

Randomized Trial

## Transversus Abdominis Plane Block in the Management of Acute Postoperative Pain Syndrome after Caesarean Section: A Randomized Controlled Clinical Trial

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**Background:** The international literature is unclear regarding the analgesic efficacy of the transversus abdominis plane block (TAPB) after a Caesarean section (CS).

**Objectives:** The aim of this study was to determine whether a correctly performed ultrasound-guided TAPB (USG-TAPB) could provide better control of acute postoperative pain during the first 72 hours after CS and if it could provide a faster postoperative recovery.

**Study Design:** A double-blind, randomized, controlled clinical trial on pregnant women who underwent CS.

**Setting:** Pain clinic and Anesthesia and Intensive Care Unit in an academic hospital.

**Methods:** A double-blind, randomized, controlled study was conducted with 96 patients who underwent CS. The patients in both groups received subarachnoid anesthesia (SAB) with 13 mg of 0.5% isobaric levobupivacaine. The patients were randomized so that some received USG-TAPB with local anesthetic, and the remainder received USG-TAPB with saline. The patients' demographic information and data regarding anesthesia, hemodynamic changes, side effects, acute rest and incident postoperative pain, painkiller consumption, recovery time of bowel function, and the time of hospital discharge were recorded.

**Results:** Our data reinforce the assumption that if TAP block is performed correctly and is part of a multimodal analgesic scheme, effective pain control is possible both for somatic and visceral acute pain. Furthermore, the need for painkillers is reduced, and their related side effects are moderate, yielding a positive benefit/cost ratio.

**Limitations:** USG-TAPB provides good analgesia for acute postoperative somatic pain, but opiates were still needed for the management of visceral acute postoperative pain.

**Conclusions:** These results could confirm the assumption that the correct performance of an USG-TAPB as part of a multimodal analgesic treatment could represent a viable alternative to common analgesic procedures performed for acute postoperative pain control after a CS.

**Key words:** Bowel function, Caesarian section, incident pain, local anesthetics, multimodal analgesic treatment, postoperative recovery, rest pain, ultrasound-guided TAP block

**Clinical trial number and registry.** The protocol number is 0057864/13, the date of registration is 13/09/2013, and the ClinicalTrials.gov Identifier is NCT02728323.

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**C**aesarean section (CS) rates have been increasing in many member countries of the Organization for Economic Cooperation and Development (OECD). The rate of CS is particularly high in the south of Italy, where some provinces show rates 6 times higher compared to other countries (1).

Results from a United States national survey suggest that patients have a 50% – 70% chance of experiencing moderate to severe pain after surgery (2).

Many studies have attributed this problem to the lack of knowledge and poor attitude of both health personnel and patients toward pain, as well as the lack of a dedicated pain management service (3).

Neuraxial analgesia (4) and systemic opiates (5) are commonly used for postoperative pain relief after CS.

Spinal or systemic opiates are frequently associated with adverse effects such as nausea, vomiting, sedation, itching, and a risk of delayed maternal respiratory depression, all of which increase patient discomfort (6).

After CS, patients can experience significant discomfort; in fact, 79% of women have pain at the surgical site for up to 2 months (7).

Transversus abdominis plane block (TAPB) is a regional anesthetic technique that can provide analgesia for lower abdominal surgical procedures (8). Previous meta-analyses and recently published clinical trials have demonstrated promising results for this technique when it is used as part of multimodal postoperative pain treatment, but no consensus exists regarding the potency of this type of anesthetic procedure for analgesia after a CS.

Thus, it is important to stress that the incorrect execution of this anesthetic procedure results in a failure of the block, with consequently weak acute postoperative pain control (9,10).

The use of intrathecal opiates affects both somatic and visceral afferents (11), and postoperative analgesia is improved compared with a TAPB alone; however, this effect is achieved at the expense of an increased incidence of opioid-related side effects (12). The role of a TAPB in addition to intrathecal opiates is unclear (12).

The primary goal of this study was to determine whether a correctly performed ultrasound-guided TAPB (USG-TAPB) could provide patients who underwent a CS with better control of acute postoperative pain during the first 72 hours after surgery. In our study, the correct execution of an USG-TAPB was verified, and then the procedure was matched with the obtained analgesic effect after a CS.

Our secondary aims were to determine whether USG-TAPB could ensure a decline in postoperative re-

quests for opiates and fewer opiate-related side effects, the return of faster bowel function, and shorter recovery time without generating critical hemodynamic changes.

## **METHODS**

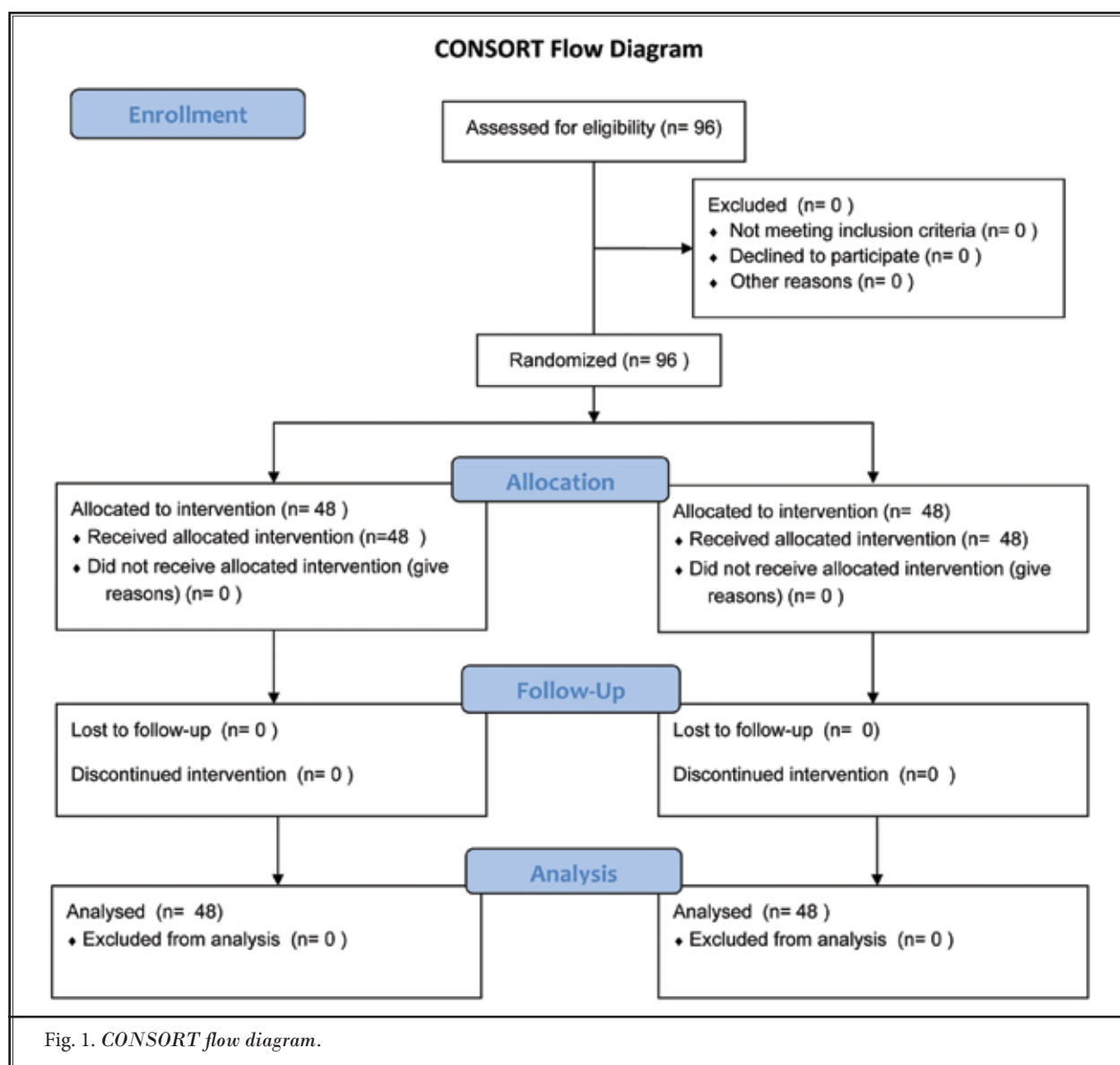
This study was approved by the local research ethics committee of the Health Unit of L'Aquila (Italy). The study was conducted at San Salvatore Academic Hospital (L'Aquila, Italy) in accordance with the CONSORT Statement for Reporting Trials. It has been registered with the following ClinicalTrials.gov Identifier: NCT02728323. Figure 1 shows the CONSORT flow diagram.

Written informed consent was obtained from all patients or their legal surrogates. All participants fulfilled the following inclusion criteria: 18 – 45 years of age, American Society of Anesthesiologists (ASA) physical status I – III, and scheduled for CS. The Pfannenstiel incision was performed.

Patients who met the following criteria were excluded: body mass index (BMI) > 35; allergy to local anesthetics; skeletal and/or muscle abnormalities of the spine; primary and/or secondary neurological diseases; psychiatric diseases; history of chronic pain and/or neuropathic disorders; history of drug abuse; state of sepsis, infection, and/or tumors within the skin on the back; primary or secondary coagulopathies; or pre-eclampsia or eclampsia.

A co-investigator and a research assistant recruited patients on the day of surgery. The patients' demographic information and clinical histories were collected via medical chart review using data collection forms designed for the study. The information recorded included patient gender, age, level of education in years, race, employment (yes/no), BMI (kg/m<sup>2</sup>), heart rate (HR, in bpm), systolic blood pressure (SBP, in mmHg), diastolic blood pressure (DBP, in mmHg), and oxygen arterial saturation (SaO<sub>2</sub>%). To maintain a balanced number of patients in each group, we elected to use randomized blocks with an equal size using Random Allocation Software (version 1.0, May 2004, Department of Anesthesia, Isfahan University of Medical Sciences, Isfahan, Iran) for parallel group trials. The treatment was blinded, and the treatment groups were revealed only after completion of the study. The blinding was such that the surgeons and patient/family had no knowledge of who was receiving USG-TAPB versus the placebo.

The patients, proxies, attending physicians, nursing staff, and research assistant who collected the study data were blinded to the study treatment. The blinding



was assessed, controlled, and maintained for the entire duration of the study.

The patients were randomized using the sealed envelope method to receive either USG-TAPB with local anesthetic (S group, N: 48) or placebo consisting of USG-TAPB with saline (C group, N: 48).

The patients' HR, arterial blood pressure (mean arterial pressure; MAP), and SaO<sub>2</sub>% were monitored while under anesthesia during surgery and during recovery, following the ASA guidelines (13).

Peripheral venous access was obtained in each patient before performing the anesthetic procedure.

Supplemental oxygen (2 L/min) was administered with a nasal dispenser under expired CO<sub>2</sub> control (ECO<sub>2</sub>C). During surgery, the vital and respiratory parameters (HR, MAP, SaO<sub>2</sub>%, and ECO<sub>2</sub>C) were monitored; if the recorded values were greater or less than 30% of the baseline parameters, appropriate supportive and pharmacological treatments were initiated to correct the values. Either colloid fluid therapy or vasoactive agents were used to maintain the heart rate and blood pressure, while either invasive or non-invasive support ventilation maneuvers were used to maintain the SaO<sub>2</sub>% and ECO<sub>2</sub>C.

Subarachnoid block (SAB) was performed in each group using a medial approach. An initial subcutaneous injection of 40 mg of a 1% lidocaine solution was applied with a 25 G Whitacre needle with the introducer at the L3-L4 space, and 13 mg of 0.5% isobaric levobupivacaine was subsequently injected slowly (over 2 minutes).

The time required to perform anesthesia as well as any complications that occurred were recorded for each group.

Cold tests and touch tests were bilaterally performed every 2 minutes to confirm that the dermatome levels were blocked, and the patient was deemed ready for surgery when a complete loss of cold and touch sensations was observed for the T8 to L4 dermatomes. Motor blockade was assessed using the modified Bromage score (BS). The BS was also used to determine the readiness for surgery and the motor blockade.

Inadequate surgical anesthesia was converted to general anesthesia and noted as an unsuccessful block.

At the end of the surgery, the USG-TAPB was performed bilaterally with the patient in a seated position, using a 22-gauge 100-mm atraumatic Sprotte-type needle for peripheral nerve block (SonoPlex Stim cannula, PAJUNK® GmbH Medizintechnologie, Geisingen, Germany). Under aseptic conditions, a linear ultrasound probe (5–12 MHz, SonoSite MicroMAXX® M-Turbo) was used to identify the abdominal muscle plane. The probe was placed close to the inferior boundary of the costal arch, and the external oblique (EOM), internal oblique (IOM), and transversus abdominis (TAM) muscles were identified. The ultrasound probe was moved from the medial to lateral site on the anterior axillary line, and the hyperechoic fascia between the IOM and the TAM was identified. The in-plane approach was used, and the tip of the needle was always visible. When the tip of the needle was inside this fascia and a sensation of loss of resistance was perceived by the anesthetist, 3–4 mL of saline was injected into the opening of the fascial plane, and 20 mL of 0.375% levobupivacaine was then injected into each side. In the C group, patients received USG-TAPB with 20 mL of saline in each side. Before each injection, color Doppler echocardiography was performed to avoid puncturing a vessel. The SAB and the USG-TAPB were performed by the same unblinded anesthetist.

A video of each executed USG-TAPB was recorded. Then, 72 hours after surgery, each video was viewed by a second blinded and expert anesthetist to control

the validity of the anesthetic target. Any discrepancy in judgment between the 2 anesthetists about the validity of the USG-TAPB was noted as an unsuccessful block, and the results were not included in the study.

After surgery, the patients were transferred to the phase 1 post-anesthesia care unit (PACU). Blinded nurses in the phase 1 PACU evaluated the patients using a modified Aldrete score (14). The phase 1 PACU patients were admitted to the phase 2 PACU only if they fulfilled the following criteria: modified Aldrete score of 9 or more, visual analog scale (VAS) score < 3, and no postoperative nausea and vomiting (PONV). Upon admission to the phase 1 PACU, vital signs were determined according to the PACU policy, and the symptoms (e.g., PONV) were recorded. Nurses assessed whether the phase 2 PACU patients met the discharge-to-home criteria (a score of  $\geq 9$  on the post-anesthesia discharge scoring system) (15). A blinded anesthesiologist tested and recorded the BS and voiding time (in minutes) after discharge from the operating theatre. The time of discharge was recorded.

At the phase 1 PACU, ketorolac (30 mg IV) was administered if the VAS score was 3. The pain management protocol in the phase 2 PACU consisted of the following: 1,000 mg of acetaminophen IV (maximum 4,000 mg/day) every 6 or 8 hours if the pain was VAS 3–5; 30 mg of ketorolac IV (maximum 120 mg/day) if the VAS score was 5–7; and 100 mg of tramadol IV if the VAS was  $\geq 7$  (maximum 400 mg/day). After discharge from the PACU, all patients were hospitalized in the ward; pain management consisted of 1,000 mg of acetaminophen per os every 6 hours if the VAS score was 3–5 (maximum 4,000 mg/day), 500 mg of acetaminophen with 30 mg of codeine per os every 4 hours for a VAS score of 5–7, and 100 mg of tramadol per os for a VAS score  $\geq 7$  (maximum 400 mg/day).

The primary goal of our study was to determine whether a correctly performed USG-TAPB could provide better control of acute postoperative pain. The sample size was estimated for comparison of the proportions of patients with a VAS score  $\geq 4$ .

The acute incident and resting pain as well as vital signs (HR, MAP, and SaO<sub>2</sub>%) were recorded at 8, 12, 24, 48, and 72 hours after surgery. In the first 24 hours, the incident pain (16,17) was assessed while determining the BS, and then patients were asked to move their legs while lying in bed.

Resting pain was assessed at rest in the sitting or lying position (18). Wound control was performed at the same time, during the post-surgery follow-up, in ac-

cordance with the opinions of the blinded surgeons.

The longevity of the sensory blockade was assessed by repeating the touch and cold tests (in minutes after the end of the anesthetic procedure) from the T8 to L2 dermatomes.

The secondary goal of the study was to assess patient satisfaction, consumption of painkillers, and healing of the surgical wound. Patient satisfaction regarding the executed anesthesiological procedure was assessed using a 4-step satisfaction scale (not at all/slightly/somewhat/very satisfied), and wound healing was assessed using a 3-step scale (unacceptable/acceptable/excellent healing), in accordance with the surgeon's opinion.

The time of recovery of bowel function (in days after the surgery) and the time of hospital discharge were also recorded.

During the entire perioperative period, the following adverse effects were assessed: hypotension (30% decrease in blood pressure), severe hypotension (> 30% decrease in blood pressure), cardiac arrest, spinal cord lesions, PONV, headache, infections, side effects of local anesthetics, and urinary retention.

### Statistical Analysis

The sample size was estimated in order to compare the proportions of patients with a VAS score  $\geq 4$ , as required for the primary endpoint. A total of 48 patients were needed in each group to detect a difference of 30%, with a power of 80% and an alpha value of 0.05 (2 sided).

Descriptive statistics (mean and standard deviation for numeric variables as well as frequencies for categorical variables) were calculated for all variables in the study. The chi-square or Fisher's exact test was used to examine differences between categorical variables. Continuous variables were tested for normality with the Shapiro-Wilk test and were analyzed using either the independent samples t-test to compare means or the Wilcoxon rank-sum test when adequate. A *P* value < 0.05 was considered statistically significant.

For analysis of the primary endpoint, a single cutoff of 4 was used to create a dichotomous variable (yes/no) for the VAS pain score (incident or rest pain). The Bonferroni correction for multiple statistical comparisons was used. Repeated measurements of pain (incident or rest pain) were analyzed with a repeated-measures analysis of variance (ANOVA) cal-

Table 1. Demographic and other baseline characteristics .

Characteristics	S group n=48	C group n=48
Allergy – Yes/No	9/39	9/39
Age – years	33.75 ± 5.55	33.45 ± 5.35
Grade/education 13 years (yes/no)	33/15	25/23
Race: - European: yes/no	42/6	46/2
- African: yes/no	2/46	0/48
- Asian: yes/no	2/46	1/47
Employment – Yes/No	25/23	26/22
Previous surgeries – Yes/No	20/28	18/30
BMI – Kg/m <sup>2</sup>	28.19 ± 5.23	26.91 ± 4.51
SBP	121.87 ± 12.44	124.68 ± 10.78
DBP	72.81 ± 7.91	72.70 ± 6.35
HR	88.77 ± 14.86	84.00 ± 11.16
SaO <sub>2</sub> %	98.83 ± 1.01	98.85 ± 1.16
ECO <sub>2</sub> C	32.66 ± 1.26	33.08 ± 1.48
Time to perform surgical procedure: minutes	62.81 ± 22.64	53.22 ± 16.02
Time to perform anesthetic procedure: minutes	7.16 ± 2.3	8.64 ± 3.17

Plus-minus values are means and standard deviations. BMI: Body Mass Index

SBP: Systolic Blood Pressure

DBP: Diastolic Blood Pressure

HR: Heart Rate

SaO<sub>2</sub>%; oxygen arterial saturation

ECO<sub>2</sub>C: expired CO<sub>2</sub> control

culated on the rank-transformed data. Statistical analysis was performed using STATA 12 software (StataCorp. 2011. Stata Statistical Software: Release 12. College Station, TX: StataCorp LP) and SAS 9.4 (SAS 2002-2012 by SAS Institute Inc., Cary, NC, USA).

### RESULTS

A total of 96 consecutive patients were enrolled and randomized. Of these, 48 patients were randomly selected to receive USG-TAPB with local anesthetic; the remainder received USG-TAPB with saline (Fig. 1).

The demographic and other clinical characteristics of the patients are presented in Table 1.

There were no differences between the 2 groups in terms of the level of anesthesia within the dermatomes, which was evaluated with the touch and cold tests, after SAB. The patients had sensory blockade from the T10 to L2 dermatomes with the same proportion of positive and negative anesthetic responses to the sensory tests. All patients in each group experienced a bilateral block after SAB.

During the surgical procedure, externalization of the uterus was needed in each patient in both groups.

No patient in either group had intraoperative complications such as intraoperative mild hypotension (30% decrease in blood pressure) or severe hypotension (> 30% decrease in blood pressure). No patient in either group exhibited PONV or headache related to spinal block.

No postoperative complications were recorded during hospitalization.

The time of recovery of bowel function was shorter in the S group, while patient satisfaction and time of hospital discharge were significantly different between the groups (Table 2).

Sensory and motor blockade showed similar results in both groups ( $4.2 \pm 1.3$  hours and  $3.6 \pm 1.6$  hours, respectively).

No discrepancy in judgment between the 2 anesthesiologists regarding the validity of the USG-TAPBs was noted, and no unsuccessful block was recorded. All performed anesthetic blocks were included in the study.

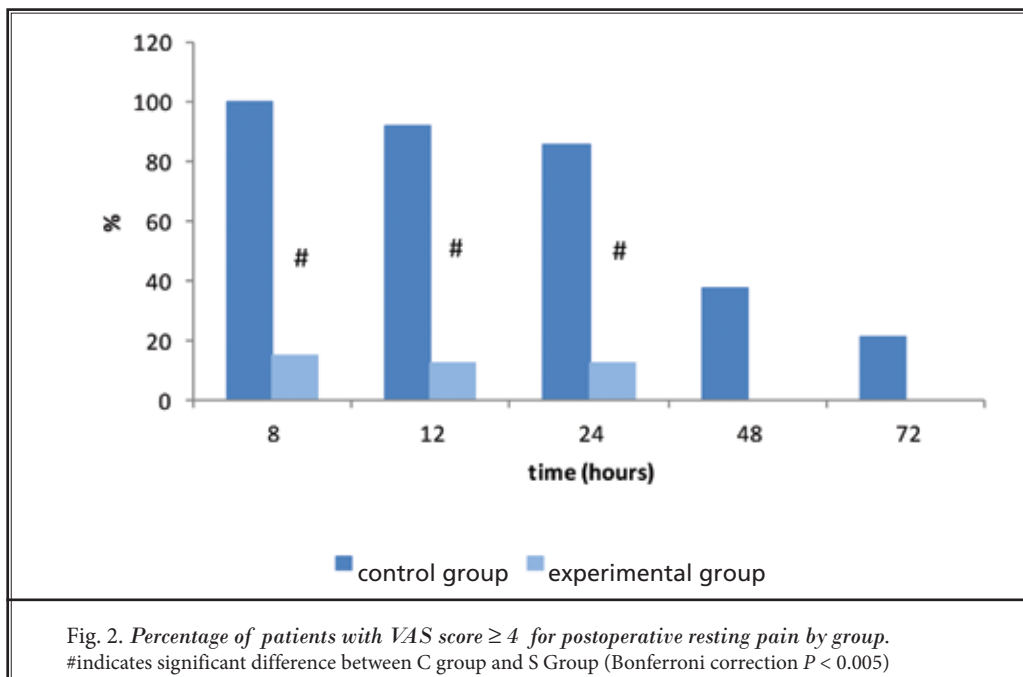
Our analysis revealed that the proportion of patients with a pain score  $\geq 4$  (incident or rest pain) was significantly different between the S and C groups (Figs. 2, 3). ANOVA on ranks revealed that the main effect existed only on the treatment of incident pain ( $P < 0.0001$ ) and resting pain ( $P < 0.0001$ ). Patients in the S group commonly required acetaminophen to control their postoperative pain during follow-up. S group patients also required Ketorolac in the first 24 hours, as did the patients in the C group, although the consumption of this drug (in mg) was significantly lower in the S group. Requests for painkillers decreased over time in both groups, although the proportion of patients who needed these drugs was significantly different between groups (Table 3).

Table 2. Comparison of studied parameters between groups post surgery.

Variables	S group n=48	C group n=48	P-value
<b>Time of recovery of the bowel function</b>			
hours median	31.5 ± 11.2	47.5 ± 14.4	P = 0.000
median	24	48	
range	24 – 48	24 – 72	
<b>Hospital discharge</b>			
days mean	3.0 ± 0.0	3.46 ± 0.8	P = 0.000
range	3 – 3	3.23 – 3.68	
<b>Satisfaction</b>			
Not at all satisfied	0/48	0/25	P < 0.001**
Slightly satisfied	2/48	18/48	
Somewhat satisfied	18/48	29/48	
Very satisfied	28/48	1/48	

\*Two-sample Wilcoxon rank-sum (Mann-Whitney)

\*\*chi square test



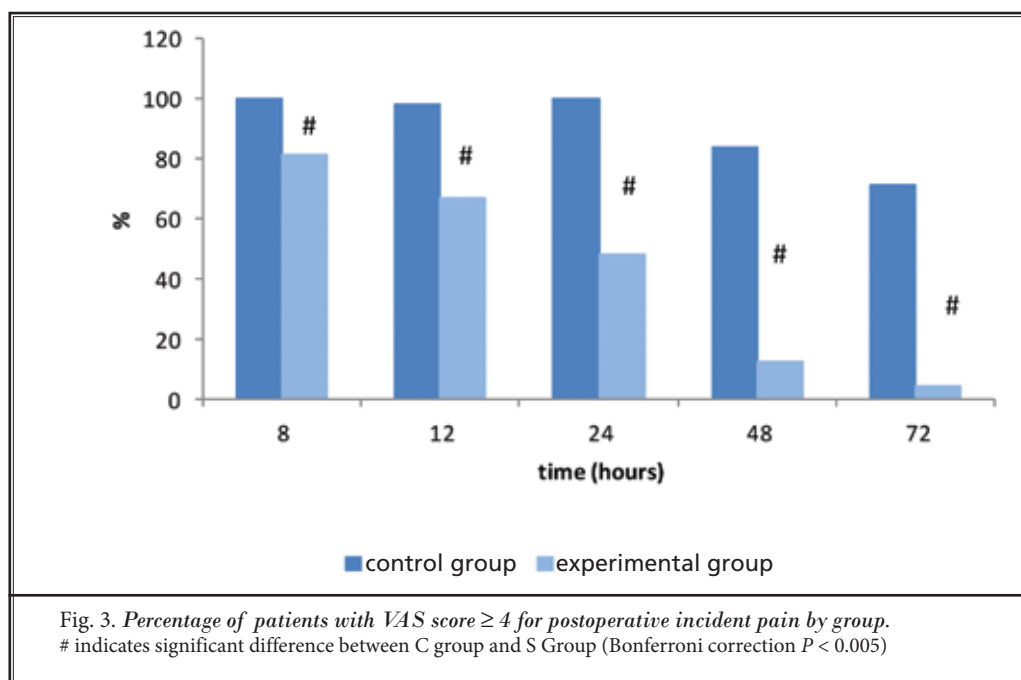


Table 3. Request of pain-killers, during follow-up (consumption in mg) -

Pain-killer	S group Number of patients (consumption in mg)	C group Number of patients (consumption in mg)	P*
<b>Post-surgery follow-up</b>			
Ketorolac after:			
- 8 hours	20 (600)	41 (840)	0.000
- 12 hours	13 (390)	37 (1110)	0.0000.000
- 24 hours	8 (240)	36 (1080)	0.004
- 48 hours	2 (60)	13 (390)	0.026
- 72 hours	0 (0)	6 (180)	
Acetaminophen after:			
- 8 hours	48 (48000)	48 (48000)	-
- 12 hours	32 (32000)	45 (45000)	0.002
- 24 hours	26 (26000)	47 (47000)	0.000
	-	-	-
	-	-	-
Tramadol after:			
- 8 hours	3 (300)	33 (3300)	0.000
- 12 hours	3 (300)	27 (2700)	0.000
- 24 hours	0 (0)	28 (2800)	-
- 48 hours	0 (0)	5 (500)	-
- 72 hours	-	-	-

\*Chi square test or Fisher exact test

## DISCUSSION

This clinical study demonstrated that the proper choice of anesthetic technique is essential for postoperative pain relief after CS. Neuraxial or systemic

analgesia with or without opiates is a common and widespread approach, although these drugs have been associated with several adverse effects.

No clinical trials have been performed in which the video of each USG-TAPB procedure was recorded and then viewed by a second, blinded, expert anesthetist to control the validity of the anesthetic target. The double control measures that matched procedure judgment between the 2 anesthetists ensured the correct execution of the block; therefore, its analgesic potency can be measured.

Our findings suggest that correct performance of this myofascial block, along with multimodal postoperative pain treatment, may control acute postoperative pain (10).

Patients in the S group experienced effective pain control; the proportion of patients with a resting pain score  $\geq 4$  was significantly greater in the C group. In the S group, less than 20% of the patients experienced resting pain with a VAS score  $\geq 4$ , and after the first 48 hours, no patient perceived pain during rest in bed.

The proportion of patients with an incident pain score  $\geq 4$  decreased over time in both groups. However, in the S group, this proportion was less than 20% after 48 hours, while in the C group it remained greater than 80%.

These data suggest that USG-TAPB provides effective postoperative analgesia, and our results may also explain why the patients preferred USG-TAPB.

Pain after CS is likely related to nociceptive stimuli from the surgical site due to mechanical irritation and damage to the terminals of the anterior branches of spinal nerves that are responsible for the sensibility of the abdominal wall from the T6 to L1 dermatomes. Visceral and uterine cramping pain is another important component of acute postoperative pain after CS.

The longer sensory blockade provided by USG-TAPB and its higher-quality and longer-lasting analgesia ensure high-quality control of somatic pain, although this approach cannot block visceral afferent nerves.

This lack of visceral nerve control may explain the persistence of acute postoperative pain 48 hours after surgery. However, if a multimodal scheme for acute postoperative pain is initiated early, it is possible to decrease the number of painful components of the surgical wound in the abdomen.

Carney et al (19) demonstrated that the mechanism of analgesia produced by abdominal TAP block might not solely involve the blockade of distal sensory efferents; instead, this result may be due to a more proximal effect, perhaps at the level of the paravertebral space.

The experiment conducted by Borglum et al (20)

with magnetic resonance imaging in the sagittal plane found the distribution in the paravertebral space ranged cranially to T6 and caudally to T12 after a dual bilateral USG-TAPB. Thirty milliliters of 0.375% ropivacaine was injected bilaterally at T9, and this distribution pattern did not change from 30 to 180 minutes (20).

In agreement with the results of Borglum et al (20), USG-TAPB consistently resulted in anesthesia of the sensory afferent nerves of Th6-Th12 bilaterally in the anterior abdominal wall. Moreover, dermatomal anesthesia was consistently present on the upper and lower medial quadrants of the anterior abdominal wall with a high-quality and long-lasting block.

Many clinical trials in the international literature do not contain information that verifies that the anesthetic block was performed in a proper manner.

The matching judgments of the 2 anesthetists regarding the validity of the block in the videos of the anesthetic procedures ensured that the USG-TAPB was correctly performed.

Therefore, based on our results, it is possible to argue that when this anesthetic block is performed correctly, it could have promising results in for postoperative pain treatment after a CS, even without the addition of intrathecal opiates.

Under ultrasound guidance, it is possible to correctly place the proper volume of anesthetic drugs in the myofascial plane between the IOM and the TAM.

One limitation of this study is that, while USG-TAPB could provide good analgesia for acute postoperative somatic pain related to the surgical wound, opiates or others painkillers were still needed for the management of visceral acute postoperative pain.

Our data suggest that if a TAPB is correctly performed and is part of a multimodal analgesic scheme, effective pain control is possible for both somatic and visceral acute pain. Furthermore, the need for painkillers is reduced and their related side effects are moderate, yielding a positive benefit/cost ratio.

Moreover, decreasing the amount of opiates consumed could have a positive effect on the time of recovery of bowel function, which was shorter in the S group.

It would have been useful to record and match the infusion of oxytocin with the abdominal pain. Therefore, further studies are needed to understand whether the choice of a peripheral myofascial block such as TAPB could completely control the acute postoperative pain after CS as part of a multimodal pain treatment.



## CONCLUSIONS

In conclusion, the results of this study suggest that a properly performed USG-TAPB should be considered a viable alternative to common analgesic procedures

performed for acute postoperative control after a CS, as suggested by Factor and Chin (9).

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