinded randomized comparative controlled clinical trial enrolled 198 women undergoing cesarean section under spinal anesthesia who attended Maternity Hospital, Cairo, Egypt, from January 2021 to June 2021. The study protocol was approved by Ethical Research Committee. All women were advised about the study and possible consequences and written informed consent was obtained. Two hundred and fifty-one women were checked to guarantee that they fulfilled the study's inclusion criteria. Inclusion criteria involved (1) Women who underwent cesarean section under spinal anesthesia. (2) Aged ≥ 19 years and >40 years. (3) Gestational age ≥ 37 Weeks. Exclusion criteria included (1) Body mass index (BMI) ≥ 40 kg/m². (2) History of recent opioid exposure. (3) Hypersensitivity to any of the drugs used in the study. (4) Significant cardiovascular, renal, or hepatic disease. The study subjects were randomly assigned to 3 equal groups, the first group (TAP group), the second group (infiltration), and the third group (control group), using a computer-generated table of random numbers. A single investigator (author) assessed the patients for eligibility, obtained written informed consent, and recorded the baseline data for each participant before delivery. The primary investigator opened sequentially numbered, sealed opaque envelopes containing group allocation after administering spinal anesthesia and achieving an upper sensory level of T6 or higher. The study group was unknown to neither the study subjects nor the outcome assessors. All participants underwent uneventful lower segment cesarean section by an obstetrician with three years of experience. The Anesthesiologist, who

had at least three years of experience in ultrasound-guided TAP block, performed the TAP block procedure after the skin closure when the patients were still lying on the operating table. The operating obstetrician performed the local anesthetic wound infiltration. An anesthesiology resident who was not involved in the study administered the spinal anesthetic, recorded intraoperative data (the upper sensory level at 30 minutes and surgery duration), and prepared the local anesthetic solution for the TAP block and wound infiltration as instructed by the primary investigator. The outcome data (opioid consumption, time to the first opioid dose, pain scores, side effects) was recorded by a blind investigator who visited the patient in the ward at 2, 4, 6, 12, and 24 hours postoperatively. No premedication was administered. Standard monitors (noninvasive blood pressure, electrocardiography, and pulse oximetry) were applied, and spinal anesthesia was administered in the sitting position at the L3-L4 or L4-L5 interspaces using a 27-gauge or 25-gauge spinal needle; 12.5 mg of hyperbaric bupivacaine (2.5 mL 0.5%) (sunnybupivacaine®, sunny pharmaceutical pharmacy) and 15 µg of fentanyl (fentanyl®, sunny pharmaceutical pharmacy) was administered intrathecally. Surgery was started after attaining an upper sensory level of T6 or higher, tests with a pinprick. After 20 minutes, if the upper sensory level was below T6, the spinal was declared a failure, and the patient was removed from the trial. After surgery, a 12–4-MHz linear array transducer (ClearVue 350; Philips) was placed transversely between the iliac crest and costal margin in the anterior axillary line and slid medial-lateral to visualize the external oblique, internal oblique, and trans-versus abdominis muscles; the most lateral (posterior) position obtaining a satisfactory ultrasound image was used in the TAP group (Group A). A 22-gauge spinal needle was introduced from medial to lateral in-plane to the ultrasound probe, and 20 mL of bupivacaine 0.25% was injected under visualization in the plane between the transversus abdominis muscle and the fascia deep to the internal oblique muscle on each side. In the infiltration group (Group B), at the end of the surgery, 40 mL of bupivacaine 0.25% was injected subcutaneously into the surgical wound (20 mL on each of the upper and lower sides) by the obstetrician before skin closure. In the control group (Group C), routine analgesia was administered (NSAIDs (ketorolin ®, PHARO PHARMA) 1 amp (30 mg/2ml) every 6 to 8 hours according to the protocol used in Maternity Hospital and added 50 mg pethidine IM on demand) and recorded. Duration of surgery (time from the start of skin incision to the end of skin closure) was recorded. At 2, 4, 6, 12, and 24 hours postoperatively, the severity of pain at rest and on movement (hip flexion and coughing) was assessed using a visual analog scale (VAS) score (0 = no pain and 10 = the worst possible pain). Cumulative opioid consumption was recorded (50 mg pethidine IM on demand). The occurrence of nausea and vomiting was also recorded. The primary outcome was the degree of pain at rest and on movement (hip flexion and coughing) at 2, 4, 6, 12, and 24 hours postoperatively, using a visual analog scale (VAS) score for pain intensity reported on 0–10-point scale for analysis. (0 = no pain and 10 = the worst possible pain). Furthermore, the Secondary outcome measures the time to the first postoperative opioid dose, cumulative opioid consumption at 2, 4, 6, and 12 hours. And The incidence of side effects (nausea, vomiting, and pruritis). Opioid intake, time to first opioid dose, pain scores, and side effects).

Sample size: Sample size calculation was done using the mean time to the first postoperative analgesia request after CS under spinal anesthesia with TAP block and local anesthetic wound infiltration group. As reported in a previous publication (Aydogmus et al., 2014), the mean time to first postoperative analgesia request after CS under spinal anesthesia with TAP block was approximately 6.11 ±6.2 hours (mean±SD). At the same time, with the LAWI group, it was approximately 2.63±1.83 hours (mean±SD). Accordingly, we calculated that the minimum proper sample size was 28 participants in each group to be able to reject the null hypothesis with 80% power at $\alpha = 0.05$ level using a t-test for independent samples. Our study divided the sample size into three equal groups with 66 patients in each group, group A (TAP block group), group B (LAWI group), and group C (control group). Sample size calculation was done using MedCalc® Statistical Software version 19.5.3 (MedCalc Software Ltd, Ostend, Belgium; <https://www.medcalc.org>; 2020).

Data were analyzed by using SPSS version 26.0 (IBM Corp., Armonk, NY USA). Continuous data were tested for normality using Kolmogorov–Smirnov test. Normally distributed, non-normally distributed, and categorical data are presented as mean ± SD, median (range), and number (percentage), respectively. The normally distributed outcome data (the cumulative fentanyl consumption at 24 hours) in 3 groups were compared using the ANOVA test. The non-normally distributed outcome data (pain scores at rest and on movement at 2, 4, 6, 12, and 24 hours) were compared using the ANOVA test; Bonferroni correction was used for multiple testing. The categorical outcome data (the incidence of nausea/vomiting and pruritis and need to opioid dose) were compared using Chi square test and the Fisher exact test. The data for the time to the first fentanyl dose were analyzed using the Kaplan–Meier analysis and compared using the log-rank test. A 2-tailed P value of <.05 was considered statistically significant.

Results

In total, 251 women were assessed for inclusion in the study. Of these, 53 women were excluded because they had one or more exclusion criteria. Thus, 198 women were randomized to the TAP group (n = 66), infiltration group (n = 66) and the control group (n=66) (Fig 1). There were no differences in baseline demographic characteristics between the three groups (Table 1). Patients' pain perception was highest in the control group, followed by the infiltration group, and least in the TAP group. The differences were statistically significant between different groups at all follow-up times (Table 2, Fig 2). Table 3 showed Need for opioid dose was most frequent in the control group, followed by the infiltration group, and the least frequent in the TAP group. The differences were statistically significant between different groups. The first opioid dose was the shortest time in the control group, followed by the infiltration group, and the longest in the TAP group. The differences were statistically significant between different groups (Table 4). Kaplan-Meier curve for opioid use among the studied groups showed that the rate of opioid use was highest in the control group, followed by the infiltration group, and lowest in the TAP group. The differences were statistically significant between different groups (Fig 3). Table (5) showed that the

Cumulative 24-hours opioid dose was the largest in the control group, followed by the infiltration group, and the smallest in the TAP group. The differences were statistically significant between different groups. Nausea and vomiting were most frequent in the control group, followed by the infiltration group, and least frequent in the TAP group. The differences were statistically significant between different groups—no significant differences between the studied groups regarding pruritus (Table 6).

Variables	Measures	TAB (N=66)	Infiltration (N=66)	control (N=66)	p- value
Age (years)	Mean±SD	29.2±5.7	29.5±5.5	28.6±5.4	^0.635
	Range	17.0–40.0	18.0–40.0	17.0–38.0	
BMI (kg/m²)	Mean±SD	28.4±2.2	28.7±1.7	28.7±1.7	^0.560
	Range	23.1–33.5	24.5–34.4	24.2–32.7	
Parity	Nulli	14 (20.9%)	9 (13.8%)	13 (19.7%)	#0.534
	Multi	53 (79.1%)	56 (86.2%)	53 (80.3%)	
Gestational age (weeks)	Mean±SD	37.8±0.8	37.8±1.0	37.7±0.8	^0.783
	Range	37.0–40.0	36.0–41.0	37.0–40.0	
Operation duration (minutes)	Mean±SD	68.1±7.0	68.0±6.6	68.2±6.7	^0.990
	Range	55.0–85.0	52.0–81.0	52.0–88.0	

^ANOVA test. #Chi square test.

Table 1: Baseline characteristics of the studied groups

Time	Measures	TAP (N=66)	Infiltratio n (N=66)	control (N=66)	^P-value
Hour-2	Mean±SD	2.3±0.7	2.7±0.5	3.6±1.1	<0.001*
	Range	1.0–3.0	2.0–3.0	2.0–6.0	
Hour-4	Mean±SD	2.6±0.6	3.5±0.8	4.3±1.0	<0.001*
	Range	2.0–4.0	3.0–6.0	3.0–6.0	
Hour-6	Mean±SD	3.1±0.3	4.0±1.0	4.6±0.9	<0.001*
	Range	3.0–4.0	3.0–6.0	3.0–6.0	
Hour-12	Mean±SD	3.9±0.6	4.5±0.7	4.9±0.8	<0.001*
	Range	3.0–6.0	4.0–6.0	4.0–6.0	
Hour-24	Mean±SD	4.5±0.7	4.8±0.5	5.1±0.4	<0.001*
	Range	3.0–6.0	4.0–6.0	4.0–6.0	

^ ANOVA test with post hoc Bonferroni test. *Significant

Table 2: Patients' pain perception (VAS-10) among the studied groups

Findings	TAP (N=66)	Infiltration (N=66)	control (N=66)	#p-value
Needed	6 (9.0%)	30 (45.45%)	55 (83.3%)	<0.001*
Not needed	60 (91.0%)	36 (54.55%)	11 (16.7%)	

#Chi square test with post hoc Bonferroni test. *Significant

Table 3: Need to opioid dose among the studied groups

Measures	TAP (N=6)	Infiltration (N=30)	control (N=55)	^p-value
Mean±SD	16.0±6.2	11.8±6.8	3.7±1.4	<0.001*
Range	12.0–24.0	6.0–24.0	2.0–6.0	

^ANOVA test with post hoc Bonferroni test. *Significant.

Table 4: Time of first opioid dose (hours) among the studied groups

Measures	TAP (N=6)	Infiltration (N=30)	control (N=55)	^p-value
Mean±SD	41.7±12.9	67.5±25.6	107.3±27.1	<0.001*
Range	25.0–50.0	25.0–100.0	50.0–150.0	

^ANOVA test with post hoc Bonferroni test *Significant

Table (5): Cumulative 24-hours opioid dose (mg) among the studied groups

Side effects	TAP (N=66)	Infiltration (N=66)	Control (N=66)	p-value
Nausea	2 (3.0%)	10 (15.15%)	24 (36.4%)	#<0.001*
Vomiting	0 (0.0%)	6 (9.1%)	17 (25.8%)	#<0.001*
Pruritus	1 (1.5%)	0 (0.0%)	1 (1.5%)	§0.999

#Chi square test with post hoc Bonferroni test. §Fisher's Exact test. *Significant

Table 6: Maternal side effects among the studied groups

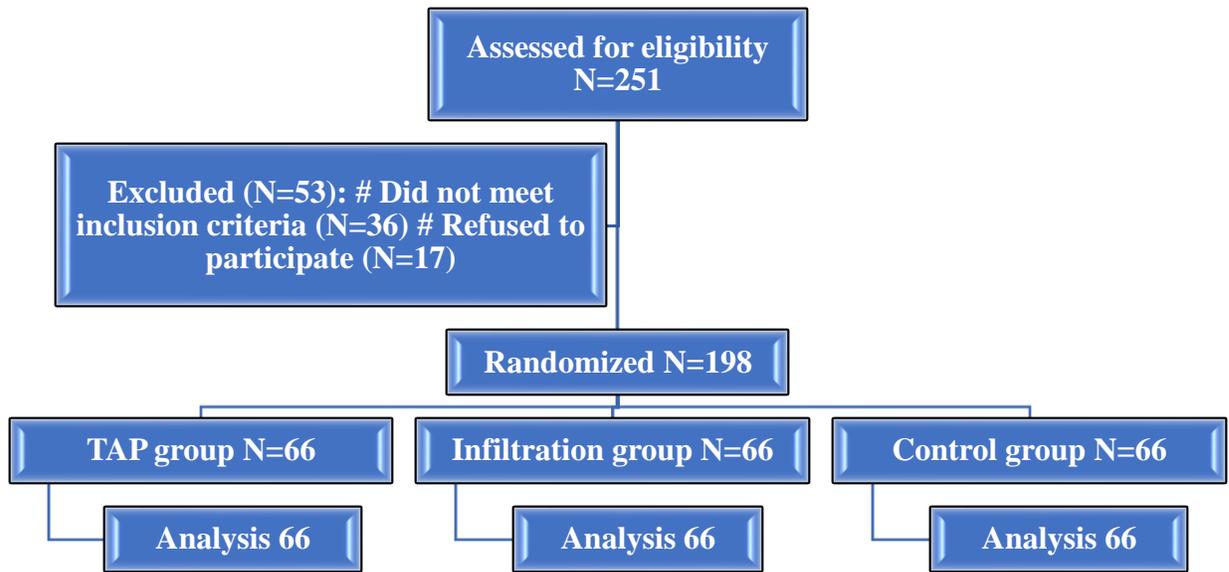


Figure 1: Flow chart of the studied cases

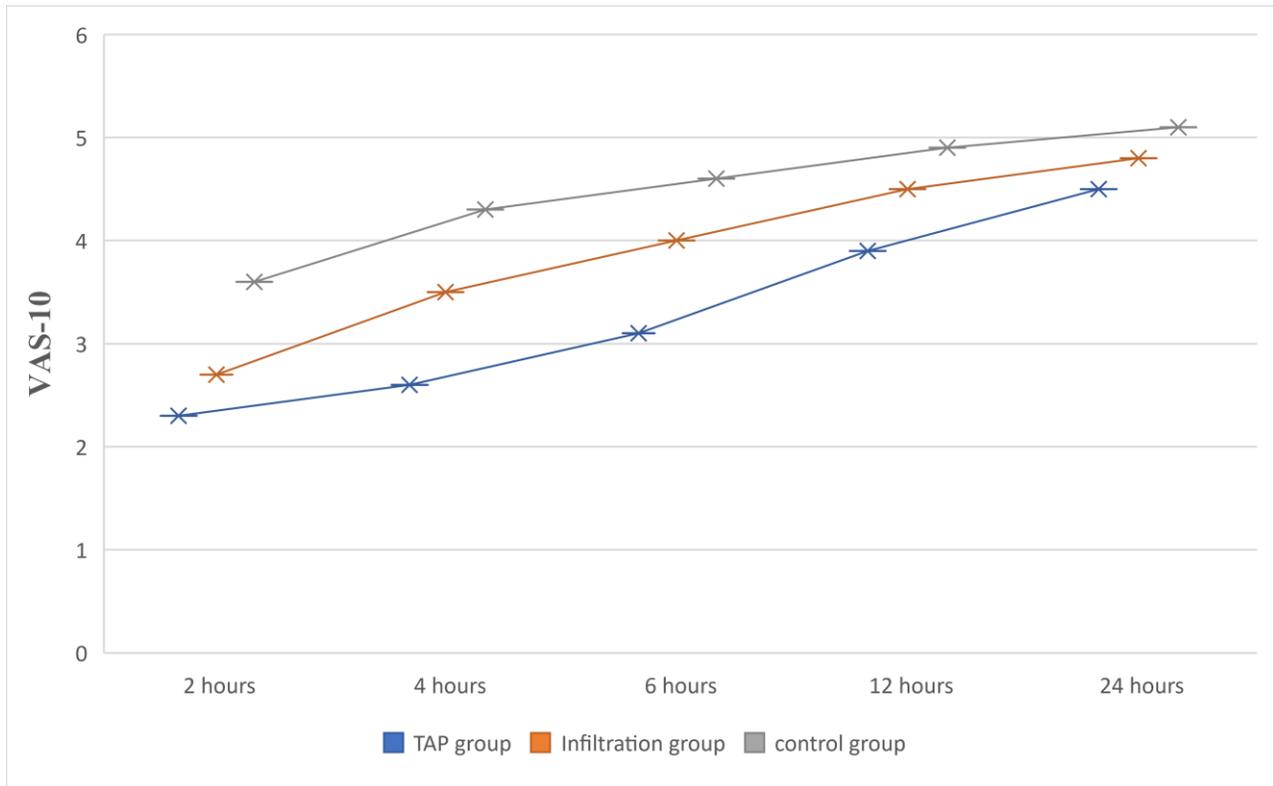


Figure 2: Patients' pain perception (VAS-10) among the studied groups

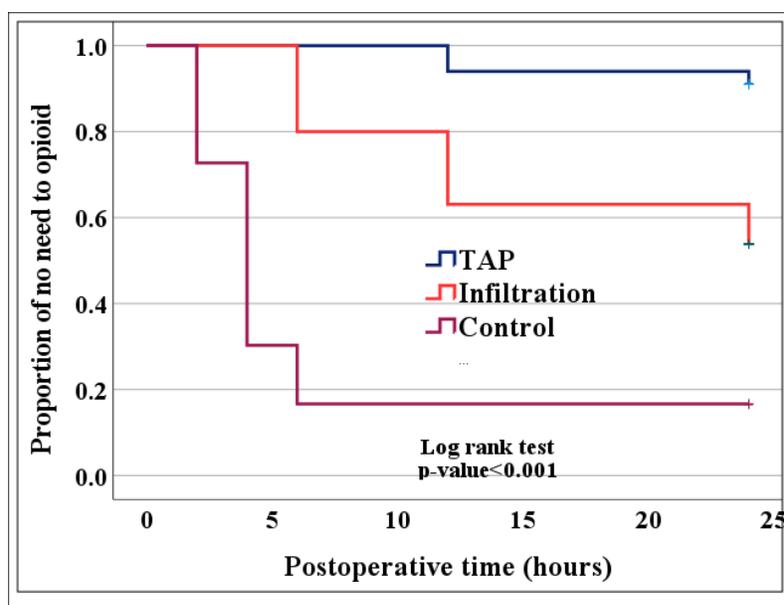


Figure 3: Kaplan-Meier curve for opioid use among the studied groups

Discussion

This double-blind, randomized comparative-controlled trial to compare bilateral ultrasound-guided TAP block to single-shot local anesthetic wound infiltration and control group for analgesia after cesarean delivery performed under spinal anesthesia demonstrated a highly significant difference in cumulative opioid consumption at 24 hours, the time to the first postoperative opioid dose, need to opioid dose and Patients' pain perception in parturients receiving bilateral TAP block or subcutaneous wound infiltration and routine analgesia after cesarean delivery performed under spinal anesthesia. The incidence of side effects (nausea and vomiting and pruritis) was most frequent in the control group, followed by the infiltration group, and least frequent in the TAP group. The differences were statistically significant between different groups—no significant differences between the studied groups regarding pruritus. In line with our findings, prospective cohort studies conducted on 60 and 62 patients showed that TAP block had reduced opioid consumption compared to wound infiltration during the first 24 h after cesarean section (P value < 0.001) (Alemnew & Lemma, 2020; Wayu, Germa, Shitemaw, & Dendir, 2018). A randomized control trial reported the lower cumulative total diclofenac consumption in the TAP group compared with local infiltration (local infiltration 162.5 ± 34.585 vs. TAP: 107.5 ± 37.800) ($p < 0.001$) (Das, Shukla, Singh, & Yadav, 2018). Two systematic reviews and meta-analyses support our findings and demonstrate that the TAP block reduced the mean 24 h morphine consumption as postoperative analgesia after Cesarean delivery performed under spinal anesthesia (Abdallah, Halpern, & Margarido, 2012; Johns et al., 2012). Contrary to our findings, randomized trials on 60 and 78 patients within the first 48 and 24 h of the postoperative period found no difference in cumulative consumption of fentanyl

and morphine between TAP block and wound infiltration during the first 48 h after cesarean section (Tawfik et al., 2017; Telnes, Skogvoll, & Lonnee, 2015). The difference may come from the use of patient-controlled analgesia in the previous study. Our finding showed that a prolonged time to the first analgesic requirement in the TAP group compared to wound infiltration and control group with mean \pm SD (TAP 16.0 \pm 6.2 hours vs. WI 11.8 \pm 6.8 Vs. control 3.7 \pm 1.4) ($P < 0.001$). A prospective cohort and randomized trial studies agreed with our finding and reported a prolonged time to first analgesia request in the TAP block group compared to wound infiltration (Alemnew & Lemma, 2020; Aydogmus et al., 2014; Das et al., 2018). A randomized control trial on 60 patients used 20 ml of 0.25% bupivacaine with adrenaline 5 mg/ml for both groups and found a comparable time to the first analgesic requirement (64 min wound infiltration group and 46 min in the TAP block group ($P=0.74$) during the first 48 h after operation (Telnes et al., 2015). This difference may be due to the addition of adrenaline in the previous study, which results from poor absorption of local anesthetics into the systemic circulation and patient-controlled analgesia technique. The current study showed that Patients' pain perception was highest in the control group, followed by the infiltration group, and least in the TAP group. The differences were statistically significant between different groups at all follow-up times. Subsequently, the needed opioid dose was most frequent in the control group, followed by the infiltration group, and least frequent in the TAP group. The differences were statistically significant between different groups. A randomized trial study on 78 patients during the first 24 h after cesarean section did not agree with our findings in that there was no significant difference in pain score between groups at 1, 3, and 6 h ($P > 0.05$). At the same time, there is a lower pain score in the TAP group at 12 h after surgery (TAP =6.80 \pm 2.0 and WI group =8.92 \pm 1.256 ($p \leq 0.001$) (Tawfik et al., 2017). A prospective cohort study on 62 patients after cesarean section within the first hours of the postoperative period found a significant difference in pain scores between groups at 6, 12, and 24 postoperative hours ($P \leq 0.005, 0.002, \text{ and } 0.001$, respectively (Alemnew & Lemma, 2020). Randomized control trials during the first 24 h after operation showed a reduced pain score in the TAP group at 2, 6, 12, and 24 postoperative hours ($p < 0.0001$) when compared to wound infiltration ($P < 0.001$) (Das et al., 2018; Pratheeba et al., 2018) and these results are similar with our study. Meta-analysis of four randomized trials showed that patients in the TAP-block group had lower pain scores for 24 postoperative hours both at rest ($p < 0.01$) and during movement ($p < 0.01$) compared to the wound infiltration (Yu et al., 2014). A controlled trial on 78 patients during the first 24 h of operation showed pain severity based on the numerical rating scale for 24 post-cesarean section hours were not different between the TAP block and wound infiltration group (Tawfik et al., 2017); findings are not in agreement with our study. Nevertheless, A RCT by Sivapurapu et al. on the Comparison of analgesic efficacy of TAP block with direct infiltration of local anesthetic into a surgical incision in lower abdominal gynecological surgeries resulted in TAP, and the time to rescue analgesic was significantly more ($P= 0.001$). The 24 h morphine consumption was less in the TAP block with a P-value of 0.001 (Sivapurapu, Vasudevan, Gupta, & Badhe, 2013) Contrary to our finding, a randomized control trial on 60 patients after total abdominal hysterectomy found a significantly lower pain score at rest and with

coughing in the wound site infiltration group at 2, 6, 12, 24, and 48 h post operatively ($p < 0.0001$) (Gasanova et al., 2015). The discrepancy may be due to liposomal bupivacaine, which has a prolonged effect on the infiltration group. Contrary to our result, A RCT by Klasen et al. on Postoperative analgesia after cesarean section with TAP or continuous infiltration wound catheter show no differences between the groups regarding pain and side effects and satisfaction scores (Klasen et al., 2016).

Conclusion

Finally, our study demonstrated that TAP block is more effective than WI for postoperative pain control and total 24-hour postoperative opioid and analgesic consumption in mothers who have had cesarean delivery under spinal anesthesia. It provided longer-lasting and more efficient analgesia.

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