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Efficacy of Fentanyl Patches Versus Ultrasound-guided Transversus Abdominis Plane Block in Postcesarean Section Pain Relief: A Randomized Clinical Study

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Abstract

Background: Preoperative education and perioperative pain management planning are crucial for the efficient treatment of postoperative pain. In order to complete a field block, the transversus abdominis plane (TAP) block was originally used as a landmark-guided technique. Numerous drugs, including nitroglycerin, clonidine, and scopolamine, have been confirmed to be administered transdermally.

Objective: The efficacy of ultrasonic-guided Transversus Abdominis Plane (TAP) block versus fentanyl patches in postcesarean section pain management throughout a 24-h period.

Material and methods: 100 pregnant women who were planned for an elective caesarean birth under spinal anaesthesia were enrolled in a prospective cohort study. Following surgery, subjects were divided into two equal groups at random and given patches containing 25 g/h of fentanyl (TFPs). Following surgery, 20 mL of 0.25% bupivacaine was administered to the second group as a transversus abdominis plane (TAP) block.

Results: In terms of VAS score and pain threshold, statistical analysis of present results revealed that pain was lower with TFPs versus TAP block at 2, 4, 6, and 24 h. When TFPs were used instead of TAP block, hypotension was much more common.

Conclusions: In women undergoing cesarean section, transdermal fentanyl patches were more effective than transversus abdominis plane block regarding postoperative analgesia.

Keywords: Cesarean section, Fentanyl patches, Transversus abdominis plane block

1. Introduction

Preoperative education and perioperative pain management planning that includes a preventative analgesic approach that includes multimodal therapies are required for optimal postoperative pain control.¹

As a landmark-guided technique employing the Petit triangle, the transversus abdominis plane

(TAP) block was initially employed to complete a field block. A plane between the internal oblique muscle and the transversus abdominis muscle is injected with a local anaesthetic solution.²

A range of drugs, including nitroglycerin, clonidine, and scopolamine, have been administered transdermally. The concentrations of these drugs in plasma are constant and stable after transdermal delivery.³

The goal of this study is to examine the efficacy of an ultrasonic-guided Transversus Abdominis

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Plane (TAP) block versus fentanyl patches for postcesarean section pain management during a 24-h period.

2. Material and methods

Between February 2021 and February 2022, healthy pregnant women born by caesarean section were studied in the labour ward of the obstetrics and gynaecology department at Imbaba General Hospital in Giza, Egypt. Before beginning the research, the ethical committee at Al-Azhar University gave their approval.

2.1. Inclusion criteria

Pregnant women between the ages of 18 and 35 who are scheduled for an elective caesarean delivery under spinal anaesthetic and have an American Society of Anesthesiologists (ASA) Class I or II physical status and a BMI of less than 30 kg/m² are eligible.

2.2. Exclusion criteria

Women between the ages of 18 and 35 with central neuropathy, mental health conditions, diabetes mellitus (DM) to rule out peripheral neuropathy, a history of drug abuse or chronic drug use, an allergy to study drugs, liver or renal impairment, coagulopathy or anticoagulation therapy, infection close to the site of needle insertion, or chronic pain syndrome.

2.3. Methodology

The study involved 100 pregnant women who were divided into two groups of similar size. A computer-generated randomization sheet was used for the randomization. One hundred opaque envelopes were serially numbered, and the matching letter denoting the assigned group was placed in each envelope according to the randomization table. The envelopes were then sealed and placed in a single box. The first envelope was opened when the first patient arrived, and the patient was assigned based on the letter inside. This study was authorised by the department's ethical committee at Al-Azhar University's Faculty of Medicine. All participants were given the chance to give their informed consent prior to enrollment in the study after being informed of its goals and methods. The subject's written, signed informed permission was acquired by the investigator before any study-specific procedures were carried out on a patient. The investigator held onto the original, duly-signed informed consent form. All data were collected in a discreet

manner. The side effects of the study process were explained to all of the ladies. The study was self-funded by the investigator. Participants' privacy and data confidentiality were protected in accordance with the Declaration of Helsinki. After the research protocol was approved, women were admitted based on inclusion and exclusion criteria. The medical and surgical histories of the patient were investigated. A complete blood count, prothrombin time and activity, liver, and renal function tests were also performed as part of the clinical assessment. Electrocardiography was used to monitor heart rate and rhythm, and pulse oximetry was used to measure arterial blood pressure (including systolic, diastolic, and mean arterial blood pressure) and peripheral oxygen saturation (SPO₂). Ten minutes before to the beginning of anaesthesia, lacerated Ringer's solution (10 mL/kg) was administered via an IV line with an 18 gauge cannula. Each group of 50 patients received 25 g/h transdermal fentanyl patches (TFPs) after surgery (Durogesic, Janssen Pharmaceuticals, Belgium) and the other group also received 25 g/h TFPs after surgery (Durogesic, Janssen Pharmaceuticals, Belgium). Participants were randomly assigned to one of the two groups. An impartial nurse who was not informed of the study's procedures administered the patches. After surgery, 20 mL of 0.25% bupivacaine was used to administer a transversus abdominis plane (TAP) block on the second group (50 patients). Vital indicators (heart rate, blood pressure, breathing rate, and SPO₂) were observed in the post-anaesthesia care unit. Pain was measured using a visual analogue scale (VAS) score before and after surgery, as well as at 1, 2, 4, 6, 12, and 24 h afterwards. All patients got 1 g of IV paracetamol every 8 h, and when the VAS was less than 3 or at the patient's request, IV ketolac was given. An impartial nurse who was not informed of the study's procedures administered the patches. After surgery, 20 mL of 0.25% bupivacaine was used to administer a transversus abdominis plane (TAP) block on the second group (50 patients). Vital indicators (heart rate, blood pressure, breathing rate, and SPO₂) were observed in the post-anaesthesia care unit. An evaluation of pain at rest and during exercise, as well as at 1, 2, 4, 6, 12, and 24 h following surgery, was done using a visual analogue scale (VAS) score. All patients got 1 g of IV paracetamol every 8 h, and when the VAS was less than 3 or at the patient's request, IV ketolac was given.

3. Results

Tables 1–6.

Table 1. Comparison between the studied groups as regard demographic data.

	Group A (n = 50)	Group B (n = 50)	Test	P
Age (years)				
Range	19–35	19–35	t = 0.743	0.459
Mean ± SD	26.16 ± 5.23	26.92 ± 4.99		
Parity	No. (%)	No. (%)		
Nulliparous	19 (38.0)	14 (28.0)	$\chi^2 = 1.131$	0.395
Multiparous	31 (62.0)	36 (72.0)		
Previous abortion				
No	45 (90.0)	43 (86.0)	$\chi^2 = 0.379$	0.760
Yes	5 (10.0)	7 (14.0)		
Surgical history				
Non	26 (52.0)	35 (70.0)	$\chi^2 = 3.405$	0.100
CS	24 (48.0)	15 (30.0)		
Comorbidity				
Non	45 (90.0)	43 (86.0)	$\chi^2 = 2.469$	0.291
Hypertension	3 (6.0)	4 (8.0)		

4. Discussion

According to our knowledge, this is the first study to compare TFPs with (TAP) block for pain control following CS.

Regarding basic demographic, anthropometrics data and laboratory investigations; statistical analysis of current results showed that there was no statistically significant difference between the studied groups as regard age, parity, previous abortions, surgical history, comorbidities (hypertension), weight, height and BMI. There was no statistically significant difference between the studied groups as regard Hb, PLTs, WBCs, INR, PT, ALT, AST, urea and creatinine.

The current study concurred with Sevarino and colleagues, who conducted a placebo-controlled double-blind study to investigate the safety and efficacy of the transdermal therapeutic system (TTS) of fentanyl delivery in the postoperative environment, as well as its prospective clinical use. 95 women were given TTS patches that released 25 or 50 mg/h or a placebo 1 h before abdominal gynecologic surgery under general anaesthesia. They claimed that there were no disparities in demographic data between research groups (age and weight).⁴

In a randomised, double-blind, placebo-controlled research, Sandier and colleagues

examined the analgesic, pharmacokinetic, and clinical respiratory effects of two transdermal fentanyl (TTSF) patch sizes in patients having abdominal hysterectomy. 120 women received either placebo patches or TTSF patches that provided fentanyl at rates of 50 mg/h (TTSF-50) or 75 mg/h (TTSF-75) two hours before undergoing an abdominal hysterectomy under general anaesthesia. All patients were provided access to additional morphine after surgery via patient-controlled analgesia pumps. They found no significant differences between the three groups in terms of age (33–36 years), weight (61–64 kg), anaesthesia duration (112–115 min), or PACU observation period (169–184 min) 5.

In a randomised, placebo-controlled, double-blind investigation with 81 patients who underwent full abdominal hysterectomy, Broome and colleagues assessed postoperative analgesia supplied by transdermal fentanyl administered at 25, 50, or 75 pg h for 72 h to a placebo group. They claimed there were no appreciable variations in height, weight, or age across the four groups.¹²

The current investigation supported the findings of Jadon and colleagues from a randomised controlled trial that looked at the analgesic efficacy of Tap block for post-caesarean analgesia. Following

Table 2. Comparison between the studied groups as regard anthropometrics.

	Group A (n = 50)	Group B (n = 50)	t	P
Weight				
Range	58.5–85	59–87	1.604	0.112
Mean ± SD	70.9 ± 6.38	73 ± 6.7		
Height				
Range	157–173	157–173	1.737	0.085
Mean ± SD	163.36 ± 4.32	164.98 ± 4.98		
BMI				
Range	23.1–30	23–30	0.702	0.459
Mean ± SD	26.54 ± 1.79	26.79 ± 1.86		

Table 3. Comparison between the studied groups as regard Blood pressure before surgery.

	Group A (n = 50)	Group B (n = 50)	t	P
Systolic				
Range	110–170	110–170	0.712	0.478
Mean ± SD	124 ± 12.12	122.2 ± 13.14		
Diastolic				
Range	70–100	70–100	0.768	0.444
Mean ± SD	76.6 ± 6.58	75.6 ± 6.44		
Mean arterial				
Range	83.3–116.7	83.3–116.7	0.883	0.380
Mean ± SD	92.4 ± 7.13	91.13 ± 7.28		

Table 4. Comparison between the studied groups as regard Lab investigation.

	Group A (n = 50)	Group B (n = 50)	t	P
Hb				
Range	10.8–12.6	10.8–12.6	0.867	0.388
Mean ± SD	11.83 ± 0.52	11.73 ± 0.61		
PLTs				
Range	126–246	120–250	0.206	0.837
Mean ± SD	187.88 ± 34.29	189.38 ± 38.48		
WBCs				
Range	4.7–7.6	4.7–7.6	0.000	1.0
Mean ± SD	6.22 ± 0.84	6.22 ± 0.86		
INR				
Range	0.7–1.1	0.7–1.1	0.476	0.635
Mean ± SD	0.89 ± 0.16	0.88 ± 0.13		
PT				
Range	11.9–13.7	11.9–13.7	1.624	0.107
Mean ± SD	12.77 ± 0.52	12.94 ± 0.55		
ALT				
Range	10–40	9–40	1.170	0.245
Mean ± SD	26.12 ± 9.84	23.88 ± 9.3		
AST				
Range	12–45	12–45	0.029	0.977
Mean ± SD	27.04 ± 10.24	26.98 ± 10.48		
Urea				
Range	5–20	5–20	0.250	0.803
Mean ± SD	12.16 ± 5.05	12.4 ± 4.55		
Creatinine				
Range	4.5–9.2	4.5–9.3	1.252	0.214
Mean ± SD	6.79 ± 1.55	6.41 ± 1.46		

informed consent, 139 caesarean birth moms were randomly assigned to have TAP block with either 20 mL 0.375% ropivacaine or 20 mL saline. All individuals received standard spinal anaesthetic as well as diclofenac for postoperative pain. According to the researchers, maternal characteristics (age, height, weight, parity, and gestational age) were similar in both groups ($P > 0.05$).⁵

Table 5. Comparison between the studied groups as regard VAS score.

	Group A (n = 50)	Group B (n = 50)	t	P
1st hr				
Range	1.7–4.8	1.9–4.8	1.789	0.077
Mean ± SD	3.2 ± 0.96	3.51 ± 0.8		
2nd hr				
Range	1.5–4.8	1.8–4.7	2.163	0.033
Mean ± SD	2.99 ± 0.96	3.37 ± 0.81		
4th hr				
Range	1.2–4.7	1.6–4.6	2.297	0.024
Mean ± SD	2.81 ± 1	3.23 ± 0.82		
6th hr				
Range	0.7–4.6	1.4–4.5	2.774	0.007
Mean ± SD	2.52 ± 1.01	3.04 ± 0.85		
12th hr				
Range	0.7–4.1	1.2–4.4	3.158	0.002
Mean ± SD	2.25 ± 0.98	2.84 ± 0.86		
24th hr				
Range	0.6–3.6	0.7–4.2	3.159	0.002
Mean ± SD	1.78 ± 0.9	2.36 ± 0.95		

Alemnew and Lemma investigated the analgesic efficacy of Transversus Abdominis Plane block (TAP) versus wound site infiltration after caesarean birth under spinal anaesthesia (WI). In a hospital-based prospective cohort study at Debre Tabor General Hospital, 62 parturites scheduled for elective caesarean delivery under spinal anaesthetic were studied. They discovered that demographic and perioperative characteristics such as age, gestational age, and higher sensory level after spinal anaesthesia were equivalent ($P > 0.05$) in both groups.⁶

Regarding VAS score; statistical analysis of current results showed that VAS score and pain threshold were lower with TFPs compared with TAP block at 2, 4, 6, 12 and 24 h with $P = 0.077, 0.033, 0.024, 0.007, 0.002$ and 0.002 respectively.

I The current study differed with Sevarino and colleagues' claim that there were no significant variations in VAS pain scores at rest across treatment groups in terms of TFPs. They did, however, agree with the current trial, indicating that persons who received the 50 mg/h patch had considerably lower VAS pain levels after 24 h of ambulation than those who received placebo. When compared to the placebo group, a higher proportion of patients in group 3 (50 mg/h) had superior or good analgesia ($P 0.05$).⁴

In the current study, Sandier and his colleagues found that the TTSF-50 group did not differ significantly from the placebo group in terms of rest or movement discomfort. All three groups reported considerable VAS pain ratings in the early postoperative phase. There was no significant difference in VAS pain levels at rest or with movement across the three groups. These disparities may be the result of disparities in study methodologies and population criteria.⁷

In the current investigation, Miguel and his coworkers looked at two different fentanyl strengths—70–80 mg/kg/h and 90–100 mg/kg/h—for transdermal administration methods. In 143 patients who underwent a gynecologic exploratory laparotomy, the postoperative pain management effects of both dosages were investigated. A prospective, randomised, placebo-controlled, double-blind trial was conducted at four locations. Two placebo patches were given to Group 1, two fentanyl

Table 6. Comparison between the studied groups as regard Complications.

	Group A (n = 50)	Group B (n = 50)	χ^2	P
Complications	No. (%)	No. (%)		
Nausea	24 (48.0)	21 (41.0)	0.364	0.546
Vomiting	13 (26.0)	10 (20.0)	0.508	0.476

patches totaling 40 cm² and 60 cm² were given to Group 2, and two patches totaling 60 cm² and 40 cm² were given to Group 3. Patients in group 3 often had significantly lower mean VAS ratings than patients in groups 1 and 2. In five of the ten evaluation periods, patients in group 3 significantly exceeded those in group 1 in terms of their overall self-assessment of analgesia. During one of the 10 assessment periods, individuals in group 2 reported significantly more pain relief than did patients in group 1. No statistically significant differences existed between patient groups 2 and 3.⁸

According to Broome and colleagues, in the current investigation, the 75 mg/h group had the lowest scores for linear analogue pain while the placebo group had the highest values. Compared to the placebo group, the combined transdermal fentanyl groups reported considerably reduced overall discomfort ($P = 0.007$). The unpaired *t*-test findings showed that there were significant differences between the groups 6.

In addition, Lehmann and colleagues⁹ claims that pain alleviation was equivalent in both groups after 8, 16, 24, and 36 h as measured by a VAS at rest and with movement were refuted by the current study. This study's objective was to evaluate the effectiveness and safety of a transdermal fentanyl administration system for pain management following abdominal surgery. 40 patients scheduled for abdominal surgery under general anaesthesia were randomly allocated to one of two groups in a non-blinded, non-crossover, placebo-controlled experiment. Fentanyl 0.16 mg/cm² transdermal patches were given to Group I patients. 20 individuals in a second group were given 10 mm placebo patches.

Onishi and colleagues looked at whether TAP block gives postcaesarean women extra analgesic effects to epidural morphine alone, and the current study supported their findings. The test patients were pregnant women getting combination spinal and epidural anaesthesia for a caesarean section. Two milligrammes of morphine were injected into the epidural space at the conclusion of the procedure. The TAP group was assigned to women who indicated interest in joining it. The TAP block was not administered to the ladies in the control group. They claimed that TAP block provided analgesic benefits in addition to epidural morphine. In comparison to control participants, TAP individuals had a longer median time to first morphine request (555 vs. 215 min) and lessened median total morphine consumption within 24 h (5.3 vs. 7.7 mg).¹⁰

According to Khasay and colleagues,¹¹ post-operative pain levels were considerably lower (p

0.05) in the TAP block group at all time points, both at rest and during stressors (on deep breaths, deliberate coughing, and mobilisation).

Alhosainy and coworkers recently investigated the effectiveness and safety of bilateral continuous transversus abdominis plane (TAP) block versus continuous wound infiltration for pain management after surgery. Forty patients with an American Society of Anesthesiologists (ASA) physical status I or II who were scheduled for elective CS participated in this randomised controlled experiment. TAP block was more effective than CWI during movement, opioid consumption was significantly lower in the TAP group than in the CWI group, and the time of first analgesic request was earlier in the CWI group than in the TAP group, but they found no differences in pain relief between TAP block and CWI during rest.¹³

The current research confirmed Jadon and colleagues' results that pain scores were consistently considerably lower in the TAP block group than in the placebo group throughout the course of the trial ($P = 0.0001$).⁵

Alemnew and Lemma found no statistically significant difference in pain intensity on the Numeric Rating Scale (NRS) from the time patients first entered the recovery room and the third hour following caesarean birth. With a p -value of 0.05, there was a statistically significant difference between the NRS recorded in the median and interquartile range, nevertheless.

A statistical examination of the current data showed that, in terms of issues, hypotension was much more prevalent with TFPs than with TAP block (16 vs. 2%), $P = 0.031$. There were no appreciable variations in vomiting or nausea between the two groups, though ($P = 0.546$ and 0.476 , respectively).

The current study concurred with Sevarino and coworkers about TFPs, who discovered no significant variations in nausea, vomiting, respiratory depression, urine retention, or itching between study groups.⁴

According to Sandier and colleagues, there was no significant difference in the occurrence of adverse effects such as nausea, vomiting, pruritus, mean hourly apnea rate, or mean number of episodes of slow respiratory rate (SRR)/h among groups throughout the 8-h preoperative monitoring period.⁷

In terms of nausea and vomiting, the current study concurred with Miguel and colleagues, showing that incidence was high in all groups and that there were no notable differences between them. Patients in group 3 were more likely to have pruritus. In three patients in Group 1, ten patients in Group 2, and six patients in Group 3, pruritus was typically mild. Statistically insignificant difference More erythema was present in Group 2 patients

than in the other groups, however it was mild and did not require treatment. All groups had respiratory depression, although group 3 patients had it a lot more often than group I patients did.

Systolic arterial pressure and respiration rate significantly varied at 4, 32, 36, and 60 h following transdermal delivery system application, according to Broome and colleagues. At these periods, the 75 mg/h transdermal fentanyl group had the lowest respiration rate, whereas the placebo group had the highest. Between groups 6, there was no discernible change in heart rate, diastolic blood pressure, nauseousness or vomiting, or usage of antiemetic drugs.

The recent investigation supported Kahsay and his colleagues' assertion that TAP block injection had no negative effects or challenges in terms of TAP block. There was no statistically significant difference between the two study groups in terms of nausea (5.8% vs. 1.9%) and vomiting (7.7% vs. 0%; $P = 0.06$), despite the fact that the control group had higher postoperative nausea and vomiting.⁸

The current study refuted Jadon and his colleagues' assertion that the study group's nausea scores were significantly decreased ($p < 0.05$) only in the second half of the trial (10, 12, 18, and 24 h).⁵

The current study, in part, supported Alemnew and Lemma's assertion that there was no statistically significant difference between the two groups in the incidence of nausea and/or vomiting within 24 h after caesarean birth ($P > 0.05$).⁶

4.1. Conclusions

Transdermal fentanyl patches were more effective than transversus abdominis plane block in providing postoperative analgesia to women who had a caesarean section.

4.2. Statistical analysis

The data that was sent into the computer was examined using the IBM SPSS software programme, version 20.0. Number and percentage were utilised to describe qualitative data (IBM Corporation, Armonk, NY). The distribution's normality was checked using the Kolmogorov-Smirnov test. Quantitative data were described using the range (minimum and maximum), mean, standard deviation, median, and interquartile range (IQR). A 5% threshold of significance was used to determine if the gathered data were significant.

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Ethical approval

The study was approved by the Institutional Ethics Committee.

Conflict of interest

The authors declared no conflicts of interest.

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