Clinical Comparative study between subcutaneous Continuous Analgesia versus continuous transversus abdominis plane block post caesarian section

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Abstract
Background: post cesarean section pain is associated with a variety of unfavorable post-operative consequences; affect both mother and the newborn, especially the first 48 h after delivery. The pain can be improbable, disrupting mother/child bonding and also affects mental, chest, heart problems, and prolong the hospital stays. Aim of the Work: to compare the efficacy and safety of bilateral continuous transversus abdominis plane (TAP) block versus continuous wound infiltration for pain relief after surgery. Patients and Methods: this study was conducted on forty patients of American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective CS were enrolled in this controlled study. Information about the study was explained comprehensively both orally and in written form to the patients. All patients gave written informed consents prior to their inclusion in the study. Results: there was no difference between TAP block & CWI as regarding pain during rest but TAP block was more effective during movement than CWI, opioid consumption was much less in TAP group than in CWI group and the time of first analgesia request was earlier in CWI group than in TAP group. Conclusion: both TAP block & CWI provided post-operative analgesia but USG TAP block increased the time to first analgesic request, reduces the total pethidine consumption with hemodynamic stability and decreases the incidence of adverse effects in patient undergoing caesarian section compared to continuous wound infiltration.

Keywords: subcutaneous Continuous Analgesia, continuous transversus abdominis plane block, caesarian section

Introduction
Caesarean section (CS) is one of the most common surgical procedures in the world. Post-operative pain affects both mother and newborn, especially the first 48 h after delivery. The pain can be improbable, disrupting mother/child bonding (1).

The well-known side effects of the opioids such as nausea, vomiting, itching and sedation, may disturb the interaction between mother and child, breastfeeding and post-partum experience in a dose-dependent manner. But a number of alternative strategies have been described to reduce opioids consumption post-operatively (2).

One of the alternative strategies is the transversus abdominis plane (TAP) block, a regional anesthetic technique which can provide sensory and motor block of anterior abdominal wall from T10 to L1 although lacking any visceral effect. It is used for lower abdominal surgery such as CS (3).

The Interest in TAP block increased in the last few years after introduction of ultrasound in anesthetic practice (4).

Previously, local anesthetic wound infiltration through subcutaneous or subfascial catheters was used to treat postoperative pain in many types of surgery including CS (5).

Local anesthetic wound infiltration is now widely recognized as a useful, easy and safe adjunct in a multimodal approach to postoperative pain management in different surgeries. This relatively simple technique as the surgeon directly places a multiorifice subcutaneous or subfascial catheter to infuse local anesthetic or NSAID into wounds at the end of the procedure, it is technically efficient and safe, offers the potential to provide complete analgesia or to substantially reduce the need for opioids and their related side effects, can be used for several days, and can be used with portable pumps, which may be used in an ambulatory setting (6).

Continuous wound infiltration with local anesthetic through a multiorifice subcutaneous or subfascial catheter increases the duration of action and efficacy of local anesthetic compared with a one-time wound injection of local anesthetic (7).
Clinical Comparative study between subcutaneous Continuous Analgesia…

Mother and baby obtain multiple benefits by TAP block and continuous wound infiltration as Long and effective analgesia, earlier oral nutrition, earlier mobilization and short duration of hospital stay (8).

Aim of the Work
The aim of the current study is to compare the efficacy and safety of bilateral continuous transversus abdominis plane block versus continuous wound infiltration for pain relief after surgery.

Patients and Methods
After approval of the Medical Ethical Committee at Al-Azhar University hospitals, Department of Anesthesia, and after patient written consent, forty patients of American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective CS are enrolled in this randomized controlled study. Information about the study was explained comprehensively both orally and in written form to the patients. All patients gave their written informed consents prior to their inclusion in the study.

Patients were randomized by simple randomization method utilizing closed envelopes into two groups:
1. I Group: Continuous wound infiltration.
2. T Group: Continuous bilateral transversus abdominis plane.

- Exclusion criteria:
  1- Patient refusal.
  2- Known allergy to local anesthetics.
  3- Body mass index >35 kg m².
  4- History of chronic use of opioids.
  5- Emergency CS.
  6- Coagulopathy.
  7- Infection at puncture site.
  8- Physical status ASA III or more.

- Preoperative evaluation:
  The patients were screened for suitability by:
  1- History including assessment of the cardio-respiratory status.
  2- Physical examination: chest and heart examination and special airway assessment.
  3- Investigations: complete blood picture, coagulation profile, liver function tests and kidney function test.

  4- ECG.

- Patient monitoring (standard monitoring):
  1- Pulse oximetry.
  2- Continuous ECG.
  3- Non-invasive blood pressure monitoring. 5min. interval.
  4- Temperature.

- Materials:
  1- Monitor for vital signs: Electrocardiograph (ECG), noninvasive blood pressure (NIBP), Oxygen Saturation (SpO2).
  2- Ultrasound machine. (sonosite M turbo)
  3- Epidural set for tap block. (B. Brawn)
  4- Subcutaneous infusion set (needle, introducer, multilumenal catheter).
  5- Resuscitation equipment and drugs.
  6- Bupivacaine 0.5% - Lidocaine 2%.

- Preparation:
  Patients were randomized by simple randomization method utilizing closed envelopes into two groups (Group I: Wound site infiltration, n = 20 or Group T: TAP block, n = 20 Group).

  Before initiation, methods of our study were explained to the patients then standard monitors applied to the patients, peripheral vascular access was obtained with a 16 or 18-gauge (G) intravenous cannula in all patients and preoperatively 8 mL kg⁻¹ h⁻¹ NaCl 0.9% was infused, Pre-oxygenation with 100% oxygen done for 3 min. General anesthesia induced with rapid sequence crush induction by succinylcholine (1 mg / kg) following injection of Propofol (1.5-2.5 mg/kg) to facilitate orotracheal intubation and 0.25 mg ketamine for analgesia. Anesthesia maintained using isoflurane in an air/oxygen mixture, then Atracurium (0.5 mg/kg) after recovery from succinylcholine. Intermittent boluses of 0.1 mg/Kg Atracurium were used to achieve muscle relaxation.

  Minute ventilation was adjusted to maintain normocapnia (end tidal carbon dioxide; etCO2, between 34 and 38 mm Hg), fentanyl (1-2 mcg / kg) after delivery of fetus.

  In Group T, after skin closure, patient kept anesthetized and bilateral ultrasound-guided transversus abdominis plane (US-guided TAP) block were performed under complete aseptic block. A linear (5–13
MHZ) US probe was positioned transversely in the mid-axillary line midway between the lower costal margin and iliac crest. A 9-cm 18-G epidural needle was inserted in-plane under real-time US visualization from medial to lateral to be positioned in the plane between internal oblique and transversus abdominis muscles. One milliliter of normal saline was used to confirm the needle position, then, 10 ml of 0.25% bupivacaine + 10 ml 1% lidocaine were injected through the needle (20 mL) on each side. A multi-orifice 20-G epidural catheter was threaded where 7–8 cm of the catheter was left inside the TAP. Maintenance dose of 5 ml of 0.25% bupivacaine + 5 ml 1% lidocaine /2 hours (10 mL per each catheter) for 24 hours (study period).

In Group I, before completion of the surgical procedure, the introducer of the subcutaneous continuous analgesia set was introduced through the angle of the incision, catheter introduced through introducer, left in subcutaneous tissue above the abdominal fascia, peelable sheath removed and catheter fixed by the end of surgery in total 40 mL (20 ml for each wound site) 10 mL bupivacaine of 0.25% plus 10 mL lidocaine 1% were used for subcutaneous wound site infiltration, then 20 mL (10 mL for each side); 5 mL bupivacaine of 0.25% plus 5 mL lidocaine 2% two hourly for 24 hours (study period).

All patients received ketorlac (30 mg / 6 hr) not to exceed 120 mg/ day. If pain persisted they received pethiden (50 mg / IV).

Assessment

Data were recorded by staff unaware of the group allocations at the end of the 2, 4, 8, 12, and 24 h time after surgery.

1. Heart rate, blood pressure measured at 0, 2, 4, 8, 12, 24 hours post-operative.
2. First postoperative rescue analgesic administration time.
3. Patient pain was evaluated by visual analogue scale (VAS), this tool comprises a 10-cm line with ‘no pain’ located at one end and ‘worst imaginable pain’ located at the opposite end. The patient was asked to place or move the marker to a level that best indicates the intensity of pain he feels.
4. The incidence of nausea and vomiting recorded.

Patients are asked to report any adverse event (e.g. pain) that had occurred at any time.

Statistical analysis:

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). Quantitative data were expressed as mean± standard deviation (SD). Qualitative data were expressed as frequency and percentage.

The following tests were done:

- Independent-samples t-test of significance was used when comparing between two means.
- Mann Whitney U test: for two-group comparisons in non-parametric data.
- Chi-square ($\chi^2$) test of significance was used in order to compare proportions between two qualitative parameters.
- The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following:
  - Probability (P-value) $\leq 0.05$ was considered significant.
  - P-value $<0.001$ was considered as highly significant.
  - P-value $>0.05$ was considered insignificant.

Results

The results of the present study are demonstrated in the following tables and figures:

A- Demographic data & clinical data:

There was no statistically significant difference between the two groups of the study as regards their demographic data (age and BMI), ASA classification.

Table (1): Comparison between groups according to demographic data
Clinical Comparative study between subcutaneous Continuous Analgesia…

Demographic Data

<table>
<thead>
<tr>
<th>Group I: TAP (n=20)</th>
<th>Group II: CWI (n=20)</th>
<th>t/x2#</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>26.80±4.93</td>
<td></td>
<td>0.201</td>
</tr>
<tr>
<td>Range</td>
<td>19-35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMI [wt/(ht)^2]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean±SD</td>
<td>25.95±3.79</td>
<td></td>
<td>1.604</td>
</tr>
<tr>
<td>Range</td>
<td>20-33</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>16 (80.0%)</td>
<td></td>
<td>0.173#</td>
</tr>
<tr>
<td>II</td>
<td>4 (20.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>t- test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent Sample t-test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>x2: Chi-square test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p-value &gt;0.05 NS</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**B- Time of first analgesia rescue:**

There was statistically significant difference between the two groups of the study as regards Time of first analgesia rescue; it was prolonged in TAP group while it was earlier in CWI group.

**Table (2): Comparison between groups according to time of first analgesia rescue (hrs)**

<table>
<thead>
<tr>
<th>Time of First Analgesia Rescue (hrs)</th>
<th>Group I: TAP (n=20)</th>
<th>Group II: CWI (n=20)</th>
<th>t-test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean±SD</td>
<td>8.38±2.60</td>
<td>5.46±1.89</td>
<td>7.765</td>
<td>0.012*</td>
</tr>
<tr>
<td>Range</td>
<td>3.45-12</td>
<td>3-8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>t- test</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent Sample t-test; *p-value &lt;0.05 S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**C- Pethidin consumption:**

There was statistically significant difference between the two groups of the study as regards total pethidin consumption, as it was higher in CWI group than TAP group.

**Table (3): Comparison between groups according to pethedine 50mg**

<table>
<thead>
<tr>
<th>Pethedine 50 mg</th>
<th>Group I: TAP (n=20)</th>
<th>Group II: CWI (n=20)</th>
<th>x2</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Pethedine 50 mg</td>
<td>8</td>
<td>14</td>
<td>3.109</td>
<td>0.046*</td>
</tr>
<tr>
<td>x2: Chi-square test; *p-value &lt;0.05 S</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**D- VAS at rest:**

There was no statistically significant difference between the two groups of the study as regards VAS at rest.

**Table (4): Comparison between groups according to VAS at rest**

<table>
<thead>
<tr>
<th>VAS at Rest</th>
<th>Group I: TAP (n=20)</th>
<th>Group II: CWI (n=20)</th>
<th>z-test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 2hrs</td>
<td>Median (IQR)</td>
<td>0 (1)</td>
<td>0 (1)</td>
<td>0.340</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0-3</td>
<td>0-2</td>
<td></td>
</tr>
<tr>
<td>After 4hrs</td>
<td>Median (IQR)</td>
<td>0 (1)</td>
<td>0 (1)</td>
<td>0.734</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0-2</td>
<td>0-2</td>
<td></td>
</tr>
<tr>
<td>After 8hrs</td>
<td>Median (IQR)</td>
<td>1 (0)</td>
<td>1 (1)</td>
<td>1.179</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0-2</td>
<td>0-3</td>
<td></td>
</tr>
<tr>
<td>After 12hrs</td>
<td>Median (IQR)</td>
<td>1 (0)</td>
<td>1 (1)</td>
<td>1.547</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0-1</td>
<td>0-3</td>
<td></td>
</tr>
<tr>
<td>After 24hrs</td>
<td>Median (IQR)</td>
<td>1 (0)</td>
<td>1 (1)</td>
<td>0.218</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0-1</td>
<td>0-1</td>
<td></td>
</tr>
<tr>
<td>z-Mann-Whitney test; p-value &gt;0.05 NS</td>
<td>Data are expressed median and interquartile range (IQR)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**E- VAS at movement:**
There was statistically significant difference between the two groups of the study as regards VAS at movement, as the TAP group had the least score while the CWI group was higher. It was highly statistically significant difference after (2 and 4 hrs) hours where the highest value was in CWI group & the lowest value was in TAP group. It was statistically significant difference after (8 and 12 hrs) hours where the highest value was in CWI group & the lowest value was in TAP group. There was no statistically significant difference after (24 hr) hours where the highest value was in CWI group & the lowest value was in TAP group.

Table (5): Comparison between groups according to VAS at movement

<table>
<thead>
<tr>
<th>VAS at Movement</th>
<th>Group I: TAP (n=20)</th>
<th>Group II: CWI (n=20)</th>
<th>X2</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>After 2hrs</td>
<td>Median (IQR)</td>
<td>1 (0)</td>
<td>2 (2)</td>
<td>13.347</td>
</tr>
<tr>
<td>Range</td>
<td>0-3</td>
<td>0-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After 4hrs</td>
<td>Median (IQR)</td>
<td>1 (1)</td>
<td>3 (2)</td>
<td>11.976</td>
</tr>
<tr>
<td>Range</td>
<td>0-2</td>
<td>0-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After 8hrs</td>
<td>Median (IQR)</td>
<td>1 (1)</td>
<td>3 (2)</td>
<td>6.293</td>
</tr>
<tr>
<td>Range</td>
<td>0-5</td>
<td>0-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After 12hrs</td>
<td>Median (IQR)</td>
<td>1 (1)</td>
<td>2 (2)</td>
<td>4.086</td>
</tr>
<tr>
<td>Range</td>
<td>0-1</td>
<td>0-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>After 24hrs</td>
<td>Median (IQR)</td>
<td>0 (1)</td>
<td>1 (1)</td>
<td>1.421</td>
</tr>
<tr>
<td>Range</td>
<td>0-1</td>
<td>0-1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

z-Mann-Whitney test; *p-value <0.05 S; **p-value <0.001 HS; Data are expressed median and interquartile range (IQR)

Discussion

TAP block is considered a new technique, yet many investigations have been done to explain its efficacy\(^9,10\). TAP block is used to anesthetize the anterior abdominal wall nerves which supply the skin, muscles, and parietal peritoneum through the anterior rami of the lower three thoracic nerves and the first lumbar nerve which provide analgesia for lower abdominal incisions such (CS)\(^11\).

Introduction of ultrasound in anesthetic field increased the accuracy of instillation of the local anesthetic in the correct plane between the internal oblique and transversus abdominis muscles where the lower three thoracic nerves and the first lumbar nerve run to supply the abdominal wall. The site of local anesthetic injection (between the lower costal margin and iliac crest at the anterior axillary line) usually results in involvement of four nerves (T10–L1) which is enough to cover the transverse lower abdominal incision\(^12\).

Higher levels (T6–T9) need a modified higher subcostal approach\(^13\).

Higher blocks may achieve with continuous TAP blocks as described in a case report. They used continuous bilateral TAP block for postoperative analgesia in a patient with severe cardiopulmonary disability having total abdominal hysterectomy. They reported extension of the block higher to T6\(^14\).

Subcutaneous or subfascial Infiltration of the wound by local anesthetics results in analgesia through different mechanisms. As Simple local anesthesia is the main mechanism. Systemic absorption of the local anesthetic from the site of infiltration may have a role in analgesia especially after tissue injury\(^15\).

Anti-inflammatory properties of local anesthetics may play a role in analgesic effects especially after tissue injury\(^16\).

Results of investigations studying CWI in postoperative analgesia are not uniform. Some studies showed favorable results\(^17\), while others did not show any benefit\(^18\). These paradoxical results can be explained by the different types of surgeries, different types of catheters and local anesthetic, the plane where the catheter inserted in, and even the types of pumps used.

Most of favorable results were associated with lower abdominal surgeries such
as cesarean deliveries and gynecologic procedures [16].

Post-operative analgesia with catheter inserted above the abdominal fascia was more effective than inserting it deep to the fascia, Hafizoglu et al. [19] found that postoperative analgesia was much better with CWI catheters inserted above the abdominal fascia than with catheters inserted deep to the fascia.

This study has compared the efficacy of continuous TAP block with subcutaneous continuous analgesia in providing post-operative analgesia over 24 hours following caesarian section, the time to first analgesic request, total pethidine consumption over 24 hours, pain score using VAS and the post-operative satisfaction, complications were also recorded.

The two groups were comparable according to the demographic data in terms of age, sex and BMI, ASA classification, yet no statistically difference has been recognized among the studied patients (p>0.05).

The two groups were comparable according to the baseline parameters in the term of mean arterial blood pressure and heart rate (HR), yet no statistically difference had been recognized among the studied patients (p>0.05).

In our study we found that time of first analgesia rescue was longer in TAP group Mean±SD (8.38±2.60) than in CWI group Mean±SD (5.46±1.89).

Siddiqui et al. [20] is consistent with our results as he reported TAP block not only reduced postoperative opioid need but also prolonged the first analgesia request.

In our study we found that consumption of opioids was less in TAP group rather than CWI group as there were 12 patinas did not take opioids in TAP group vs. 6 in CWI.

In consistence with our study Belavy et al. [21] reported that morphine consumption was lower when Ultrasound guided TAP block is used as a component of a multimodal regimen after spinal anaesthesia.

Abdallah et al. [22] reported that TAP blocks post CS as a part of multimodal regimen without intra thecal morphine (ITM) has reduced post-operative opioids consumption.

In controversy to our study Telnes et al. [22] reported that Ultrasound guided TAP block compared with local infiltration of the wound after CS did not reduce postoperative opioid consumption.

And Charlton et al. [23] concluded that TAP block didn't reduce post-operative opioid consumption after abdominal surgery.

As regard VAS at rest there was no statistically significant difference between two groups, but during movement there was a significant difference between two groups as the VAS was low in TAP group in 2, 4, 8, 12 hr and was nearly zero after 24 hours in contrast to CWI group we found the VAS was low after 2 hours started to increase at 4, 8 hr then started to decline at 12 hr to be nearly zero at 24 hours.

In consistence with our study McDonnell et al. [24] compared a placebo with TAP block and reported that TAP block provided superior analgesia up to 48 hours.

Also Scharine et al. [25], reported that TAP block provided long and effective analgesia, also lowered pain score with earlier oral nutrition, and earlier mobilization are seen, and short duration of hospital stay, as when no opioids are used.

Atim et al. [25] reported that Pain scores of the group with TAP block were found to be lower than with infiltraion group in the 6 and 24th hours, also TAP block was more effective than wound infiltration in reducing postoperative pain.

Abdallah et al. [25], reported that the analgesic effect of TAP is strongly related to the surgical intervention performed, so the surgical procedures where TAP block provides optimal analgesia not considered yet.

In controversy to our study Bamigboye and Hofmeyr [26], compared wound infiltration with a placebo in patients who had caesarean sections with spina anaesthesia and reported that NPS at first hour with wound site infiltration was lower. Also, they reported that wound site infiltration applied as a single dose for pain relief after caesarean section is an active, reliable, and easy method for the first four hours after delivery.

Aydognus et al. [27], reported NPS scores (NPS0) after surgery were lower in Group I than in Group T. it may be due to rapid application of wound site administration in contrary to USG guided TAP block, which was more time consuming.

As regard satisfaction we found statistically difference between two groups, the TAP group was satisfied more than CWI group as there was (3 (15.0%)) not satisfied in CWI
group vs (0 (0.0%)) in TAP group, satisfied was (6 (30.0%)) in CWI group vs (1 (5.0%)) in TAP group, very satisfied was (5 (25.0%)) in CWI group vs (9 (45.0%)) in TAP group and the patients who Recommend this procedure in CWI (6 (30.0%)) group vs (10 (50.0%)) in TAP group.

In some newly conducted studies, it has been reported that patient satisfaction in TAP group was better (28).

Tan et al. (2) applied ultrasound guided TAP block after general anesthesia in caesarean section operations, and they found that mother satisfaction was increased.

As regard complications PONV, respiratory depression and itching it was insignificant in both groups.

Although we did not experience any complications, there were reports of different injuries following TAP blocks and adverse effects as high plasma concentration of local anesthetic, convulsions and peritoneal perforations with subsequent visceral damage (29).

These should be kept in mind when discussing the potential benefits from TAP block, even though complications are rare and less frequent when Ultrasound is applied.

Conclusion
Both TAB block & CWI provided postoperative analgesia but ultrasound guided TAP block increased the time to first analgesic request, reduced the total pethidine consumption with hemodynamic stability and decreased the incidence of adverse effects in patient undergoing caesarian section compared to continuous wound infiltration.

References
Clinical Comparative study between subcutaneous Continuous Analgesia…


27. Aydogmus MT1, Sinikoglu SN1, Naki MM2, Ocak NB1, Sanli N1, Alagol A (2014): USG-guided TAP block might be superior to infiltration anaesthesia for postoperative pain management of patients who have had caesarean section and it provided longer-lasting and more efficient analgesia. Hippokrati, 18 (1): 28-31.
