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The efficacy of ultrasound guided transversus abdominis plane (TAP) block *vs.* local wound infiltration for post-operative analgesia after cesarean section under general anesthesia: A randomized controlled double-blinded clinical trial

Haitham A. Sabaa[1], Ayman A. Abo Elnor[1], Mohamed A. Abdelnaiem[2], Rana Moheb Soliman Ahmed[1]*, and Salma A. Nassar[1]
[1]Department of Obstetrics and Gynecology, Faculty of Medicine, Ain Shams University, Cairo, Egypt
[2]Department of Anesthesia, Intensive Care and Pain Management, Ain Shams University, Cairo, Egypt

AUTHORS' CONTRIBUTION: (A) Study Design · **(B)** Data Collection . **(C)** Statistical Analysis · **(D)** Data Interpretation · **(E)** Manuscript Preparation · **(F)** Literature Search · **(G)** No Fund Collection

SUMMARY

Aim: Cesarean Section (CS) sometimes causes post-surgical pain, which prevents early discharge and breastfeeding. We here compared analgesic effectiveness of bilateral US guided Transversus Abdominis Plane block (TAP) vs. single-shot local anesthetic Wound Site Infiltration (WI) after CS under general anesthesia.

Patients and methods: The present randomized controlled trial was conducted at Ain Shams University hospitals from January to June 2021 on 195 cases. Patients were divided into 3 groups (65 in each): TAP group, infiltration group, and control group.

Results: Demographic characteristics did not differ between the three. In the following outcomes, TAP was most favorable, followed by WI, and worst in control group. In almost all these, significance was observed. 1) Postoperative patients' pain perception (at hours 1, 2, 4, 6, 12 and 24); 2) Patient satisfaction; 3) Time/rate to/of first rescue analgesia; 4) Total NSAID dose; 5) Time/rate to/of first opioid dose; 6) The onset of mobilization; 7) Postoperative nausea and vomiting. Postoperative pruritis were not observed in all.

Conclusion: TAP block provided better pain relief, less analgesic requirement, and early mobilization than local wound infiltration after CS under general anesthesia.

Keywords: TAP block; Ultrasound; Wound infiltration; Analgesia cesarean section; General anesthesia

Address for correspondence:

Dr. Rana Moheb Soliman Ahmed,
Department of Obstetrics and Gynecology, Faculty of Medicine,
Ain Shams University, Cairo, Egypt
E-mail: rana1990mheb@gmail.com

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INTRODUCTION

Pain has both sensory and emotional components that interact to produce an overall pain experience. According to International Association for Study of Pain (IASP) pain is defined as unpleasant emotional and sensory experience due to actual or potential tissue damage or described in terms of such damage [1].

Inability to control postoperative pain after Cesarean delivery (CD) can negatively affect ambulation, breastfeeding, and maternal bonding. Substantial pain is anticipated after cesarean delivery; therefore analgesic regimen should ensure effective and safe analgesia [2].

Specific benefits of minimizing opioid use may include the reduction of nausea and vomiting, ileus, urinary retention and hyperalgesia. So other techniques are needed to replace or reduce opioid and thus reducing their side effects [3].

There are numerous means of providing postoperative pain relief as part of multimodal analgesia. This includes intravenous or oral medications, epidural analgesia, wound infiltration or peripheral nerve blockade like TAP block [4].

Transversus Abdominis Plane block first described in 2001, a blind "double pop" Technique by which the needle passes the external oblique and internal oblique muscles used in clinical practice. The subcostal nerves that branch at the level of the mid-axillary line are blocked prior to their branching anteriorly and superficially to supply the abdominal wall. This has been shown to be an effective analgesic adjunct for lower abdominal surgeries [5,6].

Wound infiltration with local anesthetics has been investigated as a potentially useful and easy method in reducing the consumption of opioids and decrease opioid-related side-effects this is a part of multimodal analgesic approach this simple safe, low invasion and low cost technique commonly performed by surgeon [7,8].

Wound site infiltration and TAP block have opioid sparing analgesics effects but their relative efficacy is not well established.

The aim of this study is to compare the effectiveness of bilateral US guided TAP block *vs.* wound site infiltration for cesarean delivery under general anesthesia [9].

Aim of the work

The aim of the study is to compare analgesic effectiveness of bilateral US guided Transversus Abdominis Plane block (TAP) *vs.* single-shot local anesthetic Wound site Infiltration (WI) after cesarean delivery under general anesthesia.

PATIENTS AND METHODS

After ethical committee approval and informed consent from the patients, the present randomized controlled trial was conducted at Ain Shams University hospitals during the period from January to June 2021 on 195 cases with 3 groups 65 in each group TAP group, infiltration group and control group.

Study population

Inclusion criteria:

- Patients undergoing elective cesarean section under general anesthesia
- Pfannenstiel skin incision
- Age between ≥ 18 and ≤ 40 years old
- BMI between 18 and 35 kg/m^2

Exclusion criteria:

- Patient refusal
- BMI <18 kg/m^2 or >35 (require different dose of analgesia)
- Height <150 or >180 cm (require different dose of analgesia)
- Patients with any neurological deficit due to neuropathy and pain score affection
- Patients with bleeding disorders which may lead to hematoma
- HTN (Vasculopathy which can lead to hematoma)
- Cardiac disease (Vasculopathy on anticoagulant which can lead to hematoma)
- DM (decrease systemic and local immunity which can lead to abscess at injection site and due to neuropathy and pain score affection)
- Liver disease (defective clotting factors)
- A history of relevant drug allergy or hypersensitivity to any of the drugs used in the study due to impair of proper follow up of pain postoperative
- History of recent opioid exposure due to affection on pain score
- Local skin infection due to abscess formation
- Obstetric complications e.g. placenta previa and rupture uterus due to extensive tissue damage and dissection

Randomization and allocation concealment

The study subjects were randomly assigned to 3 equal groups TAP group, infiltration group and control group using a computer-generated table of random numbers. A single investigator assessed the patients for eligibility, obtained written informed consent, and records the baseline data for each participant before delivery. Sequentially numbered, sealed opaque envelopes containing group allocation will be opened by the primary investigator after administration of general anesthesia. Neither the study subjects nor the outcome assessors knew the study group.

Ethical considerations

The study will be performed after approval of Research ethical committee, Faculty of medicine, Ain shams university and written informed consent from the patient. The study protocol will be explained to the patients after taking their consent to the type of anesthesia and surgical procedure.

Study tools

Spinal needle 22 g with injection lines.

Portable Ultrasound unit, Mindray DP-20linear probe (high frequency 10-12 MHz).

Study procedure

The Anaesthesilogist is senior staff trained on such procedure.

Pre-operative settingsl

- The study subjects will randomly assigned to 3 equal groups (TAP group, infiltration group and narcotics only group) using a computer-generated table of random numbers. A single investigator will assess the patients for eligibility, obtained written informed consent, and record the baseline data for each participant before delivery. Sequentially numbered, sealed opaque envelopes containing group allocation will be opened by the primary investigator after administration of general anesthesia. Neither the study subjects nor the outcome assessors knew the study group.
- Routine preoperative investigations will be done to all patients including laboratory investigations as (complete blood picture, liver function tests, prothrombin time and partial thromboplastin time).
- Demographic data as age, weight, will be recorded.

All mothers who scheduled for elective cesarean delivery who fulfilled inclusion criteria and volunteer are assessed by:

- Postoperative pain by visual analogue Scale (VAS)

pain score on arrival in the post-labor ward at 1, 2, 4, 6, 12, and 24 hours postoperatively.

- The duration of block (defined as the interval between performing the block and the time of the first request for analgesia) and total pethidine consumption were recorded in the 24 hours after surgery.
- The level of patient satisfaction was measured numerically by a Likert scale ranging from one to five, 1: "not satisfied at all" 2: "slightly satisfied" 3: "moderately satisfied" 4: "very satisfied" and 5: "highly satisfied". Any adverse effects or complications will be recorded.
- Wide bore venous access will be secured by 18 G intravenous canula.
- The procedure is done in the operating rooms (OR) under complete aseptic technique with prophylactic antibiotics (e.g. 2 gm ceftriaxone).

Intra-operative settings:

- The patient will be monitored during the procedure using pulse oximetry, non-invasive blood pressure & ECG and capnography.
- Patients receive General anesthesia induction by propofol (2 mg/kg), Rocuronium(0.5 mg/kg) for rapid sequence intubation& Fentanyl (1 mcg/kg).
- Maintenance with rocuronium & isoflurane 1.2%.

Equipment's that will be used for each patient are:

- Sterile towels, sponges, 4-inch gauze packs and povidone iodine 10% for sterilization.
- Sterile gloves, marking pen, 18-gauge cannula and 10-ml syringes containing drugs for administration of the procedure. Ultrasound device with Linear probe with high frequency (6 -13 MHz) will be used in imaging of patient.

Drugs that will be used in our study are:

- A 20 ml vial of 0.5% Bupivacaine HCl, pethidine IV (50-150 mg).
- Lower segment cesarean section will be performed using the Pfannenstiel incision.
- An anesthesiology resident will administer the general anesthesia, will record the intraoperative data (the duration of surgery), and prepared, as instructed by the primary investigator, the local anesthetic solution for the TAP block and wound infiltration. The outcome data (pethidine consumption, time to the first pethidine dose, pain scores level, side effects, and patient satisfaction) will be recorded by a blind investigator who will visited the patient in the ward at 1, 2, 4, 6, 12, and 24 hours postoperatively.

Group A: TAP group formed of 65 patients

- After completion of LSCS and skin closure and while the patient is still on the operating table U/S guided TAP block will be done using the following procedure:
- After preparing the skin with antiseptic solution, a linear high frequency ultrasound probe (Superficial probe of mindray DP-20) will be placed transversely on the anterolateral abdominal wall between the iliac crest and the costal margin. Under US guidance, the three layers of muscles -external oblique, the internal oblique, and the transversus abdominis will be identified. A Spinal needle 22 g attached with flexible tubing to a syringe filled with saline will be used to perform the block. The needle will be then introduced through the skin anteriorly in the plane of the ultrasound beam and advanced into the fascial plane between the internal oblique and transversus abdominis muscles with its tip lying in the mid axillary line. To assist with identifying these structures, the probe will be moved anteriorly to the rectus sheath and the fascial planes followed laterally. The final position of the probe will to be no further anterior than the anterior axillary line. If satisfactory views are not obtained, the TAP block will not be performed. Hydro dissection with saline (2-5 ml) will be used to separate the fascial layers. After aspiration to exclude inadvertent vascular puncture, a test dose of 1-2 ml of the drug will be injected to confirm needle placement. After a negative test dose, 20 ml of the 0.25% bupivacaine will be injected while closely observing for signs of toxicity e.g. CVS toxicity which may be in form of early features e.g. hypertension, tachycardia and ventricular arrhythmia or may be in form of late features e.g. hypotension, bradycardia, heart block and decreased contractility and other toxic signs e.g. tinnitus, perioral numbness, metallic taste in mouth, slurring of speech and mental status changes). TAP block will be performed in a similar fashion on the opposite side.

Group B: The Infiltration Group formed of 65 patients

- This group will B wills provided with single-shot local anesthetic wound infiltration with 20 ml of 0.25% bupivacaine injected subcutaneously above and below skin incision before closure of skin.

Group C: Narcotics only group formed of 20 patients

- Routine analgesic was taken only without any intervention

Post-operative settings:

- At the end of the surgery and complete recovery

from anesthesia, the patient will be kept under observation postoperatively for 4 hours to monitor vital signs (conscious level, blood pressure, heart rate, respiratory rate and pattern & any possible limb weakness or abnormal sensation) then discharged to ward & observed to be followed for returning of pain.

- Duration of surgery (time from the start of skin incision to the end of skin closure) will be recorded.
- The patients will be observed for the occurrence of any adverse effect and/or complication related to the procedure (e.g. hematoma), or to the study drugs (e.g. hypotension/hypertension (i.e. 20% decrease or increase from the baseline value), bradycardia (HR <50 beats/min) or tachycardia (HR >120 beats/min), nausea, vomiting, and hypoxemia (SpO2 <90%).
- Assessment of pain involves asking a patient to rate her pain from 0 to 10 (VAS) with the understanding that 0 is equal to no pain and 10 equal to the worst possible pain after first hour, 2nd hour, 4th hour, 6th hour, 12th hour and 24th hour at wards after end of surgery.
- Pain is usually managed by pethidine IV based on patient complain. The analgesic dose of pethidine will be 50 mg to be repeated on demand (provided that the total 24 hour dosage will not exceed 150 mg. At recovery room mothers asked to report their pain based on VAS score during first 24 hour. Patient satisfaction from postoperative analgesia will be assessed at 24 hours postoperatively using a 5-point scale (1 = very unsatisfied, 2 = unsatisfied, 3 = fair, 4 = satisfied, and 5 = very satisfied) after first hour, 2nd hour, 4th hour, 6th hour, 12th hour and 24th hour at wards after end of surgery.
- A time in minutes from end of surgery to first analgesia request were documented together with total analgesia consumed in the first 24 h. In addition, incidence of postoperative nausea and vomiting will be documented within 24 h.

Operational definitions

Postoperative pain: The presence of pain in the postoperative period was defined as a patient complaining pain and any pain score other than zero within 24 h.

Time to first analgesia request: A time in minutes from the end of surgery to a first time analgesia requested by the patient.

Total analgesia consumption: Total dose of analgesic medication given in mg within the first 24 h after end of surgery.

Visual analogue scale: The patient marks on the line the point that they feel represents their perception of their current state. The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks.

Statistical methods: The collected data will be coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 22.0, IBM Corp., Chicago, USA, 2013.

Descriptive statistics will be done for quantitative data as minimum& maximum of the range as well as mean ± SD (standard deviation) for quantitative normally distributed data, median and 1st& 3rd inter-quartile range for quantitative non-normally distributed data, while it will be done for qualitative data as number and percentage.

Inferential analyses will be done for quantitative variables using Shapiro-Wilk test for normality testing, ANOVA test and Kruskal Wallis test for more than two independent groups with non-normally distributed data. In qualitative data, inferential analyses for independent variables will be done using Chi square test for differences between proportions and Fisher's exact test for variables with small expected numbers. Log rank test will be used to test survival functions. The level of significance will be taken at P value <0.050 is significant, otherwise is non-significant.

RESULTS

Tab. 1. shows that, no significant statistical differences between the studied groups regarding demographic characteristics; maternal age, body mass index and parity as well as gestational age and operation time.

Tab. 2. shows that, postoperative patients,' pain perception in the studied groups increased slowly in TAB and WI group in the first six hours to reach its peak in hour 12, then decreased rapidly until hour-24. While it increased rapidly in the first six hours to reach its peak in hour 6 then decreased slowly until hour-24. The peak was lowest TAP group, followed by WI group and highest in control group.

Postoperative patients' pain perception at hours 1, 2, 4, 6, 12 and 24 was lowest in TAP group, followed by WI group and highest in control group, the differences were statistically significant between all the studied groups but at hours 1 and 2 the differences were statistically significant between control and each of TAP and WI groups with no significant difference between TAP and WI groups. **Tab. 3.** shows that, time to first rescue analgesia was longest in TAP group, followed by LW group and shortest in control group, the differences were statistically significant between all the studied groups. **Tab. 4.** shows that, total NSAID dose was lowest in TAP group, followed by LWI group and highest in control group, the differences were statistically significant between the studied groups. **Tab. 5.** shows that, opioid consumption was least required in TAP group, followed by WI group and most required in control group, the differences were statistically significant between all the studied groups. **Tab. 6.** shows that, time to first opioid dose was least in TAP group, followed by WI

Tab. 1. Comparison between the studied groups regarding demographic characteristics.

Variables	Measures	TAP (N=65)	WI (N=65)	Control (N=65)	p-value
Age (years)	Mean ± SD	28.7 ± 4.5	28.5 ± 4.4	27.8 ± 4.5	^0.460
	Range	20.0–39.0	19.0–39.0	19.0–37.0	
BMI (kg/m^2)	Mean ± SD	28.9 ± 2.6	29.2 ± 3.2	29.1 ± 2.9	^0.817
	Range	23.2–34.9	21.7–34.8	20.1–34.6	
Parity (n, %)	Nulli	24 (36.9%)	25 (38.5%)	29 (44.6%)	#0.836
	Parous	41 (63.1%)	40 (61.5%)	36 (55.4%)	
GA (weeks)	Mean ± SD	39.4 ± 0.8	39.6 ± 0.8	39.4 ± 0.7	^0.266
	Range	38.0–41.0	38.0–41.0	38.0–41.0	
Operation time (minutes)	Mean ± SD	45.4 ± 8.4	46.5 ± 7.3	46.8 ± 6.6	^0.498
	Range	26.0–68.0	28.0–63.0	34.0–65.0	

BMI: Body mass index. GA: Gestational age. ^ANOVA test. #Chi square test

Tab. 2. Comparison between the studied groups regarding postoperative patients' pain perception (VAS-10).

Time	Measures	TAP (N=65)	WI (N=65)	Control (N=65)	^p-value
Hour-1	Mean ± SD	0.1 ± 0.3a	0.2 ± 0.4a	1.4 ± 0.7b	<0.001*
	Range	0.0–1.0	0.0–1.0	0.0–3.0	
Hour-2	Mean ± SD	0.2 ± 0.4a	0.4 ± 0.5a	1.9 ± 0.6b	<0.001*
	Range	0.0–1.0	0.0–1.0	1.0–3.0	
Hour-4	Mean ± SD	0.4 ± 0.5a	0.8 ± 0.8b	2.4 ± 0.7c	<0.001*
	Range	0.0–1.0	0.0–3.0	2.0–4.0	
Hour-6	Mean ± SD	2.6 ± 0.7a	2.9 ± 0.8b	4.1 ± 0.4c	<0.001*
	Range	2.0–4.0	1.0–4.0	3.0–5.0	
Hour-12	Mean ± SD	2.9 ± 0.8a	3.3 ± 0.7b	3.8 ± 0.8c	<0.001*
	Range	2.0–4.0	2.0–4.0	2.0–5.0	
Hour-24	Mean ± SD	0.9 ± 0.5a	1.6 ± 1.3b	2.1 ± 0.7c	<0.001*
	Range	0.0–2.0	0.0–4.0	1.0–3.0	

^ANOVA test. *Significant. Homogenous groups had the same symbol (a,b,c) based on post hoc Bonferroni test

Tab. 3. Comparison between the studied groups regarding time to first rescue analgesia (hours).

Measures	TAP (N=65)	WI (N=65)	Control (N=65)	^p-value
Mean ± SD	11.6 ± 0.9a	10.9 ± 0.6b	3.4 ± 1.1c	<0.001*
Range	11.0–13.0	9.0–12.0	1.0–4.0	

^ANOVA test. *Significant. Homogenous groups had the same symbol (a,b,c) based on post hoc Bonferroni test.

Tab. 4. Comparison between the studied groups regarding total NSAID dose (mg).

Measures	TAP (N=65)	WI (N=65)	Control (N=65)	^p-value
Mean ± SD	47.7 ± 9.8a	57.8 ± 10.1b	68.3 ± 11.7c	<0.001*
Range	40.0–60.0	40.0–80.0	40.0–80.0	

^ANOVA test. *Significant. Homogenous groups had the same symbol (a,b,c) based on post hoc Bonferroni test.

Tab. 5. Comparison between the studied groups regarding opioid requirement.

Findings	TAP (N=65)	WI (N=65)	Control (N=65)	#p-value
Required	3 (4.6%)a	12 (18.5%)b	25 (38.5%)c	>0.001*
Not required	62 (95.4%)	53 (81.5%)	40 (61.5%)	

#Chi square test. *Significant. Homogenous groups had the same symbol (a, b,c) based on post hoc Bonferroni test.

Tab. 6. Comparison between the studied groups regarding time to first opioid dose (hours).

Measures	TAP (N=3)	WI (N=12)	Control (N=25)	^p-value
Mean ± SD	13.7 ± 0.6a	13.1 ± 0.3b	5.9 ± 0.3c	>0.001*
Range	13.0–14.0	13.0–14.0	5.0–6.0	

^ANOVA test. *Significant. Homogenous groups had the same symbol (a, b,c) based on post hoc Bonferroni test.

group and highest in control group, the differences were statistically significant between all the studied groups. **Tab. 7.** shows that, time to mobilization was highest in TAP group, followed by WI group and least in control group, the differences were statistically significant between all the studied groups.

Tab. 8. shows that, postoperative nausea and vomiting were least frequent in TAP group, followed by WI group and most frequent in control group, the differences were statistically non-significant in nausea, while in vomiting the differences were statistically significant between control and each of TAP and WI groups with no significant difference

between TAP and WI groups. Postoperative pruritis were not recorded in all of the studied groups.

Tab. 9. shows that, patients' Satisfaction was highest in TAP group, followed by WI group and lowest in control group, the differences were statistically significant between all the studied groups.

DISCUSSION

To data, the efficacy of TAP block *vs.* wound infiltration on postoperative analgesia remains controversial [10-13].

Therefore, the main objective of the current study is to compare analgesic effectiveness of bilateral US guided Transversus Abdominis Plane block (TAP) *vs.* single-shot local anesthetic wound site Infiltration (WI) after cesarean delivery under general anesthesia.

To the best of our knowledge, data regarding the use of TAP block *vs.* wound infiltration on postoperative analgesia after cesarean section under general anesthesia are limited and conflicting and most of the previous studies were done after spinal anesthesia which interrupted the pain scores and opioid consumption postoperatively so, the success rate and sensory extent of the TAP block could not be assessed. Consequently, the occurrence of cases of failed or inadequate block is unknown.

Thus, the present study was conducted to evaluate the efficacy of TAP block *vs.* wound infiltration on postoperative analgesia after cesarean section under general anesthesia.

The current study revealed that there were no significant differences between the studied groups regarding demographic characteristics; maternal age, BMI and parity as well as gestational age and operation time.

The current research study revealed that: Postoperative patients,' pain perception in the studied groups increased slowly in TAP group and WI group in the first six hours to reach its peak in hour 12, then decreased rapidly until hour-24. While it increased rapidly in the first six hours to reach its peak in hour 6 then decreased slowly until hour-24. The peak was lowest TAP group, followed by WI group and highest in control group.

Postoperative patients' pain perception at hours 1, 2, 4, 6, 12 and 24 was lowest in TAP group, followed by WI group and highest in control group, the differences were statistically significant between all the studied groups but at hours 1 and 2 the differences were statistically significant between control and each of TAP and WI groups with no significant difference between TAP and WI groups.

At hour 1 TAP group measure Mean ± SD 0.1 ± 0.3a with Range 0.0 – 1.0, in LWI Mean ± SD 0.2 ± 0.4a with Range 0.0 – 1.0 and Mean ± SD 1.4 ± 0.7b Range 0.0 – 3.0 in control group.

At hour 2 TAP group measure Mean ± SD 0.2 ± 0.4a with Range 0.0 – 1.0, in LWI Mean ± SD 0.4 ± 0.5a Range 0.0 – 1.0 and Mean ± SD 1.9 ± 0.6b Range 1.0 – 3.0 in control group.

At hour 4 TAP group measure Mean ± SD 0.4 ± 0.5a with Range 0.0 – 1.0, in LWI Mean ± SD 0.8 ± 0.8b with Range 0.0 – 3.0 and Mean ± SD 2.4 ± 0.7c Range 2.0 – 4.0 in control group.

At hour 6 TAP group measure Mean ± SD 2.6 ± 0.7a with Range 2.0 – 4.0,In LWI Mean ± SD 2.9 ± 0.8b with Range 1.0 – 4.0 and Mean ± SD 4.1 ± 0.4c Range 3.0 – 5.0 in control group.

At hour 12 TAP group measured Mean ± SD 2.9 ± 0.8a with 2.0 – 4.0, in LWI measure Mean ± SD 3.3 ± 0.7b with Range 2.0 – 4.0 and Mean ± SD 3.8 ± 0.8c Range 2.0 – 5.0 in control group.

At hour 24 TAP group measure Mean ± SD 0.9 ± 0.5a with Range 0.0 – 2.0, in LWI measure Mean ± SD 1.6 ± 1.3b with Range 0.0 – 4.0 and Mean ± SD 2.1 ± 0.7c Range 1.0 – 3.0 in control group.

Consequently, patient Satisfaction was highest in TAP

Tab. 7. Comparison between the studied groups regarding time to mobilization (hours).

Measures	TAP (N=65)	WI (N=65)	Control (N=65)	^ p-value
Mean ± SD	3.2 ± 0.8a	4.3 ± 1.1b	5.3 ± 1.0c	>0.001*
Range	2.0–5.0	3.0–7.0	3.0–7.0	

^ ANOVA test. *Significant. Homogenous groups had the same symbol (a, b,c) based on post hoc Bonferroni test.

Tab. 8. Comparison between the studied groups regarding postoperative complications.

Complications	TAP (N=65)	WI (N=65)	Control (N=65)	p-value
Nausea	2 (3.1%)a	3 (4.6%)a	12 (18.5%)b	#0.003*
Vomiting	0 (0.0%)	1 (1.5%)	4 (6.2%)	§0.129
Pruritis	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA

#Chi square test. §Fisher's Exact test. NS: Not applicable. *Significant. Homogenous groups had the same symbol (a, b) based on post hoc Bonferroni test.

Tab. 9. Comparison between the studied groups regarding patients' satisfaction.

Satisfaction	TAP (N=65)	WI (N=65)	Control (N=65)	#p-value
Satidfied	40 (61.5%)a	26 (40.0%)b	3 (4.6%)c	0.001*
Fair	22 (33.8%)	27 (41.5%)	37 (56.9%)	
Unsatisfied	3 (4.6%)	12 (18.5%)	25 (38.5%)	

#Chi square test. *Significant. Homogenous groups had the same symbol (a,b,c) based on post hoc Bonferroni test.

group, followed by LWI group and lowest in control group, the differences were statistically significant between all the studied groups (p value=0.001).

In TAP group 40 patient were satisfied, 22 was fair and 3 were unsatisfied while In LWI group 26 patient were satisfied, 27 was fair and 12 were unsatisfied and In control group 3 patient were satisfied, 37 was fair and 25 were unsatisfied.

Görkem U, et al. [14] conducted a prospective randomized study which enrolled a total of 216 parturient women undergoing cesarean delivery under general anesthesia and divided into five groups so as to receive the planned procedure for them: i) group 1 (G1)- controls, ii) group 2 (G2)- TAP placebo, iii) group 3 (G3)- TAP, iv) group 4 (G4)- wound infiltration placebo, and, v) group 5 (G5)- wound infiltration to compare efficacy, safety, pain intensity and analgesic consumption in patients receiving either bilateral transversus abdominis plane (TAP) block or wound infiltration with bupivacaine after cesarean delivery under general anesthesia.

Görkem U, et al. [14] revealed that there were significant intergroup differences in VAS scores between the treatment, placebo, and control groups at the zero-time point (p=0.03), at 6 hours (p=0.02), 12 hours (p=0.02), and at 18 hours (p=0.02).

Görkem U, et al. [14] results were in harmony with our results in that a single injection TAP block satisfactorily provided pain relief for 12 hours postoperatively in patients who underwent elective Cesarean delivery under general anesthesia whereas such benefit was limited in patients who received wound infiltration with local anesthetic at similar doses and the difference between groups was not sustained and receded at the 18th hour, indicating the rapid onset but short duration effect of bupivacaine when used in TAP block.

Cai Q, et al. [15] conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) which involved fifteen studies with 983 participants to compare the postoperative analgesic effects and safety of TAP block with those of wound infiltration (WI) and the continuous infusion technique in adults after surgeries with general anesthesia to obtain a clear conclusion.

Cai Q, et al. [15] revealed that that wound infiltration (WI) had the same analgesic effect as TAP block in a short postoperative period (only one hour) with significant differences were found at 2, 4, 6, 12, and 24 h (p value <0.05), resulted in a shorter time to the initial rescue analgesic, and had poorer patient satisfaction and similar postoperative nausea and vomiting (PONV) incidence, with high evidence and reported higher patient satisfaction in TAP block group which agreed with our results.

Sivapurapu V, et al. [16] conducted a systematic review and meta-analysis which involved randomized controlled trials (RCTs) from PUBMED, EMBASE and CENTRAL databases and enrolled nine studies with 500 participants to compare the efficacy and safety of TAP block with wound infiltration for pain relief after surgery and all studies involved general anesthesia.

Sivapurapu V, et al. [16] revealed that TAP block showed significant lower rest pain scores at 8 hour [MD = -1.08, 95% CI (-1.89-0.26), P = 0.009] and 24-hour [MD = -0.83, 95% CI (-1.60, -0.06), P = 0.03] than wound infiltration, but no significant difference was found at 1 hour [MD = -0.94, 95% CI (-1.97, 0.09), P = 0.08] and Pain scores on movement (Dynamic pain scores)were assessed and revealed that TAP block showed significant lower dynamic pain scores at 8 hour [MD = -0.66, 95% CI (-1.30, -0.03), P = 0.04] and 24 hour [MD = -0.93, 95% CI (-1.48, -0.39), P = 0.0007], but no significant difference was seen at 1 hour [MD = -1.01, 95% CI (-2.06, 0.04), P = 0.06] compared with wound infiltration. Consequently, Sivapurapu V, et al. [16] findings indicated that local anaesthetic wound infiltration may provide brief pain relief for less than 8 hours after surgery which agreed with our results.

Tawfik MM, et al. [17] conducted a prospective study that enrolled 78 patients with full-term singleton pregnancies undergoing elective cesarean delivery to compare bilateral ultrasound-guided TAP block with single-shot local anesthetic wound infiltration for analgesia after cesarean delivery performed under spinal anesthesia.

In contrast to our results, Tawfik MM, et al. [17] revealed that there were no significant differences between the 2 groups in the time to the first opioid (fentanyl) dose, cumulative fentanyl consumption and pain scores at rest and on movement at 2, 4, 6, 12, and 24 hours (p value= 0.8) which may be explained by the presence of residual sensory block from the spinal anesthetic so, the success rate and sensory extent of the TAP block could not be assessed. Consequently, the occurrence of cases of failed or inadequate block is unknown.

Wayu B, et al. [18] shows WSI had better analgesic efficacy during the early postoperative hours but TAP was superior for the prolonged time of analgesia. The difference in the former might be attributed to the effect of the design where the study was done with a randomized trial where ours is an observational study.

Our results revealed that time to first rescue analgesia was longest in TAP group, followed by LWI group and shortest in control group, the differences were statistically significant between the studied groups (p value <0.001).

In TAP group with Mean ± SD 11.6 ± 0.9a, Mean ± SD 10.9 ± 0.6b in LWI and Mean ± SD 3.4 ± 1.1c in control group.

Our result showed that rate of first rescue analgesia was lowest in tap group, followed by LWI and highest in control group the difference was statistically significant between all studied group.

Aydogmus MT, et al. [5] conducted a prospective randomized trial and consisted of 70 pregnant women to compare the analgesic efficiency of ultrasound (USG)-guided transversus abdominis plane (TAP) block with

local anesthetic infiltration on a wound site under spinal anesthesia and revealed that reduced pain scores at 2, 6, 12, and 24 hours and increased time to the first analgesic with TAP block which is in harmony with our results.

On contrary to our results, Guo Q, et al. [19] revealed that time to first rescue analgesic (hour) was assessed and reported no significant difference between TAP block and wound infiltration [MD = 2.55, 95% CI (-0.36, 5.46), P = 0.09]

Our results revealed total NSAID dose and opioid consumption were lowest in TAP group, followed by LWI group and highest in control group, the differences were statistically significant between the studied groups (p value <0.001).

Regarding total NSAID dose in TAP group was Mean ± SD 47.7 ± 9.8a, Mean ± SD 57.8 ± 10.1b in LWI, and Mean ± SD 68.3 ± 11.7c.

Regarding opoid requirement 3 patient require opoid in TAP group with time to first opoid dose Mean ± SD 13.7 ± 0.6a, while 12 patient in LWI with time to first opoid dose Mean ± SD 13.1 ± 0.3b, and 25 in control group with time to first opoid dose Mean ± SD 5.9 ± 0.3c.

Our results show that. Rate of first opioid dose was lowest in TAP group, followed by LW group and highest in control group, the differences were statistically significant between all the studied groups.

Consequently, the onset of mobilization was shortest in TAP group, followed by LWI group and longest in control group, the differences were statistically significant between the studied groups (p value <0.001).

In TAP group with Mean ± SD 3.2 ± 0.8a and range 2-5 hours, in LWI group Mean ± SD 4.3 ± 1.1b and range 3-7 hours and in control group with Mean ± SD 5.3 ± 1c and range 3-7 hours.

Consequently, the rate of mobilization was highest in TAP group, followed by LWI group and lowest in control group the differences were statistically significant between the studied groups

These results were in concordance with the data reported by Das N, et al. [20] in which revealed that regarding the diclofenac use, patients in TAP block group used significantly less diclofenac than those in the wound infiltration group (p=0.007), TAP placebo group (p<0.001), and wound infiltration placebo group (p=0.002). Also, regarding pethidine use, patients in the TAP block group required significantly less pethidine than those in wound infiltration group (p<0.001), and control group (p<0.001).

Adesope O, et al. [7] shows significantly reduce 24 h opioids consumption mean difference 9.69 mg in morphine equivalency.

On contrary to our results, Telnes A, et al. [21] reported that Ultrasound guided TAP block compared with local infiltration of the wound after CS did not reduce postoperative opioid consumption Cumulative morphine consumption at 48 h (mean ± standard deviation) was 41 ± 34 mg in the TAP group and 38 ± 27 mg in the control group (P = 0.7); a difference of 3 mg (95% confidence interval −13 to 19 mg).

In another way, a study by Gasanova I, et al. [22]shows WSI had lower opioid requirements between 24 and 48 h compared to the TAP group (p = 0.009).

Regarding post-operative complications, our results revealed postoperative nausea and vomiting were least frequent in TAP group, followed by LWI group and most frequent in control group, the differences were statistically non-significant between the three groups while pruritis not recorded in the studied groups.

Regarding nausea 2 patients in TAP group, 3 patients in LWI and 12 patients in control group.

Vomiting not recorded in TAP group while on patient in LWI and 4 in control group. Klasen F, et al. [23] revealed that showed no significant difference in postoperative nausea and vomiting (PONV) incidence between two groups [RR = 1.08, 95% CI (0.69, 1.71), P = 0.73] which agreed with our results.

However, our study had strong point of assessing the onset of mobilization and patient satisfaction in relation to the different regimens of regional anesthesia which not assessed by the previous studies.

Detection bias was avoided by blinding the outcome assessors. Performance bias was avoided by the following: enrollment of patients and recording of the baseline data by a single investigator not involved in the further steps study conduct; recording of intraoperative data, and preparation of local anesthetics by an anesthesiology resident not involved in the study; and blinding the patients using opaque screen and sham procedure.

Blinding the operators performing the TAP block and wound infiltration was not done because it was considered unethical (necessitating injection of saline into the TAP or the surgical wound) and unnecessary (the only possible way of introducing bias was to intentionally inject the local anesthetic outside the TAP or the surgical wound, which is practically and ethically impossible).

The strength points of this study

The strength points of this study are that Firstly, it is double-blinded randomized controlled study design and having no patients lost to follow-up. Secondly, relatively larger sample size related to the previous studies, being a multicentric study and it is the first study in Ain Shams Maternity Hospital to compare analgesic effectiveness of Transversus Abdominis Plane block (TAP) *vs.* local anesthetic wound site Infiltration (WI) after cesarean delivery under general anesthesia. Thirdly, analysis of pain and satisfaction was carried out using the standard VAS, which is the most reliable tool for assessment of pain.

CONCLUSION

- TAP block appeared to be superior to local anesthetic

wound infiltration with respect to postoperative analgesia in the setting of a multimodal analgesic regimen.

- TAP block provided better pain relief, less analgesic requirement and early mobilization than local wound infiltration after Cesarean section under general anesthesia. Moreover, it is associated with minimal postoperative complications, so should be preferred over local anesthetic wound infiltration as postoperative analgesic regimen.

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