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# The new trending pain-free cesarean section: TAP block versus IV PCA

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# **Abstract**

**Background:** Women's pain satisfaction post-cesarean section remains a challenge. Accurate assessment of pain severity of post-cesarean section helps to choose the most appropriate anesthetic approach, drug, and dose, as well as improvement of treatment of postoperative pain. Our objective was to compare the efficacy of ultrasound-assisted transversus abdominis plane (TAP) block versus IV patient-controlled analgesia (PCA) in the first 24 h postoperative in women who underwent cesarean section. The primary outcome was postoperative pain at 2, 4, 6, 12, and 24 h. The secondary outcomes were intestinal mobility, early mobilization, nausea, vomiting, heart rate, and respiratory rate.

**Results:** A cross-sectional study has been conducted on 70 women who are planned for elective cesarean section. They were divided into 2 groups; "group A" (n = 35), women who received TAP block, and "group B" (n = 35), those who received PCA. Pain score, heart rate, respiratory rate, intestinal motility, nausea, and vomiting have been assessed 2, 4, 6, 12, and 24 h postoperatively. The degree of pain was significantly lower in "group B" than in "group A" in all time intervals (p < 0.001). Heart rate was significantly higher in women in "group B" compared to those in "group A" only at 2 and 4 h postoperative (p < 0.001). Nausea and vomiting were also significantly higher in women in "group B" compared to those in "group A" (p value 0.03 and 0.04, respectively). Regarding intestinal motility, it was audible in "group A" earlier than in "group B."

**Conclusions:** Both TAP block and PCA are effective in postoperative pain relief after cesarean section; however, PCA is more superior, especially for visceral pain. Nevertheless, TAP block has the privilege of avoiding systemic action of opioids used in PCA. PCA can easily be applied while TAP block needs more training and an intraoperative ultrasound machine. Complications and side effects of both were minimal when adjusting the doses.

**Keywords:** TAP block, IV PCA, Pain-free cesarean section

# **Background**

Recent literature has reported that worldwide, including Egypt, there has been a dramatic surge in the cesarean delivery rate (Mobarak and Sultan 2019). Such surge is accompanied by increased women's awareness and demands for pain-free techniques during and after the surgery. This motivates obstetricians to use new approaches and methodologies rather than the routine

methods of postoperative analgesia. Normally, uncomplicated cesarean section (CS) may result in moderate to severe pain during the first 48 h following surgery (Gerbershagen et al. 2013). Hence, pain relief is critical, as it affects both the mother and her care for the newborn. Moreover, insufficient pain control may badly influence recovery, mother—infant bonding, which in turn could lead to more persistent postsurgical pain. Women undergoing cesarean delivery have further compelling reasons to receive sufficient pain relief since early mobilization represents an essential factor that decreases the risk of thrombo-embolic disease, which is known to be increased throughout pregnancy and puerperium. Relieving pain in such women improves their care for the

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newborn and helps them breastfeed efficiently (DiNicola 2011).

There are many various methods to control postoperative pain. However, searching for the best method is still ongoing. Several techniques have been used. Nevertheless, using opioids throughout different routes is still the gold standard (Taneja et al. 2017).

In cesarean delivery, TAP block represents a convenient primary analgesic for women not receiving neuraxial morphine for any reason. TAP block is an assisting analgesic technique used to decrease either the use of opioids during the intraoperative period or the use of systemic analgesics for postoperative pain management. The TAP block is a field block of the thoracolumbar nerves, running in the fascial plane between the internal oblique muscle and the transversus abdominis muscles. The anterior primary rami course between the internal oblique and the transversus abdominis muscles and subsequently branch into the lateral and anterior cutaneous nerves at approximately the midaxillary line (Tsai et al. 2017).

Patient-controlled analgesia "PCA" results in greater patient satisfaction, as it is more effective to relieve pain than non-patient opioid injections (McNicol et al. 2015). Moreover, PCA is recommended for women in labor pain. Pain accompanying contractions, particularly when intensified by the use of induction agents, i.e., oxytocin, can be effectively controlled and minimized (Srivastava et al. 2009). The purpose of using PCA is to effectively control pain at a desired dose and schedule. This is done by allowing patients to administer a predetermined bolus dose of medication on demand. Each bolus could be administered alone or together with another medication. However, PCA is used for the treatment of acute, chronic, postoperative, and labor pain. The most commonly used drugs are opioids and local anesthetics, although other analgesics can be used (Mann et al. 2005).

Our objective was to compare the efficacy of ultrasound-assisted transversus abdominis plane (TAP) block versus IV patient-controlled analgesia (PCA) in the first 24 h postoperative in women who underwent cesarean section. The primary outcome was postoperative pain at 2, 4, 6, 12, and 24 h. The secondary outcomes were intestinal mobility, early mobilization, nausea, vomiting, heart rate, and respiratory rate.

# **Methods**

Our study is a pilot cross-sectional study. It is a multicentric study as it was conducted in 3 different private hospitals (El-Nada, Al-Safwa, and Al-Zohour hospitals) at 6th October City, Giza, Egypt, from January 2020 to September 2020. The medical board of Al-Zohour hospital endorsed the ethical approval for this study.

Seventy pregnant women with repeated elective cesarean sections were included if they fulfilled the following criteria: age from 20 to 35 years, gestational age from 37 to 39 weeks, body mass index (BMI) 20–30 kg/m², hemoglobin level above 11 g/dl, and history of previous CS to have a previous experience with postoperative pain. Women with only one previous cesarean section and no contraindication for vaginal delivery have been offered vaginal delivery after cesarean section, and those who denied have been included in the study.

Pregnant women with any of the following medical disorders have been excluded from the study; diabetes, hypertensive disorders with pregnancy, coagulation disorders, depression, chronic pelvic pain, allergy to analgesic drugs, and any psychological disorders.

Participating women were classified into 2 groups: "group A" (n=35), women who received TAP block, while "group B" (n=35) received PCA. Pregnant women were recruited to participate in the study from the outpatient antenatal clinic when the elective CS was scheduled. The following were done for the participating women: complete medical history, obstetric history, routine antenatal and preoperative investigations checked, antenatal fetal growth monitoring by ultrasound and Doppler when needed. All women asked for new trends in relieving pain as TAP block or PCA were counseled preoperatively, and oral explanation, using no medical jargon, was given to all women, and written consent was taken.

All women were operated on under spinal anesthesia by a consultant obstetrician. All women had uncomplicated cesarean sections with minimal blood loss < 500 ml. After the end of the operation, consultant anesthetist under aseptic precautions introduced TAP block under ultrasound guidance with a single injection as follows: The needle was introduced in the plane of the ultrasound probe directly under the probe and advanced until it reached the plane between the internal oblique and transversus abdominis muscles. The probe followed the needle entry point in order to avoid intraperitoneal injection, intramuscular, or even intravascular injections. Aspiration was done before injection to ensure that all local anesthetic (LA) was in the right plane.

Upon reaching the plane, 2 ml of saline was injected to confirm the correct needle position (hydro-dissection), after which 20 ml of local anesthetic solution is injected. We used 0.2% isobaric marcaine and 0.5% lidocaine (Sigma Tec pharmaceutical, Egypt) in order to decrease local anesthetic systemic toxicity (LAST) and to take advantage of the synergistic effect of both drugs, marcaine 8 ml and lidocaine 5 ml. Then, 7 ml saline was injected. The transversus abdominis plane is visualized expanding with the injection (appears as a hypoechoic spread) (Tsai et al. 2017).

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For women chose to have PCA for postoperative pain relief, an elastomeric PCA pump single-use with 300 ml capacity was used. A basal 8 ml/hour infusion of analgesic-containing infusion with a button was used to give an additional bolus dose of 1 ml with a lockout time of 15 min. Nalbuphine 80 mg (Amoun pharmaceutical), ketolac 120 mg (Amriya pharm, Egypt), and granitryl 3 mg (Egyphar, Egypt) were used. The rest of the bottle was normal saline.

Postoperative follow-up of all women was done at those intervals: 2 h (after cessation of the effect of spinal anesthesia), 4 h, 6 h, 12 h, and 24 h postoperatively. The following data were recorded: nausea, vomiting, pain score, heart rate, respiratory rate, uterine contractility by fundal level, intestinal mobility, time to start mobilization, need for additional analgesics. Maternal pain score was evaluated and documented in the patients' notes in the maternity ward. A numeric rating scale (NRS) was used. The pain was rated at 2, 4, 6, 12, and 24 h after surgery. The pain scale ranged from 0 (= no pain) to 10 (= worst pain imaginable) (Safikhani et al. 2018).

# Statistical analysis

Statistical Package for the Social Sciences "SPSS" v. 25 was used to perform all statistical analyses. Quantitative parameters were expressed as mean  $\pm$  standard deviation, while numbers and percentages were used for categorical variables. To compare group 1 with group 2, we used the independent samples t test, while differences in frequencies were analyzed using the chi-square test. p value <0.05 was considered to be statistically significant.

#### Results

The present study results revealed that no significant differences were detected between both groups regarding age, BMI, and the number of previous cesarean sections (Table 1). Although pain sensation degree (using NRS) is decreased in both groups along the first 24 h postoperative, the NRS values were significantly lower in the PCA

**Table 1** Comparisons between the two groups regarding age, BMI, and previous cesarean sections

	"Group A" (n = 35)	"Group B" (n = 35)	<i>p</i> value
Age (years)	27.64 ± 4.49	$26.61 \pm 3.96$	0.316
BMI	$28.57 \pm 6.64$	$29.02 \pm 5.33$	0.756
Previous CS			0.607
Previous 1 CS	25 (71.41%)	23 (65.72%)	
Previous 2 CS	10 (28.57%)	12 (34.28%)	

Independent samples t test was used to compare normally distributed variables between both groups; Values are expressed as Mean  $\pm$  SD. Pearson chi-square test was used for qualitative data between both groups; Values are expressed as number and percentage

group "group B" than in the TAP block group "group A" (p < 0.001) (Table 2).

Heart rate was significantly higher in women in "group B" compared to those in "group A" at 2 and 4 h postoperatively (p<0.001); however, there is no significant difference between both groups in other time periods (p>0.05). Concerning respiratory rate, there is no significant difference between both groups in all time periods (p>0.05). On the contrary, nausea, and vomiting were significantly higher in women in "group B" compared to those in "group A" (P value 0.03 and 0.04, respectively) (Table 3).

Regarding intestinal motility, it was observed to be audible in "group A" earlier than "group B." At 2 h postoperative, intestinal motility was found significantly audible

**Table 2** Comparisons between the two groups regarding pain sensation degree (numeric rating score)

	"Group A" (n = 35)	"Group B" (n = 35)	p value
2 h	3.12±0.78	$2.52 \pm 0.66$	< 0.001*
4 h	$2.37 \pm 0.71$	$1.47 \pm 0.61$	< 0.001*
6 h	$1.46 \pm 0.43$	$0.92 \pm 0.22$	< 0.001*
12 h	$1.12 \pm 0.25$	$0.83 \pm 0.15$	< 0.001*
24 h	$1.23 \pm 0.39$	$0.68 \pm 0.12$	< 0.001*

Independent samples t test was used to compare normally distributed variables between both groups; Values are expressed as Mean  $\pm$  SD

**Table 3** Comparisons between the two groups regarding heart rate, respiratory rate, nausea, and vomiting

	"Group A" (n = 35)	"Group B" (n = 35)	<i>p</i> value
Heart rate			
2 h	$72.9 \pm 7.6$	$83.3 \pm 7.1$	< 0.001*
4 h	$72.8 \pm 6.9$	$83.7 \pm 6.7$	< 0.001*
6 h	$72.6 \pm 9.4$	$74.9 \pm 7.9$	0.272
12 h	$71.6 \pm 8.7$	$75.0 \pm 9.1$	0.115
24 h	71.9 ± 9.2	$74.9 \pm 7.5$	0.139
Respiratory rate			
2 h	$17.8 \pm 2.6$	$17.4 \pm 1.4$	0.427
4 h	$16.9 \pm 2.6$	$16.8 \pm 1.3$	0.839
6 h	$16.9 \pm 2.9$	$16.8 \pm 1.4$	0.854
12 h	$16.5 \pm 2.7$	$16.9 \pm 1.5$	0.446
24 h	$16.4 \pm 3.1$	$16.7 \pm 1.1$	0.591
Nausea	3 (8.57%)	10 (28.57%)	0.03*
Vomiting	1 (2.86%)	6 (17.14%)	0.04*

Independent samples t test was used to compare normally distributed variables between both groups; Values are expressed as Mean  $\pm$  SD. Pearson chi-square test was used for qualitative data between both groups; Values are expressed as number and percentage

<sup>\*</sup>Statistically significant ( $p \le 0.05$ )

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in "group A" than in "group B," while there is no significant difference between both groups at 6 and 24 h post-operative (Table 4).

#### Discussion

Surgery and anesthesia represent critical healthcare services, aiming to minimize the risk of mortality and disability. Moreover, anesthetic measures help to reduce the incidence and intensity of acute pain during and immediately after surgery (Gan 2017).

As the cesarean section rate increased steeply all over the world, obstetricians and anesthetists should search for optimal pain management techniques to improve postoperative outcomes and patient satisfaction. Accurate assessment of pain severity of post-cesarean section helps to choose the most appropriate anesthetic approach, drug, and its dose, as well as improvement of treatment of postoperative pain. However, the ideal route and dose of the postoperative analgesia after CS are still debatable.

This study was conducted on 70 women who had at least one previous CS without TAP block or PCA, so they can compare their past experience of pain with the pain-relieving techniques used in this study. We selected all our women with an age range of 20–25 years (in their reproductive age). The BMI was chosen to be 20–30 kg/m² in order not to have any weight influence on postoperative mobility that could affect our results. We have excluded women with systemic medical disorders that could affect their heart rates, intestinal mobility, or their perception and expression of pain.

Women were classified into "group A" received TAP block, and "group B" received PCA. Data analysis showed no significant differences between both groups regarding age, BMI, and the number of previous cesarean sections.

**Table 4** Observation of intestinal motility

	"Group A" (n = 35)	"Group B" (n = 35)	p value
2 h			
Audible	20 (57.14%)	5 (14.29%)	< 0.001*
Sluggish	9 (25.71%)	12 (34.29%)	
Inaudible	6 (17.14%)	18 (51.43%)	
6 h			
Audible	26 (74.29%)	24 (68.57%)	0.861
Sluggish	6 (17.14%)	7 (20.00%)	
Inaudible	3 (8.57%)	4 (11.43%)	
12 h			
Audible	35 (100%)	35 (100%)	NA

Pearson chi-square test was used for qualitative data between both groups; Values are expressed as number and percentage

However, the PCA was superior in postoperative pain relief rather than TAP block.

In our study, we used 0.2% isobaric marcaine and 0.5% lidocaine in order to decrease local anesthetic systemic toxicity (LAST) and to take advantage of the synergistic effect of both drugs and marcaine 8 ml, lidocaine 5 ml; then, 7 ml saline was injected. The toxicity of local anesthesia in truncal regional anesthesia blocks can exceed a systemic threshold. This had been confirmed in a recent meta-analysis done by Rahiri et al. via assessing the systemic concentrations of local anesthesia after perioperative single-shot TAP or rectus sheath block. They discovered that 8.6% of patients had systemic concentrations that were higher than the widely agreed threshold for LAST (Rahiri et al. 2017).

However, the anesthesiologists are facing the challenge of finding a balance between utilizing a LA, which provides effective analgesia while minimizing the risk of LAST. Higher sensitivity can increase the risk of LAST in pregnancy as a result of altered physiology. However, reduced protein binding, higher vascularity, cardiac activity, and tissue blood flow, as well as increased neuronal susceptibility to LA, can all be clarified. Because of the consequences of pregnancy, TAP block for CS necessitates the administration of significant amounts of local anesthesia agent bilaterally in such a highly vascular region (Tsen et al. 1999; Ng et al. 2018).

In the present study, after a detailed explanation about techniques' pros and cons, both techniques have been accepted by women. NRS is one of the most commonly used pain scales in medicine. It is highly recommended, as the optimal response scale, to assess pain among adult patients without cognitive impairment (Safikhani et al. 2018).

The present study revealed that, although pain sensation degree (using NRS) is decreased in both groups along the first 24 h postoperative, the NRS values were significantly lower in PCA group "group B" than in TAP block group "group A" (p < 0.001) (Table 2).

The meta-analysis carried out by Champaneria et al. (2016) evaluated and compared TAP block for acute pain relief following CS to normal/control practice. The study concluded that, for pain at rest and pain with movement, TAP block was more efficient than control, i.e., TAP block significantly controls pain at rest when compared with placebo or no TAP block (Champaneria et al. 2016).

Similarly, a meta-analysis by Mishriky et al. (2012) showed that post-cesarean TAP block is associated with lower pain scores at rest (6 and 12 h) and with movement (6 and 12 h) (Mishriky et al. 2012). So, TAP block appears to be beneficial for postoperative analgesia based on this available evidence. Overall, the studies concluded that TAP block reduces the need for opioids and can

<sup>\*</sup>Statistically significant ( $p \le 0.05$ )

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reduce pain scores in the first 12 h following CS. Regarding the effectiveness of TAP block to control pain following cesarean delivery, our findings are in agreement with other previous studies as participant women already had a past experience with postoperative pain during their previous cesarean sections. However, those studies did not compare TAP block with PCA for post-cesarean pain relief. They compared the TAP block technique to the routine postoperative medications given post-cesarean.

In 2018, Ng et al. carried out a meta-analysis to evaluate the efficacy of a high dose of TAP block versus a low one given. The results of their meta-analysis revealed that both groups (low-dose and high-dose groups) showed similar postoperative analgesia and opioid-sparing effects (opioid consumption, time-to-first request, 24 h pain scores). As a result, it was concluded that there would be no enhanced advantage of local anesthetic above a certain dosage threshold. Furthermore, low-dose approaches for post-cesarean TAP block can reduce the risk of local anesthetic toxicity while maintaining analgesic efficacy (Ng et al. 2018). This comes in concordance with our results.

In our study, women who received IV PCA "group B" had pain scores significantly lower than those in those TAP block "group A" after 2, 4, and 6 h. Nalbuphine has been chosen rather than morphine to reduce the well-known side effects of morphine, e.g., respiratory depression, pruritus, and postoperative nausea vomiting. Nalbuphine, on the other hand, being  $\mu$  antagonist and k agonist, has a ceiling effect in its respiratory depression; hence, it is considered to be safer than morphine. The incidence of adverse effects like pruritus and PONV is lower with nalbuphine than morphine (Gal et al. 1982). Yeh et al. (2008) used different combinations of morphine and nalbuphine and found no difference in PCA requirements in the postoperative period in patients undergoing open gynecological surgeries (Yeh et al. 2008).

The superiority of PCA over TAP block regarding pain relief and patient satisfaction might be due to the effect of combinations of PCA drugs systemically, affecting visceral pain, in contradiction with TAP block, which acts on somatic pain only in the anterior abdominal wall. On the contrary to our results, Erbabacan et al. (2015) concluded that, in lower abdominal surgeries, 30 mL of TAP block is as effective as intravenous PCA in pain treatment. In addition, comparing intravenous PCA with TAP block revealed that the latter is regarded as a more superior approach since it can avoid the systemic actions of morphine used for PCA and as its analgesic effect starts earlier (Erbabacan et al. 2015). However, this study was carried out on lower abdominal surgeries, not cesarean sections that exclude the pain from postoperative uterine contractions.

The results of the present study revealed that heart rate was significantly higher in women in "group B" compared to those in "group A" at 2 and 4 h postoperative (p<0.001); however, there is no significant difference between both groups in other time periods (p > 0.05). This might be due to the vasodilating effect of nalbuphine used in IV PCA. Thus, our findings were consistent with those concluded by Erbabacan et al. (2015), where heart rate values were found to be significantly lower in the TAP block group than in the PCA group. However, this can be attributed to less sympathetic system activation accompanied by less pain sensation in patients. Although findings do not support such effect due to the absence of significant difference between the mean values of arterial pressure, this effect can be attributed to the vasodilation effect of morphine used in PCA (Erbabacan et al. 2015). Despite this statistical finding, this did not affect the patients' general condition by clinical observation and was not felt by the women.

Comparing the effect of TAP block and IV PCA on respiratory rate, our study revealed no statistically significant differences that might be explained by the low pain score in both groups.

Regarding nausea and vomiting, they were found to be significantly higher in women in "group B" compared to those in "group A" (Table 3). This difference may be related to the dose of nalbuphine given in the PCA group. Reductions in postoperative nausea and vomiting, antiemetic requirements have been demonstrated. In disagreement with our results, Siddiqui et al. (2011) published a meta-analysis to evaluate the clinical effectiveness of TAP block on nausea alone and found no significant reduction in nausea score. However, this might be attributed to the different doses used (Siddiqui et al. 2011). Similarly, Mäkelä et al. (2019) carried out a study on 205 patients and evaluated oxycodone, which has an emetic effect, and concluded that the IV PCA patients experienced more nausea at 4 h and more vomiting at 8 h (p=0.001 and p=0.01, respectively) (Mäkelä et al. 2019). Those studies disagreed with our results, but we can explain this by using different doses than we used in our study.

In our study, 3 cases from "group A" (TAP block) required additional analgesics taken intramuscularly. Using PCA or TAP block to relieve pain after CS minimizes the need for additional analgesics.

Uterine contractility can be detected by fundal level palpation. In our study, 5 patients out of 70 from both groups were recorded to have a fundal level above the umbilicus when compared to others (65/70) who all had a fundal level below the umbilicus. Furthermore, no significant differences were recorded between IV PCA and TAP block on uterine contractility.

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Regarding intestinal motility, auscultation using a stethoscope was done at 2, 6, and 24 h intervals. It was observed to be audible in "group A" earlier than "group B." At 2 h postoperative, intestinal motility was found significantly audible in "group A" than in "group B," while there is no significant difference between both groups at 6 and 24 h postoperative (Table 4). This might be attributed to the systemic effect of PCA drugs. In the Cochrane review, Charoenkwan and Matovinovic (2014) concluded that after major gynecological surgery, early postoperative feeding is safe and enables earlier recovery of bowel function, a shorter hospital stay, and higher satisfaction (Charoenkwan and Matovinovic 2014).

Regarding early mobilization of women in the studied groups, PCA with its sedative effect played a role in delaying patient mobilization when compared to those receiving TAP block. Similarly, Mäkelä et al. (2019) found that the mean time of mobilization was 17 h, which is longer when compared with a 6-h recommendation (Mäkelä et al. 2019).

It has been reported that complications and common side effects of the PCA approach are connected to the essential mechanism of the procedure and the medications used. The most common complications of PCA pumps comprise failure to use anti-reflux valves, "runaway" pumps, PCA by proxy, incorrect syringe placement, and machine tampering (Pastino and Lakra 2021).

Although TAP block in cesarean delivery is useful as a primary mode of analgesia in women not receiving neuraxial morphine for any reason, difficulties in performing the block might occur due to anatomical changes after cesarean delivery. However, to perform the block, the ultrasonographic anatomy is ideally recommended to solve this problem, even following cesarean delivery. The main drawback of TAP block is that it does not provide visceral analgesia. As a result, this may explain why certain studies have failed to demonstrate TAP block's dominance over other modalities.

TAP block is a minimally invasive technique with a very high safety profile. However, still it may encounter possible complication as needle trauma, intraperitoneal injection, neural ischemia, inadvertent intravascular injection, local anesthetic toxicity, infection, femoral nerve palsy, and poor/failed block. However, with proper training, only a few cases of serious events were reported in the literature (Walker 2010).

We searched in the literature and found out that most of the research published on both techniques was done on surgeries other than CS. So we believe that our study would open more research on this point, especially with the dramatic increase in CS rates and persistent demand for pain-free surgeries.

# Limitations of the study

Firstly, women chose the type of analgesia according to patient discretion, so no randomization was done. Also, the number of cases was limited, but the reason was that the study was carried out in private hospitals, and both techniques could add a financial burden on the women having CS, so a considerable number of our patients did not agree to participate in the study.

## Conclusion

Control of pain after cesarean section is considered a dramatic request from women nowadays. TAP block versus IV PCA was studied due to the effectiveness of both maneuvers in relieving postoperative pain. However, IV PCA was superior on TAP block due to its visceral effect, while TAP block was preferred to avoid systemic action of opioids used in PCA. PCA can be easily applied, while TAP block needs hand skills. Complications and side effects of both types were minimal when adjusting doses of drugs used.

#### Abbreviations

TAP: Transversus abdominis plane; PCA: Patient-controlled analgesia; CS: Cesarean section; NRS: Numeric rating scale; BMI: Body mass index; LA: Local anesthesia; LAST: Local anesthetic systemic toxicity.

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None.

# Authors' contributions

SS concerned with research idea, study design, data collection, and manuscript writing. SMS concerned with data collection and manuscript writing. MA concerned with data analysis and manuscript writing; MG concerned with data collection. All authors read and approved the final manuscript.

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The authors declared that this study has received no financial support.

### Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

#### **Declarations**

# Ethics approval and consent to participate

The study has been carried out as a multicenter study in 3 private hospitals and the ethical approval has been taken through Al-Zohour Hospital Medical Ethical committee. Unfortunately, some private hospitals don't have integrated system for approvals' numbering; however, the approval letter is available if requested. Written consent was taken from all participants.

# Consent for publication

Not applicable.

# Competing interest

No conflict of interest was declared by the authors.

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