VIA MEDICA
ORIGINAL PAPER / OBSTETRICS
Ginekologia Polska
2018, vol. 89, no. 2, 89–96

ISSN 0017–0011
DOI: 10.5603/GP.a2018.0015

Evaluation of the effectiveness of the Quadratus Lumborum Block type I using ropivacaine in postoperative analgesia after a cesarean section — a controlled clinical study

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ABSTRACT

Objectives: Quadratus Lumborum Block in contrast to Transversus Abdominis Plane Block contains a unique component which not only stops somatic pain but also inhibits visceral pain by spreading the local anesthetic to the paravertebral space. This study was designed to determine whether performing the Quadratus Lumborum Block type I in patients undergoing cesarean section would be associated with both decreased morphine consumption and decreased pain levels in the postoperative 48-hour period.

Material and methods: Sixty patients undergoing caesarean section under spinal anesthesia were randomly and equally assigned to one or other of two groups: QLB I (who received Bilateral Quadratus Lumborum Block type I with the use of 24 mL 0.375% ropivacaine per side) or a Control group. In both groups, on-demand morphine analgesia was administered postoperatively within the first 48 hours. The following were measured: the morphine consumption; the time elapsed from the C-section until the first dose of morphine; and the levels of pain intensity among patients in rest (numeral pain rating scale).

Results: There were no statistically significant demographic data differences between the QLB I and Control groups. The following significant differences were observed in the 48-hour postoperative period: morphine consumption was higher in the Control group ($p = 0.000$); the time elapsed from the C-section until the first dose of morphine was longer in QLB I group ($p < 0.05$); and the median of the pain numeric rating scale was higher in the Control group ($p < 0.05$).

Conclusions: Quadratus Lumborum Block type I significantly reduces morphine consumption and pain levels up to 48 hours postoperatively.

Key words: quadratus lumborum block type I, ropivacaine, cesarean section, multimodal analgesia

Ginekologia Polska 2018; 89, 2: 89–96

INTRODUCTION

A cesarean section is the most commonly performed surgery in gynecology and obstetrics in the world, which is a steadily increasing trend [1]. The intensity of postoperative acute pain among patients after a C-section results from the development of somatic and visceral pain which occurs due to cutting the structures of the abdominal wall and the uterus [2, 3]. Unsuccessfully conducted analgesia after a C-section results in considerable suffering in newly delivered mothers, who consequently may be less willing to feed and care for the new-born [4, 5]. Additionally, unsuccessfully conducted analgesia may impair early ambulation

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and it poses one of the risk factors for chronic pain in the abdomen, and pelvis [6]. To achieve effective analgesia, a multimodal strategy should be used with simultaneously administered painkillers from all three levels of the analgesic ladder in conjunction with specialized peripheral nerve block techniques and with either continuous epidural or spinal anesthesia [7, 8]. For several years now, one can notice a real renaissance in regional anesthesia of the anterolateral abdominal wall after a C-section, mainly due to the introduction of ultrasonography (USG) during nerve block procedures [9]. This has resulted in numerous studies proving its effectiveness, mainly through the reduction of somatic components of postoperative pain [10]. Currently, the most popular regional block after a C-section is Transversus Abdominis Plain Block (TAPB) [10–12]. Dozens of clinical trials and their meta-analyses show that TAPB, as a component of multimodal pain therapy, provides effective analgesia after a C-section within the field of somatic pain which in fact is only coming from the abdominal wall [10–12]. Conducting research on a new access to TAPB using ultrasound led to the Quadratus Lumborum Block (QLB) [13, 14]. A unique component of the QLB is not only that it stops somatic pain but also that it inhibits visceral pain due to the spread of the local anesthetic to the paravertebral space. The analgesic's effectiveness and superiority over TAPB after a C-section from a posterior approach (QLB II) were shown by Blanco [14–16]. We hypothesized that QLB type I as part of a multimodal analgesic regimen would result in decreased opioid consumption and improved analgesia in the first 48 hours after a C-section. The aim of this study was to test this hypothesis and to observe any side effects in patients undergoing elective C-section via Pfannenstiel abdominal wall incision under spinal anesthesia.

MATERIAL AND METHODS

After approval from the Bioethics Committee at the University of Warmia and Mazury, on 25 June 2014, reference number 21/2014, written informed consent was obtained from 60 ASA II patients scheduled for elective C-sections via Pfanenstiel incision under spinal anesthesia. The exclusion criteria were as follows: any history of relevant drug allergy/sensitivity; pregnancy-induced hypertension; gestation diabetes mellitus; coagulopathy; anatomical abnormalities of abdomen; and abuse of tranquilizers, paracetamol or opioids. Patients were randomised by using a website (http://www.randomization.com) and a computer-generated table of unallocated numbers; thus, determining who would receive a bilateral Quadratus Luborum Block type I (QLB I group, n = 30) or be excluded from this block (Control group, n = 30). In the operating room, an intravenous cannula (a 16-gauge) was inserted in the hand or arm to all patients who were then monitored by electrocardiogram and non-invasive arterial blood pressure; and their peripheral pulse oximetry and diuresis were checked. Patients received spinal anesthesia in the sitting position at the L3–4 interspace with 12.5 mg 0.5% hyperbaric bupivacaine (Marcaine Heavy Spinal, Astra Zeneca) and 20 µg fentanyl (Polfa Warszawa) injection. Afterwards, parturients were placed in the supine position with 15^0 left uterine displacement. The crystalloids and ephedrine iv were administered as needed to treat hypotension. The oxygen supply was delivered through a facemask at 6 L/min. A C-section was permitted to proceed after Th6 sensory block assessed by loss of cold and touch. Patients received an iv infusion of 10 IU oxytocin (Gedeon Richter Plc.) after delivery and a prophylactic metoclopramide 10 mg (Metoclopramidum 0,5%, Polpharma) iv was administered. At the end of the surgery patients received paracetamol 1g iv (Perfalgan, Bristol-Myers Squibb).

Interventions

After wound closure, in the patients allocated to the QLB I group, the Quadratus Lumborum Block I was performed using the following aseptic techniques. The patient was placed in the lateral position, the skin was sanitized with antiseptic solution. At the beginning a convex 6 MHz ultrasound probe (BK Flex Focus 400) with a protective sheath was placed above the lateral edge of the rectus muscle and USG imaging depth and gain was set. Next, the probe was inserted in the intracranial direction towards the iliac crest until three bellies of abdominal muscles were visualized. Following the internal oblique and transversus abdominis muscles, the quadratus lumborum was identified with its adherent to the lateral edge of the transverse process of the L4 vertebral body and the intermediate layer of the thoracolumbar fascia. Also, the erector spinae muscle and psoas major muscle were visualized, together giving a recognisable pattern of a three-leaf shamrock well described in the Shamrock Block technique. A 20-guage 10 mm Stimuplex Ultra 360 needle (BBraun, Melsungen AG, Germany) was attached with 100 mm flexible tubing to a syringe filled with 0.9% saline and was inserted in-plane to the probe from medial to lateral and moved until the point of injection was placed at the anterolateral border of the QLM and above the junction with the transversalis fascia (Fig. 1). Then, 5 mL of 0.9% saline was injected to visualize the solution spread and to confirm the needle placement. Patients in the QLB I group received 24 mL of 0.375% ropivacaine (Ropimol, Molteni) per side (in total 180mg) (Fig. 2). This solution was injected after aspiration in 4 mL increments. The identical technique was repeated on the opposite side. After the procedure, patients were transferred to the post-anesthesia care unit (PACU) where their heart rate, non-invasive arterial blood pressure, respiratory rate, peripheral pulse oximetry and dieresis were

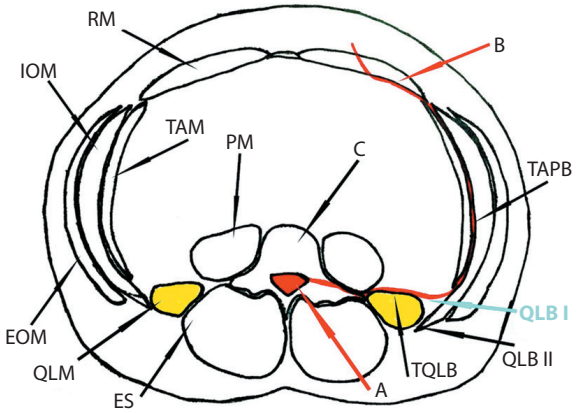

Figure 1. Diagram of abdomen cross section above the iliac crest (L4)

TQLB — Transmuscular Quadratus Lumborum Block; QLB — Quadratus Lumborum Block type I & II, TAPB — Transversus Abdominis Plane Block; A — spinal cord; B — ventral ramus of spinal nerve; C — body of lumbar vertebral (L4); ES — erector spinae muscle; PM — psoas major muscle; QLM — quadratus lumborum muscle; EOM — external oblique muscle; IOM — internal oblique muscle; TAM — transversus abdominis muscle; RM – rectus abdominis muscle

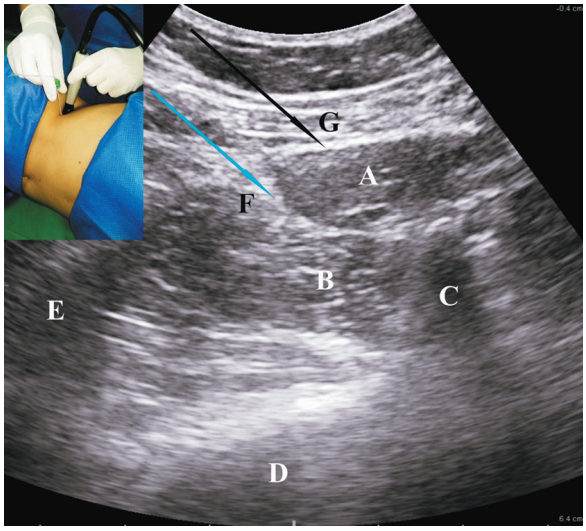

Figure 2. Ultrasound-guided Quadratus Lumborum Block Type I i II (QLB I i QLB II)

measured. Nurses providing postoperative care were given no information about which patient belonged to which study group. Over the next 48 hours, all patients received 1 g of paracetamol iv at constant intervals of time (every 6 hours) and 5 mg of morphine subcutaneously depending on their intensity of pain (NRS > 3), or, on demand with the proviso of a 4-hour administration frequency. Next, the the level of pain intensity was evaluated, only in rest among the newly delivered mothers (using NRS scale 0–10 in which 0 = no pain and 10 = worst pain imaginable) and consecutively after 2, 4, 8, 12, 16, 20, 24, 30, 36, 42 and 48 hours. At every postoperative time-point the following parameters were measured: sedation (Ramsey scale); nausea, vomiting and itching (0 = none, 1 = mild, 2 = moderate, 3 = severe); the possibility of the free movement of limbs or any other possible side effects. The primary outcome measure in this clinical study was 48 h morphine consumption. Secondary outcome measures included NRS scores, time elapsed to the first request for morphine and any side effects associated with morphine consumption and the block technique.

Statistical analysis

Reviewing the literature in 2014, we did not identify any previous studies comparing QLB type I or II with 48 h morphine consumption or NRS pain scores after C-section. The minimum patient number in each study group was calculated based on the data from the pilot study of 10 patients, in whom the 24 h morphine requirement was 25 mg. We considered that a clinically important difference in 24 h morphine consumption would be a 25% absolute reduction in the QLB I group compared with the control group. We elected to recruit 30 patients per group into the study based on a calculation of 0.05 and a power of 0.8, to minimize any effect of data loss,. The results were analysed by using SPSS Statistics (ver. 19, SPSS Inc, USA) and taking as the level of significance p = 0.05. Data was assessed for normality based on the results of the Shapiro-Wilk test. Statistical descriptions of the analysed variables included the numerical amount, the minimum and maximum value, median, mean and standard deviation. In the case where the variables exhibited a normal distribution, a parametric t-Student test was used in two independent groups. In turn, when distributed values were different from normal, a non-parametric Mann-Whitney U test was applied. The Chi-square test was used to compare differences between the variables obtained.

RESULTS

Sixty patients were enrolled in the study. Two patients from the QLB I group were excluded because of postoperative analgesic protocol violations, so results for fifty-eight patients were analyzed in total (Fig. 3). The groups did not differ in terms of demographic data (Tab. 1). Our study compares the two groups' morphine consumption, by comparing morphine use across the 48-hour period; and by comparing consumption between day 0 and day 1; to identify statistically significant differences (Tab. 2). In the group of patients who underwent the QLB I block, there was a statistically lower use of morphine at 4-hour intervals, in contrast with the control group (Tab. 3). Another statistically significant difference between the groups was the time elapsed from the C-section until the first dose of morphine, which amounted to 222 minutes on average in the Control group and 618 minutes in the QLB I group (Tab. 4). Statistically significant differences were also demonstrated between the two study groups when assessing

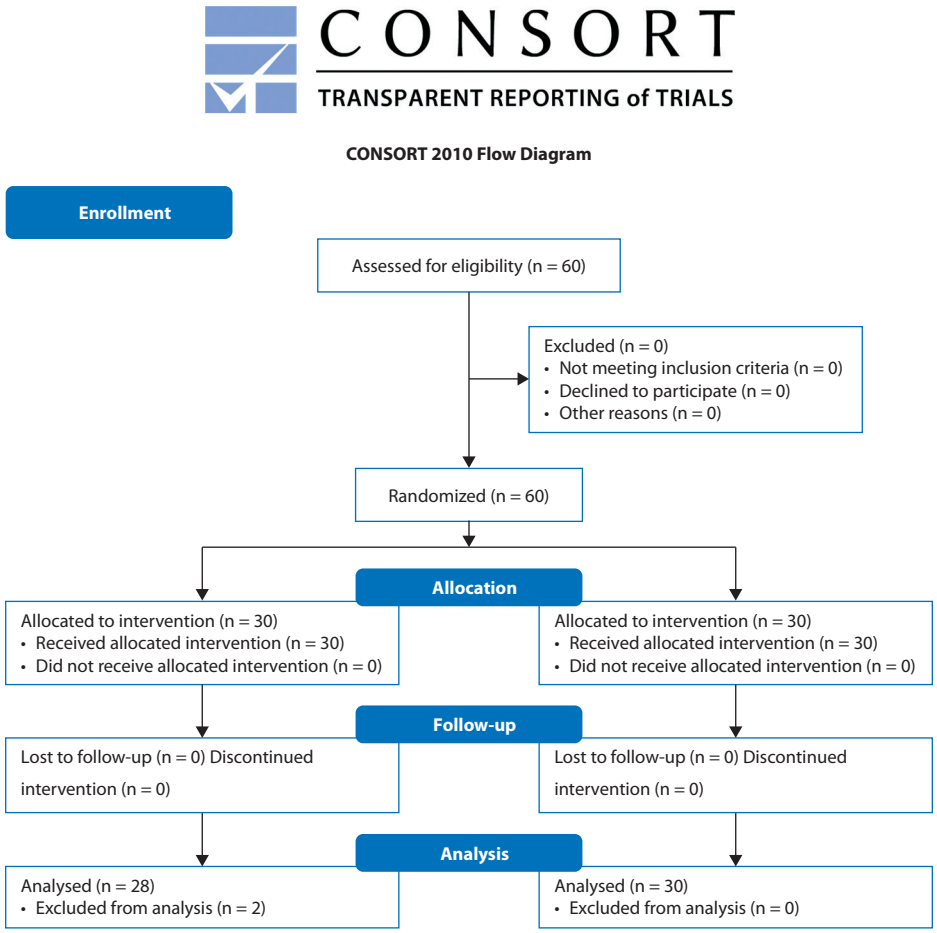

Figure 3. Consort statement

Table 1. Demographic data

	Control group (N = 30)				QLB I group (N = 28)				P value
	Median	Mean	SD	95% CI	Median	Mean	SD	95% CI	
Height [cm]	167.50	167.80	5.64	165.69–169.91	165.00	166.71	4.93	164.80–168.63	0.39
Weight [kg]	85.00	82.57	14.26	77.24–87.89	80.00	79.96	9.79	76.17–83.76	0.44
Age [years]	29.15	29.29	4.55	27.59–30.99	27.800	28.746	3.25	27.49–30.01	0.82
BMI [kg/m^2]	32	30.63	4.85	28.82–32.45	31	30.43	4.09	28.84–32.01	0.64

SD — standard deviation; QLB — Quadratus Lumborum Block

Table 2. Cumulative use of morphine with the division on day 0 and 1, and a total of 48 hours

	Control group (N = 30)			QLB I group (N = 28)			
	Mean range	Range	Median	Mean range	Range	Median	P value
Morphine use (mg) day 0	41.1	1233	20	17.07	478	10	0.0000
Morphine use (mg) day 1	36.6	1098	10	21.89	613	5	0.0001
Morphine total dose (mg) 48hours	41.77	1253	30	16.36	458	15	0.0000

QLB — Quadratus Lumborum Block

Table 3. Use of morphine at 4-hour intervals by the patients from control group and who underwent the QLB I block

	Control group (N = 30)	QLB I group (N = 28)	
4-hour intervals	**No (%) who use morphine**	**No (%) who use morphine**	**P value**
0–4 h	20 (67%)	0 (0%)	p < 0.05
4–8 h	23 (77%)	2 (7%)	p < 0.05
8–12 h	22 (73%)	22 (79%)	P = 0.64
12–16 h	20 (67%)	10 (36%)	p < 0.05
16–20 h	18 (60%)	17 (61%)	p = 0.96
20–24 h	10 (33%)	11 (39%)	p = 0.64
24–28 h	17 (57%)	6 (21%)	p < 0.05
28–32 h	16 (53%)	7 (25%)	p < 0.05
32–36 h	18 (60%)	6 (21%)	p < 0.05
36–40 h	6 (20%)	3 (11%)	p = 0.33
40–44 h	5 (17%)	3 (11%)	p = 0.51
44–48 h	0 (0%)	2 (7%)	p = 0.14

QLB — Quadratus Lumborum Block

Table 4. Time to first morphine use in minutes

	Control group (N = 30)					QLB I group (N = 25)					P value
	Min	**Max**	**Median**	**Mean**	**SD**	**Min**	**Max**	**Median**	**Mean**	**SD**	
Time (min.)	95	425	202.5	221.67	77.96	330	990	630	618.4	128.21	p = 0.000

SD — standard deviation

Table 5. Numeral Rating Scale (NRS) pain scores on days 0 and 1 postoperatively

NRS at rest (0–10)	Control group (N. = 30)		QLB I group (N. = 28)		P value
	Median	**Variance**	**Median**	**Variance**	
0 h postoperative	0 (0–0)	0.000	0 (0–0)	0.000	NS
2 h	3 (2–4)	0.372	0 (0–2)	0.476	p = 0.000
4 h	3 (0–7)	1.131	1 (0–4)	1.053	p = 0.000
8 h	3 (2–5)	0.574	2 (0–3)	0.847	p = 0.000
12 h	3 (2–6)	0.740	2 (0–3)	0.513	p = 0.000
16 h	3 (1–6)	1.306	2 (1–4)	0.851	p = 0.001
20 h	3 (2–5)	0.516	2 (0–4)	0.804	p = 0.000
24 h	3 (1–6)	0.861	2 (0–3)	0.757	p = 0.000
30 h	3 (2–5)	0.547	1 (0–3)	0.630	p = 0.000
36 h	3 (2–5)	0.648	1 (0–4)	0.988	p = 0.000
42 h	2 (1–4)	0.616	1 (0–3)	0.670	p = 0.000
48 h	1 (0–3)	0.340	0 (0–1)	0.247	p = 0.000

IQR — interquartile range; NS — not sagnificant; QLB — Quadratus Lumborum Block

the levels of intensity of pain reported by patients, using the NRS scale at these intervals: after 2, 4, 8, 12, 16, 20, 24, 30, 36, 42, and 48 hours from the C-section (Tab. 5). No difference was noticed between the groups when it came to sedation, nausea, vomiting and itching; or free limb movement or other possible side effects.

DISCUSSION

Opioids continue to play an undisputed role in the treatment of acute pain after C-sections; most often applied systemically and/or into the subarachnoid space [17]. Intravenous administration of opioids is recommenced, using the Patient Controlled Analgesia method (PCA) [4, 8]. In

the opinion of numerous authors, the most effective and longest-lasting analgesic (11–24 hours) in the postoperative period among patients after a C-section, is exhibited by morphine used as a component of spinal anesthesia [17, 18]. The side effects and limits in systemic and intrathecal usage of opioids after a C-section are: respiratory depression, nausea and vomiting, itching, excessive sedation, slowing peristaltic intestine activity and pruritus [19]. One cannot ignore the possibility of using Tramadol, which, in many cases of post-operative pain therapy after laparotomy, is more positive than morphine because, for example, there is less risk of pruritus and of respiratory depression [20]. Regional anesthesia used with non-opioid analgesics aims to reduce the total dose of opioids taken by patients during both the intra- and post-operative periods, which is the main point of multimodal analgesia [8].

Various analyses showed that the Transversus Abdominis Plane Block (TAPB) is an effective tool to fight postoperative pain in terms of reducing the total dose of opioids, but only when spinal morphine is not used [21, 22]. Carney et al. demonstrated, by using an MRI of the chest and abdomen, when comparing between four groups of volunteers, that the spread of LA after TAPB occurs only in the area of the transversus abdominis plane, determining a slowdown of only somatic pain and providing a sensory block only within the scope of the innervation of Th9-Th10 or Th11-L1. Conversely, the block within the QLM revealed the spread of the contrast towards the paravertebral space between Th4-L1 spaces [10, 13, 23]. The aim of our study was to confirm what Blanco indicated in 2007, that a new concept of the block of the abdominal wall of the inhibitory effect of somatic and visceral pain, the so called paravertebral block component, was beneficial [14, 15]. There were no published studies evaluating the effectiveness of the QLB I and post-cesarean section until 2014, when the protocol of the clinical trial presented here was developed. According to various studies published since 2015, the QLB and its variants are an effective analgesic tool compared with the TAPB due to the absence of the paravertebral component; a smaller scope of activities; and the possibility of fewer complications [15, 16, 24].

In the presented study the focus has been on the assessment of pain in the postoperative period during the first 48 hours (day 0 and 1) after a C-section. Among other researchers, the most frequently used observation time was a 24-hour cycle [11]. In contrast, the evaluation of pain intensity for a period of 48 hours after a C-section, was conducted among some authors after applying TAPB,; and by Blanco at al. after application of QLB II [14, 18, 25]. One of the main methods of assessing the effectiveness of analgesic QLB I was to compare the use of morphine for patients in two study groups [11, 14]. In our study of a Control group and the QLB I group, the median of the total morphine dose administered subcutaneously in the first 24 hours was 20mg and 10mg respectively; and during the first 48 hours 30 mg and 15 mg respectively. This result compares with other authors' studies which evaluated morphine consumption by PCA iv during the first 24 hours, where performing the QLB II or TAPB had results of 7.5 mg, 18 mg, 19 mg and 25 mg across the different studies [14, 21, 22, 26].

A comparison of our study's two research groups' results for the four-hourly intervals gave interesting results. During the first 8 hours after a C-section as many as 70% more patients took morphine in the control group comparing with the QLB I group. Then, also worth noting is the period between 8 and 12 hours after the C-section, where conversely, the morphine consumption was higher by 6% in the QLB I group. This sudden change in the morphine demand by the QLB I group from 7% to 79%, and the constancy in the control group (77% and 73% respectively for the two periods), clearly indicates the period when the effects of the analgesic block disappeared. The difference in the timing of the QLB I group's morphine requirement is reflected in the calculated difference of the timing of the first dose of morphine (10 hours and 18 minutes on average); compared with that of the Control group which was at 3 hours and 42 minutes on average. The next period of morphine usage in the Control group was statistically higher than the QLB I group by 30% and was observed between the 12 and 16 hours; and again between 24 and 36 hours from the time of the C-section. This difference, occurring during the first 12 hours of the second day, may suggest that the QLB I patients experienced less pain after night time due to a reduction of the first stage of postoperative pain by the use of block, and thus, may indicate that the use of the block could help to reduce pain for a further period of the patient's hospital stay [27].

The author applied the NRS scale to the subjective assessment of pain intensity among patients. Among other researchers of analgesic efficacy of TAPB and QLB after a C-section, VAS was the most frequently used scale [28]. The comparison of pain intensity assessments between the two groups in our study showed that in the Control group the maximum pain intensity rating reached 7 points with a median of 3 points; while in the QLB group the maximum pain intensity rating did not exceed 4 points, with a median between 1 and 2 points. Much better results from the VAS scoring was reported by Blanco et al., where, for the QLB group, the maximum pain intensity score was 3 points, with a median of 0; and in the Control group the maximum pain intensity score was 5 points, with a median of 3 points [29]. According to the recommendations of Hartrick et al., and Noblet et al., the pain therapy is well run in the postoperative period if the assessment of NRS or VAS does not exceed

3 points [29, 30]. Our literature review shows that many other authors of clinical trials of postoperative analgesia after a C-section also struggled with insufficiently effective pain treatment, showing results of NRS or VAS > 3 [31]. The more favorable results obtained by Blanco et al. for both the assessment of pain intensity using the VAS scale and the total consumption of morphine, especially in the first 12 hours in both study groups, arose mainly from the lack of the use of a controlled analgesia by the patient (PCA) [14].

The differences between our findings and those of Blanco et al. may also occur due to the different place at which the deposit of LA is made within the QLM by Blanco et al., meaning more from the rear side, described as QLB II by Blanco and McDonnell [14]. In our study by contrast, the LA was deposited according to the original 2007 concept, i.e., from the side of the anterolateral abdominal wall and next to the fascia transversalis, which is QLB I [14, 16]. Another important difference between our study and that of Blanco et al., which can affect the outcome of the efficiency of analgesic QLB, was the type, concentration and volume of the LA used. In our study, to avoid the possible toxic effects of bupivacaine, which was used in the study by Blanco et al. and other authors, we performed the QLB by using the less-toxic ropivacaine (though of a weaker efficiency than bupivacaine), which had also often been used by other researchers working on the effectiveness of analgesic TAPB [22, 32].

During the study, there were no adverse effects of the QLB applied, the most dangerous of which could be the patient experiencing Local Anesthetic Systemic Toxicity (LAST) caused by intravascular administration of the LA or associated with exceeding a total dose of the LA [33]. Thanks to the performance of ultrasound and the aspiration manoeuvre, safety of the procedure was significantly increased [9, 34].

Among the limitations of our method, we must mention the failure of using the PCA method due to the lack of proper equipment. Another limitation was the subcutaneous supply of morphine on demand in the event of pain, with a constant dose of 5 mg and a minimum time interval of 4 hours between doses. Perhaps a better comparison between our two study groups would be obtained by if the study was blinded, achieved by performing QLB in both groups, but by using 0.9% NaCl solution in the Control group.

CONCLUSIONS

Considering the results of the statistical analysis, our observations and answers to the survey, it can be concluded that the method of the Quadratus Lumborum Block type I is a safe and well tolerated procedure by patients undergoing cesarean sections. Based on both subjective and objective methods for assessing pain intensity, it was indicated that QLB I significantly reduced pain among patients. There was no occurrence of any danger to life or health side effects associated with the implementation of the QLB I block or due to the use of ropivacaine.

Acknowledgments

None

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