Ultrasound guided bilateral quadratus lumborum block vs intrathecal morphine for postoperative analgesia after cesarean section: a randomised controlled trial

Running title: Post-CS QL block vs intrathecal morphine

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Abstract

Background: Adequate pain control after cesarean section (CS) is important to help the newly delivered mothers to feed and care their neonates together with early ambulation of the parturients to avoid the risk of thromboembolism and development of chronic abdominal and pelvic pain. The aim of this randomized controlled trial was to study and compare the efficacy of quadratus lumborum (QL) block and intrathecal morphine for postoperative analgesia after CS.

Methods: Ninety pregnant female patients with a gestation of 37 weeks or more scheduled for elective CS were enrolled into the study. All patients received spinal anesthesia, and after surgery, QL block was performed. They were randomly allocated to control group (CG, 0.1ml saline added to spinal drug and 24ml saline for QL block), intrathecal morphine group (ITM, 0.1mg morphine added to spinal drug and 24ml saline for QL block), or QL block group (QLB, 0.1ml saline added to spinal drug and 24ml 0.375% ropivacaine for QL block). Integrated Analgesia Score (IAS), Numerical rating scale (NRS) at rest and during movement, morphine requirements in the first 48-h, time to first morphine dose, time to first ambulation, and morphine related side effects were recorded.

Results: IAS and NRS scores at rest and during movements were significantly less in QLB and ITM than CG. Moreover, QLB had lower IAS and NRS scores at rest and during movements in comparison to ITM. Time to first morphine dose was significantly longer in QLB than in ITM and CG. Also, morphine requirements in the first 48-h was significantly lower in QLB than ITM and CG (18.2±9.6 mg in QLB vs and 42.8±10.4 mg and 61±12.9 mg in ITM and CG respectively) (P=0.001). No significant difference between the three groups regarding time to first ambulation (13.4±1.8 h in QLB vs 11.7±1.9 h in CG and 12.9±1.6 h in ITM). Incidence of morphine related side effects was significantly higher in ITM compared to CG and QLB.
Conclusion: Quadratus lumborum block and intrathecal morphine are effective analgesic regimens after cesarean section. However, quadratus lumborum block provides better long lasting analgesia together with reduction of total postoperative morphine consumption.

Keywords: Quadratus Lumborum, Spinal, Morphine, Analgesia, Cesarean Section.
Introduction

Cesarean section (CS) is the most frequently performed surgical procedure in obstetrics and gynaecology. It represents 21.1% of birth in the developed world and 15% of those worldwide with a tendency of further increase. [1,2] Adequate pain management after CS is vital to help the newly delivered mothers to feed and care the neoborn.[3,4] Furthermore, effective analgesia is important for early ambulation of the parturients to avoid the risk of thromboembolism and development of chronic pain in the abdomen and pelvis. [5]

Most CS are carried out under spinal anesthesia and opioids are still considered as the corner-stone for the postoperative analgesia either systemic, spinal, or both.[6,7] However, it is associated with undesirable side effects including nausea, vomiting, and pruritis causing a reduction of the overall patient satisfaction. Moreover, the more serious delayed maternal respiratory depression makes the knowledge about alternative opioid free analgesic approaches important.[6,8]

Transversus abdominis plane (TAP) block is currently the most popular regional analgesic technique used for postoperative analgesia after CS. However, TAP block was found inferior to intrathecal morphine and of a little benefit if used as a part of a multimodal regimen including intrathecal morphine.[6,8] Acute pain after CS has both somatic and visceral components which results from surgical cutting of the abdominal wall and the uterus. TAP block, as a part of multimodal analgesic regimen after CS, provides effective analgesia for the somatic pain only coming from the abdominal wall. [9]

Ultrasonographic researches for a new approach of TAP block resulted in the quadratus lumborum block (QL block). QL block was first reported at the annual European Society of Regional Anesthesia (ESRA) congress in 2007 (QL block I). In 2015, QL block technique was modified with shifting the
injection point from the anterolateral border of the QL muscle to the posterior border (QL block II).[10] QL block inhibits the dual pain components (somatic and visceral) as a result of local anesthetic spread to the paravertebral space. [9,10] The analgesic efficacy of QL block II and superiority over TAP Block after CS were proved by Blanco. [10,11] The aim of this double blind randomized controlled trial was to study the efficacy of QL block and intrathecal morphine and compare the two treatment techniques for postoperative analgesia after CS.
Materials and Methods

After approval of the hospital ethics committee and written informed consent, we enrolled 90 parturients in this double-blind randomised placebo controlled study between October 2017 and August 2018. Inclusion criteria were ASA physical status II parturients, age between 19 and 40 years, and posted for elective CS via a Pfannenstiel incision under spinal anesthesia. Exclusion criteria were history of allergy to any of the study drugs, body mass index (BMI) ≥35 kg m\(^{-2}\), coagulopathy, local infection, pregnancy-induced hypertension, gestation diabetes mellitus, and opioids abuse.

Using computer generated numbers; by random allocation software; QuickCalcs (GraphPad Software Inc., La Jolla, CA, USA), and sealed opaque envelops, Parturients were allocated randomly into one of three groups: the control group (CG; n= 30), the QL block group (QLB; n= 30), and the intrathecal morphine group (ITM; n= 30).

Oral ranitidine 150-mg at night and again 2 hours before surgery were administered to all patients.

Before shifting to the operating room, an 18-gauge intravenous cannula was inserted in the nondominant arm or hand and 500 ml Hydroxyethyl starch (Voluven, 6% solution) was infused. In the operating room, standard monitors were applied including peripheral pulse oximetry, electrocardiography, and noninvasive arterial blood pressure.

Spinal anesthesia was performed while the patients were sitting under ultrasonographic guidance at the level of L2 to 3 or L3 to 4 intervertebral spaces using a 27-gauge pencil point needle (RapID™ Spinal Needle Set Pencil Point Spinal Needle, Portex, Smiths Medical international Ltd, UK) with 12.5 mg of hyperbaric bupivacaine 0.5% (Astrazeneca Pharmaceuticals, UK) and 10 µg fentanyl (Martindate Pharmaceuticals, UK) combined with 0.1 mg preservative-free morphine (0.1 ml) (Martindate Pharmaceuticals, UK) in ITM and with 0.1 ml of 0.9% saline in CG and QLB. After that, the partu-
Patients were positioned supine with left uterine displacement of 15° - 20° and a facemask was applied to deliver oxygen at rate of 6 L/minute.

Five minutes after the spinal injection, Spinal anesthesia level was assessed by a pinprick and considered successful if a bilateral sensory blockade to T4-T6 was established. Anesthesia and surgical management were carried out as per our hospital protocol.

After skin closure and covering the wound with a dressing, patients received intravenous paracetamol 1 g and rectal diclofenac 100 mg, then ultrasound guided QL block was performed through the posterior approach using the technique described by Blanco and colleagues [11], while the patients were still in the supine position and fully monitored.

A convex (5-8 MHz) ultrasound probe (SonoScape ultrasonography machine, China) with a protective sheath was used after imaging depth and gain was adjusted. The procedure was carried out under complete aseptic condition (facemask, gown, and gloves). After cleaning of the abdominal skin with antiseptic solution; the probe was positioned transversely at the level of the anterosuperior iliac spine then advanced in the cranial direction to visualize the three muscle layers of the abdominal wall.

Following the external oblique muscle posterolaterally, its posterior border was identified (hook sign) with the internal oblique muscle below it displayed as a roof above the QL muscle. The transducer was then tilted down to visualize the middle layer of the thoracolumbar fascia as a bright hyperechoic line. Stimuplex® A 21G 100-mm needle (B. BRAUN, Melsungen AG, Germany) was inserted inplane under real time US guidance from anterolateral to posteromedial direction via the abdominal wall. Two milliliters of 0.9% saline was injected to visualize the solution spread (hydrodissection) to determine the optimal point of injection over the lumbar interfacial triangle. In QLB, a volume of 24 ml of 0.375% ropivacaine was then slowly injected on each side after negative aspiration in 4 ml aliquots (in a total dose of 180 mg), while in CG and ITM; patients received same volume of 0.9% saline (placebo). The
study solution was observed during the injection with a tendency to spread posteromedially rather than anterolateral.

After shifting the patients to postanesthesia recovery unit, intravenous morphine was started via PCA pump adjusted to deliver a bolus of 1 mg with a 5 minutes lockout period, 4 h maximum dose of 48 mg and no background infusion for the next 48 hours (study period). Intensity of pain was assessed at rest and during movement (knee flexion) using Numerical Rating Scale (NRS) ranging from 0-10 (0 indicating no pain and 10 for severe intractable pain) at 2h, 6h, 12h, 24h, 36h, and 48h by nursing staff and 1 g paracetamol was given intravenously if NRS score > 3 with a maximum dose of 4g /24h. All treating staff and outcome assessors were blinded to the study group allocation.

Patients were evaluated for their level of sedation using Passero Opioid-induced Sedation Scale[12], incidence of pruritis, and severity of postoperative nausea and vomiting (PONV); using a 4-point rating score with 4= severe, 3= moderate, 2 = mild, and 1= absent, at 6h, 12, 24, and 48h. Also, patients were monitored for respiratory depression which was defined as respiratory rate ≤ 8 breaths/ minute. In addition, time to first morphine dose and time to first ambulation postoperatively were recorded.

Intravenous ondansetrone 4 mg was given to treat PONV and diphenhydramine 25 mg to treat pruritis. At the end of the study period, patients were informed to rate their satisfaction about the pain control regimen received using a 3-point scale (1 = highly satisfied, 2 = satisfied, or 3 = dissatisfied).

An integrated analgesia assessment score (IAS) was calculated at every measuring time point of NRS pain scores using the formula: (NRS+1) x (1+M/10), where M indicates morphine dosage in milligrams 2 hours before recording time of NRS. The basic formula [ PI x (1+M/10) ] [13] has been modified as PI (Pain Intensity) was replaced by NRS + 1 to avoid a zero result when NRS = 0.

The primary outcome measure of this clinical study was the IAS at rest and during movements and the secondary outcome measures were morphine consumption in the first 48 hours, NRS pain scores at rest.
and during movements, time to first morphine dose, time to first ambulation, patient’s satisfaction, and morphine related adverse effects including pruritis, nausea and vomiting, respiratory depression, and sedation.

Based on similar investigations [9,14], a sample size of 26 patients was calculated for an alpha error of 0.05, beta error of 0.1, probability (power) of 90%, and anticipated effect size of 0.40 using sample size software (G*Power Version 3.00.10, Germany). Therefore, we decided to include 30 patients per group to allow for any missing data or dropouts. Statistical analyses were done using SPSS (Statistical Package for Social Science) software version 20 (SPSS Inc., Chicago, IL, USA). Shapiro-Wilk test was first used for testing the data for normality. Data were expressed as mean±SD, median (range), or frequency and percentage as appropriate. A one-way analysis of variance (ANOVA) was used for analysis of normally distributed continuous data. Kruskall-Wallis test was used for analysis of non-normally distributed continuous data. Chi-square test was used for pair wise comparison of qualitative parameters between every two groups after Bonferroni adjustment. A value of $P < 0.05$ was considered statistically significant.
Results

One hundred eighteen patients were found eligible, of whom only 90 patients were enrolled in the study and randomized into three groups. No patient was excluded from the study thereafter due to deviation from the study protocol (Figure 1). The three groups were comparable regarding the baseline maternal characteristics (Table 1). IAS and NRS scores at rest and during movement were significantly less in ITM and QLB as compared to CG at variable check time-points. Moreover, QLB had lower IAS and NRS scores at rest and during movements in comparison to ITM (details in Figure 2, 3, 4, and 5). Table 2 showed that time to first morphine dose was significantly longer in QLB and ITM in comparison to CG. Meanwhile, it was significantly longer in QLB than in ITM. Total PCA morphine consumption during the first postoperative 48-h was significantly lower in QLB and ITM in comparison to CG. Also, it was significantly lower in QLB than in ITM (Table 2). Patients in QLB were able to ambulate after 13.4±1.8 hours compared to 11.7±1.9 hours and 12.9±1.6 hours in CG and the ITM respectively with no significant difference between the three groups (p>0.05). A significantly higher number of patients suffered from pruritis in ITM group compared to CG and QLB at 6 h. Moreover, incidence PONV was significantly higher in ITM at 12 h. Patient’s satisfaction with the assigned treatment regimen was significantly better in QLB compared to CG and ITM (Table 3). Sedation scale was not different among the three groups with no clinically detectable respiratory depression in any of the study patients (data not shown).
Discussion

Our results demonstrated that both QL block and intrathecal morphine are effective postoperative analgesic regimens after CS however QL block provides better long-lasting analgesia with decreased postoperative morphine requirements.

In our study, IAS and NRS scores were significantly less in ITM upto 12 h and 6 h at rest and during movement respectively in comparison to CG. In addition, IAS and NRS scores during movement were significantly less in QLB upto 24 h in comparison to CG and ITM.

The overall benefits provided by any proposed analgesic technique may not be well identified when using analgesic requirements and pain scores as isolated parameters.[15] So, we posited the IAS described by Silverman et al.[13] as the primary outcome measure of the current study. IAS provides a global end point based on a special formula integrating pain intensity and morphine consumption rather than a specific end point such as pain scores or analgesic requirements. We believe that IAS improves the sensitivity of assessing different treatment techniques. In our study, utilization of IAS clarifies the extended analgesic action of QL block during rest upto 36 h with a significantly less IAS in comparison to CG and ITM; however, this was not noted when using NRS scores as a pain intensity measuring tool at rest to compare QL block versus intrathecal morphine or placebo as NRS at rest was significantly less in QLB in comparison to CG and ITM till 24 h only.

Our results also revealed that QL block provided an opioid-sparing effect of 70% compared to the CG during the first 48 hours. By contrast, only 30% reduction in morphine consumption was recorded with intrathecal morphine. Furthermore, time to first morphine dose was significantly longer in QLB as compared to ITM and CG; meanwhile, it was also significantly longer in ITM than in CG.
Intrathecal morphine used to be the gold standard treatment for pain management after CS. [16] In a systemic review and metaanalysis, Mishriky et al.[17] found that intrathecal morphine had a better analgesic efficacy in comparison to TAP block however associated with high incidence of morphine-related side effects. TAP block can only control the somatic pain component but visceral pain control is absent as it is an infiltration of local anesthetic solution in the anterior abdominal wall and this was proved by Carney et al.[18], through MRI imaging of the chest and abdomen. In another systemic review and meta-analysis of Champaneria et al.[19], TAP block was confirmed to have no additional benefits if combined with intrathecal morphine. However, other studies proved no differences between the two treatment techniques.[16]

Our results are in concurrence with previous studies which reported QL block as a successful postoperative pain control regimen after different types of surgery.[20-23] Moreover, our results are in concurrence with that of Blanco et al. who initially investigated QL block for pain control after CS through injecting 0.2 ml/kg of bupivacaine 1.25mg/ml on the posterior margin of the QL muscle resulting in a significant decrease of visual analogue pain scores and morphine consumption in the first 48 hours.[10] A year later, the same authors group investigated QL block in comparison to TAP block and proved that QL block had a significantly superior analgesic efficacy extending up to 48 hours.[11] However, to our knowledge, no previous studies have investigated and compared the analgesic efficacy of QL block versus intrathecal morphine for postoperative pain relief after CS.

QL block is a superficial posterior abdominal wall block that is technically easy to carry out. It aims to target a very bright hyperechoic easily dissected fascial plane. QL block level extends from T7-T12 in comparison to T10-T12 dermatomal distribution after TAP block.[10] This can be explained by two main theories. First is the spread of local anesthetic to the sympathetic nerves network in the
thoracolumbar plane. Second, local anesthetic spread into the paravertebral space. These two theories also can explain the prolongation of the blockage effect and visceral pain control achieved with QL block but not in TAP block.[11] So, QL block is a safe, effective, and reliable analgesic option for postoperative pain control after abdominal surgeries.[23-26]

In our study, patients in QLB had no significant tendency for delay in ambulation compared to both other groups. Weakness of the iliacus, quadriceps, and psoas muscles can result from the spread of local anesthetic after QL block causing lumbar plexus block as described by Wikner in a case report.[27]

Nausea, vomiting, pruritus, and respiratory depression are the major adverse effects of intrathecal morphine. Nausea and vomiting are the most frequent adverse effect that occurs in about 30% of patients while incidence of pruritus differs from 0% to 100%.[28] In our study, incidence of pruritus was significantly higher in ITM at 6 h while PONV was significantly higher in ITM at 12 h in comparison to CG and QLB which consequently shared to the significantly lower number of patients who were satisfied with the treatment regimen in ITM compared to QLB.

Limitations

In our study, sensory testing for evaluating the block success was lacking in order to preserve blinding of group allocation. Obese patients with BMI $\geq 35$ kg $m^{-2}$ were excluded from the study to ensure similar patient groups. Therefore, further investigations of QL block in this patient category are recommended to assess its efficacy. Furthermore, morphine might be used by the parturients through PCA pumps to control nonsurgical pain; however, they were instructed before starting the study to avoid the use of PCA pumps for such purposes. The local anesthetic optimal dose in case of QL block is not yet determined, and our study could not reveal any data about the ideal dose. So, further researches should focus on this point. The evaluation of pain scores and requirements of analgesia in
pain control studies remains challenging. Hence, a combined outcome measure with improved validity was introduced as an integrated analgesic score which is more consistent and informative. However, studying the differences of treatment consequences still represents a major challenge and constitutes a limiting factor.

**Conclusion:** QL block and intrathecal morphine are effective analgesic regimens after cesarean section. However, QL block provides better long lasting analgesia together with reduction of total postoperative morphine consumption and improved patient’s satisfaction.

**Source of support:** Nil.

**Conflict of interest:** None declared.
References


Table 1. Maternal characteristics.

<table>
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<tr>
<th>Variable</th>
<th>CG (n=30)</th>
<th>ITM (n=30)</th>
<th>QLB (n=30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>32.49 ± 6.57</td>
<td>29.87 ± 7.54</td>
<td>31.09 ± 5.87</td>
<td>0.417</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>81.74 ± 11.31</td>
<td>78.91 ± 13.62</td>
<td>79.81 ± 12.63</td>
<td>0.539</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>166.74 ± 14.57</td>
<td>165.38 ± 15.63</td>
<td>164.67 ± 12.87</td>
<td>0.374</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>29.63 ± 6.74</td>
<td>28.54 ± 5.87</td>
<td>29.17 ± 6.17</td>
<td>0.518</td>
</tr>
<tr>
<td>Gestation age (weeks)</td>
<td>38.62 ± 1.43</td>
<td>39.18 ± 1.14</td>
<td>38.97 ± 1.82</td>
<td>0.508</td>
</tr>
<tr>
<td>Parity</td>
<td>1.52 ± 0.62</td>
<td>1.62 ± 0.58</td>
<td>1.59 ± 0.54</td>
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</table>

Data are presented as mean±SD. CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group.
Table 2. PCA morphine requirements

<table>
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<tr>
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<th>CG (n=30)</th>
<th>ITM (n=30)</th>
<th>QLB (n=30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 h Morphine requirement (mg)</td>
<td>61 ± 12.9</td>
<td>42.8 ± 10.4</td>
<td>18.2 ± 9.6</td>
<td>0.001*</td>
</tr>
<tr>
<td>Time to first morphine dose (h)</td>
<td>2 (0.5 – 4)</td>
<td>8 (3 – 24)</td>
<td>17 (6 – 36)</td>
<td>0.001$</td>
</tr>
</tbody>
</table>

Data are presented as mean ± SD or median (range). CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group. *P: ITM vs CG =0.001, QLB vs CG =0.001, QLB vs ITM =0.001. $P: ITM vs CG =0.008, QLB vs CG =0.001, QLB vs ITM =0.002.
Table 3. Side effects and patient’s satisfaction

<table>
<thead>
<tr>
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<th>ITM (n=30)</th>
<th>QLB (n=30)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pruritus 6 h</td>
<td>5 (16.7%)</td>
<td>12 (40%)</td>
<td>4 (13.3%)</td>
<td>0.029*</td>
</tr>
<tr>
<td>12 h</td>
<td>6 (20%)</td>
<td>9 (30%)</td>
<td>7 (23.3%)</td>
<td>0.656</td>
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<tr>
<td>24 h</td>
<td>7 (23.3%)</td>
<td>6 (20%)</td>
<td>7 (23.3%)</td>
<td>0.938</td>
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<td>48 h</td>
<td>0 (0%)</td>
<td>3 (10%)</td>
<td>2 (6.7%)</td>
<td>0.227</td>
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<td>Postoperative nausea and vomiting 6 h</td>
<td>Absent</td>
<td>12</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
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<td>22</td>
<td>13</td>
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<tr>
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<td>Moderate</td>
<td>4</td>
<td>2</td>
<td>3</td>
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<tr>
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<td>20</td>
</tr>
<tr>
<td></td>
<td>Mild</td>
<td>10</td>
<td>18</td>
<td>9</td>
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<td></td>
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<td>2</td>
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<td>Severe</td>
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<td>1</td>
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<td>24 h</td>
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<td>9</td>
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<tr>
<td></td>
<td>Severe</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Satisfaction</td>
<td></td>
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<tr>
<td>Highly Satisfied</td>
<td>11 (36.7%)</td>
<td>5 (16.7%)</td>
<td>28 (93.3%)</td>
<td>0.001*</td>
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<tr>
<td>Satisfied</td>
<td>14 (46.7%)</td>
<td>16 (53.3%)</td>
<td>2 (6.7%)</td>
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<td>Dissatisfied</td>
<td>5 (16.6%)</td>
<td>9 (30%)</td>
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Data are presented as numbers (percentage) or numbers only. CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group. *P: ITM vs CG =0.045, QLB vs CG =0.602, QLB vs ITM =0.020, $P$: ITM vs CG =0.002, QLB vs CG =0.782, QLB vs ITM =0.001, ±P: ITM vs CG =0.172, QLB vs CG =0.001, QLB vs ITM =0.001.
Figure legends

Figure 1. Consort-flow diagram of participants in the study

Figure 1. Consort-flow diagram of participants in the study
Data are presented as mean±SD. CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group; IAS, Integrated Analgesia Score. †P <0.05 ITM vs CG; ‡P <0.05 QLB vs CG; §P <0.05 QLB vs ITM.

**Figure 2.** Comparison of Integrated Analgesia Score at rest between the three groups
Data are presented as mean±SD. CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group; IAS, Integrated Analgesia Score. †P <0.05 ITM vs CG; ‡P <0.05 QLB vs CG; §P <0.05 QLB vs ITM.

Figure 3. Comparison of Integrated Analgesia Score during movement between the three groups
Data are presented as mean±SD. CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group; NRS, Numerical Rating Scale. †P<0.05 ITM vs CG; ‡P<0.05 QLB vs CG; §P<0.05 QLB vs ITM.

**Figure 4.** Comparison of Numerical Rating Scale at rest between the three groups
Data are presented as mean±SD. CG, control group; ITM, intrathecal morphine group; QLB, quadratus lumborum block group; NRS, Numerical Rating Scale. *P <0.05 ITM vs CG; †P <0.05 QLB vs CG; ‡P <0.05 QLB vs ITM.

**Figure 5.** Comparison of Numerical Rating Scale during movement between the three groups