Effect of Pre-incisional Ultrasound-guided Quadratus Lumborum Block on Perioperative Analgesia and Inflammatory Responses in Transperitoneal Laparoscopic Nephrectomy: A Single-blinded, Randomised Control Trial

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Abstract: A Quadratus lumborum (QL) block produces an effective lower abdominal surgery perioperative analgesia, which has been reported to improve perioperative pain intensity and inflammatory responses. This prospective randomised-control study evaluates the efficacy of a pre-incisional ultrasound-guided QL block in providing perioperative analgesia following a transperitoneal laparoscopic nephrectomy. Forty-four adult patients were randomly assigned into the control group or QL block group. Intraoperative fentanyl, post-operative Numerical Rating Scale (NRS) at rest and during movement and additional tramadol in the first 24 hours were recorded. Blood samples for interleukin-6 (IL-6) and hemodynamic profiles were recorded after anaesthesia induction, after two hours of surgery and two hours post-operation. The QL block group had lower intraoperative fentanyl ($P < 0.05$), lower post-operative NRS at rest and during movement ($P < 0.001$), lower IL-6 level ($P < 0.05$) and lower additional post-operative tramadol demand with a relative risk of 3.00 (1.43–6.29, $P < 0.05$). The intraoperative hemodynamic profiles and after-surgery were significantly changed, compared to the baseline in the control group ($P < 0.001$), while the QL block group showed more stable profiles ($P > 0.05$). The pre-incisional QL block with 0.25% bupivacaine reduced the need for intraoperative opioid, showed more stable intraoperative hemodynamic changes and lowered inflammatory response, post-operative pain and the need for additional opioids following transperitoneal laparoscopic nephrectomy.

1 BACKGROUND

Laparoscopic living donor nephrectomy (LLDN) is the preferred method for kidney donation that is routinely performed under general anaesthesia (Hayden and Cowman, 2011). Several studies have reported that solely using general anaesthesia leads to a risk factor of developing greater acute post-operative pain and persistent pain one year after the surgery. The higher doses of intravenous opioids have the potential to increase post-operative hyperalgesia, a higher pain score and additional opioid demands (Barreveld et al., 2013; Richebe et al., 2013; Méleine et al., 2012).

Pre-incisional block analgesia is administered before surgical manipulation to provide analgesia during and after surgery. The approach aims to prevent intraoperative pain by activating the excessive release of cytokines as the inflammatory response because it is associated with post-operative morbidity (De Oliviera et al., 2011).

Our study aimed to evaluate the efficacy of pre-incisional bilateral Quadratus lumborum (QL) block in reducing intraoperative opioid consumption as the primary outcome, when compared with a non-receiving pre-incisional QL block on patient who underwent LLDN. Secondary outcomes were the inflammatory response of interleukin-6 (IL-6) and early post-operative pain intensity.

2 METHOD

2.1 Study Design

This was a single-blinded, prospective, randomised control study that involved two groups of adult patients who underwent transperitoneal laparoscopic

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donor nephrectomy under general anaesthesia and kidney extraction via a Pfannenstiel incision. This study was part of the clinical trial approved by the university and hospital Ethics Committee of Medical Research on June 19th, 2017 (protocol number 17-06-0619), and registered on ClinicalTrials.gov (identification number: NCT03879980). We conducted the study between March 2019 and May 2019 and followed good clinical practice guidelines.

2.2 Sample Size

A preliminary study estimated intraoperative fentanyl consumption was 305 µg (SD 79.7) on the QL block group and 435 µg (SD 159.9) on the control group. Based on opioid consumption that was lower in QL block with a combined SD of 97.6, we calculated a sample size of 20 in each group could be given 90% power to detect a difference of 100 µg fentanyl between the groups with $\alpha = 0.05$. We recruited a total of 44 patients to anticipate missing data or dropouts.

2.3 Research Protocol

Forty-four healthy patients with American Society of Anesthesiologists (ASA) classification I or II gave written consent to participate and were randomly allocated into either a QL block group or a control (non-QL block) group. Randomisation used blocks of 4 into 2 groups using a list of random numbers and was performed by sealed envelopes. The surgeries were performed by 3 urology surgeon consultants with comparable distributions. Patients and principal investigators were blinded to group allocation. Patients who had a body mass index (BMI) >30, age <18 or >65 years old, chronic use of analgesics or anti-inflammatory drugs, neuropathy, allergy to local anaesthetic, surgery <4 or >6 hours and/or duration of anaesthesia <5 or >7 hours were excluded. All patients received midazolam 2 mg IV and ranitidine 50 mg IV as premedication. Monitoring of heart rate, electrocardiography, non-invasive blood pressure, pulse oxygen saturation and end-tidal carbon dioxide was conducted. Anesthesia was induced with propofol 1–2 mg/kg IV and fentanyl 1 µg/kg IV, and intubation was facilitated with atracurium 0.5 mg/kg IV.

For the QL block group, after anaesthesia induction, the anaesthesiologist consultant performed the ultrasound-guided lateral QL block (type I) before the surgical incision. The patients were in the semi-lateral supine position to present the side to be blocked. Using GE LOGIQ™ P7 (GE Healthcare, Chicago, Illinois), and 1–6 MHz convex transducer placed in the transverse plane above the iliac crest at the level of the umbilicus, a Stimuplex® (BBraun, Germany) 20G 100-mm needle was advanced in the anteroposterior direction toward the junction of the tapered abdominal muscle layer and QL muscle, and 20 mL of 0.25% bupivacaine was deposited in the anterolateral border of QL muscle at the junction where the transversalis fascia reaches outside the anterior layer of transversalis fascia. The lateral approach QL blocks were performed on both sides of patients, and the total amount of bupivacaine was 100 mg for each patient (Figure 1).

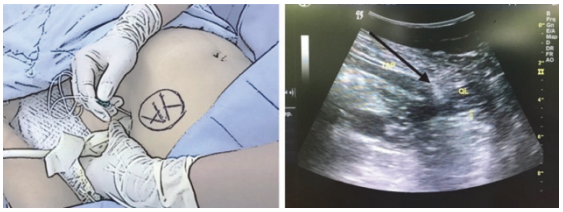

Figure 1: QL type I block technique. The arrow represents the needle tip on lateral border of the QL muscle. TAP, transversus abdominis plane; QL quadratus lumborum.

General anaesthesia was maintained using sevoflurane with end-tidal sevoflurane (ETS) target of 1.5–2% using the Aisys C2 monitor (GE Healthcare, Chicago, Illinois) to keep the bispectral index (BIS™, Covidien, Minneapolis) in the range between 40 and 50, and maintenance of atracurium 0.005 mg/kg/min IV to achieve train of four (TOF) between 0.15 and 0.25 (TOF-Watch, Organon, Ireland) intraoperatively. Both groups received fentanyl boluses 1 µg/kg IV if their heart rate or blood pressure increased ≥ 20% while BIS was 40–50, and the TOF range was 0.15–0.25; this was assessed by the anaesthesiologist as the pain response during the surgical stimulations. Venous blood samples were collected from brachial veins at the time: before the anaesthesia induction as the baseline, two hours of surgical stimulation and gas insufflation intraoperatively and two hours after recovery from anaesthesia. Inflammatory response IL-6 was analysed by the ELISA method (Quantikine, R&D system, USA) following the manufacturer's instructions, and every sample was run in duplicates. Perioperative hemodynamic profiles were represented by heart rate, systolic pressure, diastolic pressure and mean arterial pressure and were recorded using the Philips IntelliVue MP70 monitor (Philips Healthcare, Amsterdam, Netherlands) at the same time as blood samples were collected.

All patients received combination neostigmine 1.5–2.5 mg IV (0.03–0.04 mg/kg) and atropine 0.5 mg IV when the TOF ratio was 0.4–0.9 to reverse neuromuscular blockade post-operatively, and they were extubated after confirming recovery of

awareness. Both groups immediately received basic post-operative analgesia regimen paracetamol 1 gr IV 8th hourly. A combination of omeprazole 20 mg IV and ondansetron 4 mg IV 8th hourly was given to prevent post-operative nausea and vomiting (PONV). The Numerical Rating Scale (NRS) was observed between two and 24 hours after the surgery. During the observation, when the NRS began to increase to >3 at rest, the intermittent tramadol 50 mg IV boluses were given 8th hourly. If the NRS persisted >3, the intermittent tramadol 50 mg IV boluses were administered more frequently up to 4th hourly. If the pain relief was still inadequate after increasing tramadol boluses, the extra fentanyl 1 µg/kg IV boluses were given every 15 to 30 minutes until the NRS ≤3.

The analgesic effect of the intraoperative QL block and control groups was evaluated by measuring intraoperative fentanyl consumption as the primary outcome. Intraoperative fentanyl consumption was recorded as total consumption in µg and calculated into mean consumption per hour in µg/kg/h, based on the influence of the patients' body weight and the duration of surgery to the given dose of fentanyl boluses. Secondary outcomes were hemodynamic profiles, perioperative inflammation response of IL-6, immediate pain level at rest and during movement (coughing) by measuring NRS from 0 = no pain to 10 = worst pain at two hours and 24 hours after anaesthesia recovery. All patients received the NRS information during their preoperative visits and repeated explanations during the pain service team visit after their surgery. The additional opioid administration during the first 24 hours after surgery was also recorded.

The research assistant was not involved in the patient care that was randomly assigned to the patients. The anaesthesiologist consultant who performed the QL block was aware of the randomisation. Each patient, the intraoperative anaesthesiologist, the pain service team and the nurses were blind to group allocation. The primary investigator received the randomisation numbers after all measurements and calculations of the patients had been entered into the database collections. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 20 (IBM Corp, Armonk, NY) application. Patient characteristics were presented in tabular form to assess data distribution. Numerical data were analysed using the Mann-Whitney U test or estimated as log-normal distributed, then the comparison between the groups were analysed with an unpaired *t*-test and post hoc analysis with the generalised linear model (GLM) in log-transformed data. A comparison with the baseline in each group was analysed with repeated ANOVA. Categorical data were tested with the Chi-square test. Data were presented as means ± standard deviation (SD), or median (range), or mean of log-transformed data (minimum–maximum) and 95% confidence intervals.

3 RESULTS

The study CONSORT flowchart shows 44 patients were enrolled, randomly allocated into QL block group (22 patients) and control group (22 patients) and analysed (Figure 2). The baseline characteristics of both groups were comparable, except that there were more male subjects in the control group (Table 1).

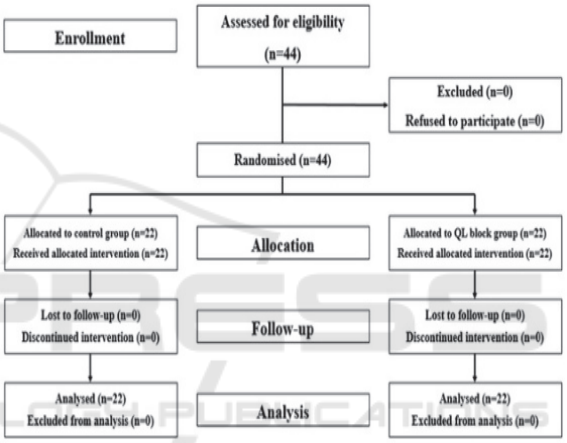

Figure 2: CONSORT flowchart.

Table 1: Baseline characteristics: Categorical data are presented as percentage, numerical data are presented as mean ± SD, median (minimum–maximum). QL, quadratus lumborum.

Variable	Control group (n=22)	QL block group (n=22)
Gender		
Male (%)	17 (77)	11(50)
Female (%)	5 (28)	11(50)
Age (years)	31 (25–54)	32 (21–63)
Weight (kg)	65.46 ± 9.40	62.79 ± 13.34
Height (cm)	162.68 ± 7.82	161.66 ± 9.34
Body mass index (kg/m^2)	24.51 ± 3.20	24.20 ± 2.90
Duration of surgery (minutes)	273 (258–288)	270 (210–360)
Pneumoperitoneum pressure (mmHg)	10.00 (8–14)	12.00 (10–14)
Duration of anaesthesia (minutes)	295 (245–385)	300 (230–390)

The mean and total intraoperative fentanyl consumption of the QL block group were significantly less than the control group (Table 2). The NRS scores at two hours after recovery, at rest and during movement were significantly lower in the QL block group ($P < 0.001$), compared to the control group. The NRS scores at 24 hours after QL block were performed at rest and during movement and were significantly lower ($P < 0.001$), compared to the control group. The additional intravenous tramadol IV was needed less in the QL block group, as compared to the control group ($P < 0.05$) (Table 2). The control group needed more additional intravenous tramadol within 24 hours, with the relative risk of this being three times higher than the QL block group [RR 3.00 (1.43–6.29), $P < 0.05$]. None of the patients needed additional fentanyl boluses during the observation.

The trends of perioperative hemodynamic profiles and IL-6 levels as the inflammatory response during and after surgery showed significant group differences (Table 3). The QL block group showed significantly higher systolic ($P < 0.001$), diastolic ($P = 0.002$), mean arterial pressure ($P < 0.001$) and heart rate ($P = 0.037$) intraoperatively, but lower values after surgery, compared to the control group. The perioperative hemodynamic profiles were significantly changing during and after surgery, compared to the baseline ($P < 0.001$) in the control group, while the QL block group showed more stable profiles ($P > 0.05$), except in terms of the heart rate.

In addition, we analysed the hemodynamic difference between time points (Table 4). The control group showed significant higher systolic ($P < 0.001$), diastolic ($P = 0.005$) and mean arterial pressure ($P = 0.001$) changes between intraoperative and post-operative time points, compared to QL block group; while the QL block group showed significant higher

Table 2: Patient's perioperative data: Numerical data were analysed with unpaired t-test and presented as mean ± SD or with Mann-Whitney U test and presented as median (maximum–minimum); categorical data were analysed with the Chi-square test and presented as a number of patients (percentage), $P < 0.05$ is significant.

	Control group (n=22)	QL Block group (n=22)	*P*-value
Mean intraoperative fentanyl consumption (μg/kg/h)	1.46 ± 0.28	1.16 ± 0.36	0.002
Total intraoperative fentanyl consumption (μg)	430 ± 105.08	322 ± 89.36	0.016
Numerical Rating Scale (NRS)			
2 hours after recovery at rest	1.00 (0.00 – 3.00)	0.00 (0.00 – 2.00)	< 0.001
2 hours after recovery in movement	2.00 (1.00 – 4.00)	1.00 (0.00 – 3.00)	< 0.001
24 hours at rest	2.00 (1.00 – 4.00)	1.00 (0.00 – 3.00)	< 0.001
24 hours in movement	4.00 (2.00 – 5.00)	2.00 (1.00 – 4.00)	< 0.001
Additional intravenous tramadol in 24 hours (n%)			
Yes	15 (34)	9 (20)	0.001
No	7 (15)	13 (30)	

Table 3: Perioperative hemodynamic response.

Parameters	Control group (n=22)	*P* value†	QL block group (n=22)	*P* value†	*P* value*	CI 95%
Systolic blood pressure (mmHg)						
baseline	100.72 (94.49–106.95)		112.16 (106.07–118.24)		0.05	11.44 (2.79–20.09)
intraoperative	106.76 (102.09–111.43)	<0.001	115.89 (109.70–122.09)	0.326	0.016	9.13 (1.77–16.50)
post-operative	118.84 (112.91–124.77)		111.42 (105.30–117.54)		0.082	-7.42 (-15.82–0.98)
Diastolic blood pressure (mmHg)						
baseline	59.84 (54.83–64.85)		70.26 (66.53–73.99)		0.05	10.42 (3.98–16.86)
intraoperative	63.00 (59.40–66.60)	<0.001	70.89 (65.69–76.10)	0.437	0.010	2.94 (1.96–13.83)
post-operative	70.40 (65.68–75.12)		66.68 (61.69–71.68)		0.273	-3.72 (-10.46–3.03)
Mean arterial pressure (mmHg)						
baseline	73.47 (68.34–78.59)		84.23 (80.48–87.98)		0.05	10.76 (4.20–17.32)
intraoperative	77.59 (73.97–81.20)	<0.001	85.89 (81.02–90.76)	0.410	0.006	8.31 (2.56–14.06)
post-operative	86.55 (81.82–91.27)		81.60 (77.05–86.15)		0.134	3.24 (-11.48–1.58)
Heart rate (beats/min)						
baseline	69.50 (64.12–75.51)		71.12 (66.99–75.68)		0.658	1.02 (0.92–1.13)
intraoperative	75.16 (69.66–81.10)	<0.001	84.33 (80.72–88.10)	<0.001	0.009	1.12 (1.03–1.22)
post-operative	82.03 (74.47–90.16)		88.31 (83.18–93.97)		0.179	1.08 (0.96–1.20)

*Data were analysed with unpaired t-test, are presented as mean of log-transformed data (maximum–minimum), $P < 0.05$ is significant.
†Data were analysed with repeated ANOVA, post hoc analysis, $P < 0.05$ is significant.
QL = quadratus lumborum.

Table 4: Hemodynamic changes between time points comparison.

Parameters	Control group (n=22)	QL block group (n=22)	*P* value*	CI 95%
Systolic blood pressure changes (mmHg)				
Baseline–intraoperative	6.04 ± 16.12	3.74 ± 13.56	0.618	-2.30 (-11.56–6.96)
Intraoperative–post-operative	12.08 ± 14.23	-4.47 ± 13.35	<0.001	-16.55 (-25.07– -8.04)
Diastolic blood pressure changes (mmHg)				
Baseline–intraoperative	3.16 ± 12.26	0.63 ± 14.82	0.539	-2.53 (-10.77–5.71)
Intraoperative–post-operative	7.40 ± 10.48	-4.21 ± 15.37	0.005	-11.61 (-19.48–-3.74)
Mean arterial pressure changes (mmHg)				
Baseline–intraoperative	4.12 ± 13.09	1.67 ± 12.99	0.540	-2.46 (-10.47–5.56)
Intraoperative–post-operative	8.96 ± 11.12	-4.30 ± 13.62	0.001	-13.26 (-20.78–-5.73)
Heart rate changes (beats/min)				
Baseline–intraoperative	5.56 ± 9.23	13.05 ± 6.96	0.005	7.49 (2.37–12.61)
Intraoperative–post-operative	7.84 ± 12.67	4.26 ± 11.20	0.335	-3.58 (-10.87–3.71)

*Data were analysed with unpaired t-test, are presented as mean ± SD, P < 0.05 is significant.
QL = quadratus lumborum.

heart rate changes (P = 0.005) between the baseline and intraoperative, compared to the control group.

The variability of the IL-6 levels from the baseline to the post-operative level was significantly different between the control and the QL block groups. In each group, the IL-6 level was significantly increased intra- and post-operatively, compared to the baseline level ($P < 0.001$). The trend of inflammatory response IL-6 plasma level from baseline to after surgery increased significantly higher ($P = 0.002$) in the control group, compared to the QL block group (Figure 3).

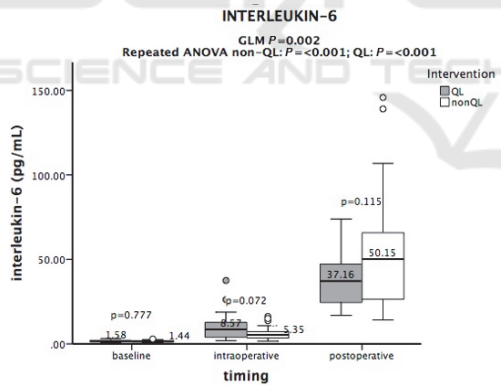

Figure 3: Inflammatory response of interleukin-6. Data are presented in log transform data (minimum–maximum); the horizontal lines indicate the medians; boxes indicate interquartile ranges; whiskers indicate ranges; P < 0.05 is significant. GLM = general linear model. QL = quadratus lumborum block. Non-QL, control group.

4 DISCUSSION

Laparoscopy surgery is increasingly performed because it promotes early mobilisation, minimises post-operative complications and reduces hospital stay, compared to open surgery. Therefore, efforts to optimise the safety of the procedure, peri-operative pain management and early daily functioning are important (Hayden and Cowman, 2011).

In 2007, Blanco first introduced the US-guided QL block technique as a posterior extension of the TAP block. It represents a more extensive abdominal analgesia by placing a curvilinear transducer in a transverse orientation slightly above the iliac crest in the posterior axillary line and uses the QL muscle as its basic sonographic landmark (Chakraborty et al., 2016; Anders et al., 2018).

The lateral QL (type I) block refers to the injection of a local anaesthetic at the lateral border of QL muscle with the spread of local anaesthetic at the junction of QL and transversalis fascia plane; QL block produces effective post-operative analgesia in lower abdominal surgery due to its spread to the thoracic paravertebral space and thoracolumbar fascia nerves. The QL block is the extension of the posterior transversus abdominis plane (TAP) block deep in the transversus abdominis aponeurosis and generates sensory blockade from T7–L1 (Ueshima et al., 2017). We performed the lateral QL (type I) block prior to the surgical incision. Although the QL (type I) block produces the local anaesthetic spread and has no visceral pain relief L1 (Ueshima et al., 2017), our findings showed that it reduced intraoperative fentanyl consumption up to 25%, which was significantly less than without the QL block.

The laparoscopy technique is sometimes associated with longer operation time, and the peak level of pain in a laparoscopy procedure is mostly during trocar port insertion, gas insufflation and the first two hours after surgery (Warle et al., 2013). Administering the pre-incisional QL block before the surgery produced a sufficient intraoperative opioid-sparing effect and reduced pain intensity 24 hours

post-operative in our study. The result was similar to the previous pre-incisional TAP-block studies in reducing intraoperative fentanyl requirements (Bhattacharjee et al., 2014). This is in line with animal studies, which have strongly suggested that peripheral nerve block reduced post-operative hyperalgesia and exposure to a higher dose of opioids during general anaesthesia and enhanced central pain sensitisation that led to reducing the effect of peripheral nerve block in preventing post-operative pain (Méleine et al., 2012).

Reducing catheter-related bladder discomfort (CRBD) incidence could also reduce a bias that obscures post-operative pain assessment. Post-operative CRBD is common, due to voluntary or involuntary detrusor muscle contraction of the bladder stimulated by acetylcholine on the muscarinic receptor. Pain during bladder catheterisation needs a sensory blockade of S3 that is outside of the QL block coverage. Tramadol is a synthetic opioid analgesic that inhibits detrusor muscle activity through inhibition of type-1 muscarinic (M1) and type-3 muscarinic (M3) receptors. Rather than using morphine, we used tramadol, because it produces an adequate analgesic effect with less urinary retention and has no impact on voiding function despite an increase in compliance of the bladder (Agarwal et al., 2008). From the urologist's perspective, it is important to have satisfactory post-operative analgesia with less of an effect on urinary retention and reduced CRBD to promote early mobilisation in LLDN patients.

The QL block group showed lower plasma IL-6 levels two hours after surgery, compared to the control group. During laparoscopy surgery, pneumoperitoneum by gas insufflation and surgical procedure produces visceral pain and somatic pain. IL-6 is one of the earliest pro-inflammatory responses induced during pain stimuli and injury, such as in surgery. Surgical stress enhances the pro-nociceptive effects of a pro-inflammatory cytokine such as IL-6, a potential mediator of stress-induced effects on nociception that is involved in the modulation of pain and contributes to hyperalgesia. In healthy volunteers, there is a correlation between pain and systemic IL-6 in response to stress and injury (Moeller-Bertram et al., 2012).

Pre-incisional analgesia is a pre-emptive treatment strategy that focuses on the prevention of central sensitisation by administering analgesia before the surgical incision to improve perioperative pain control. It becomes a part of multimodal analgesics before the stimulus arises and appears to be effective in reducing pain and consumption of analgesics during and after the surgery (De Oliviera et al., 2011; Vadivelu et al., 2014). Surgical stress induces the release of inflammatory cytokines and proteins. Patients taking a pre-emptive oral analgesic regimen one hour before surgical incision demonstrated a suppressed plasma hs-CRP level as the inflammatory mediator response in nociceptive pain (Jianda et al., 2016). However, there are various factors that influence the pre-emptive analgesia effect, such as type and duration of surgery, analgesic agents used, individual inflammation and physical responses to the extent of the injury (Farouk, 2008).

A pre-incisional TAP block could demonstrate its efficacy in reducing the hemodynamic response to a surgical stimulus (Bhattacharjee et al., 2014). We expected that the QL block would blunt the hemodynamic response during surgical procedures. However, the QL block group showed higher intraoperative hemodynamic systolic pressure, diastolic pressure, mean arterial pressure and heart rate, compared to the control group. These hemodynamic responses between the groups could be the result of higher consumption of intraoperative fentanyl in the control group. However, we found that the control group had higher perioperative hemodynamic changes in systolic, diastolic and mean arterial pressure, compared to the QL block group; while the QL block group showed a more stable perioperative hemodynamic variability, compared to the control group. While we ensured adequate muscle relaxation and monitored the depth of anaesthesia with BIS and ETS monitoring, it was difficult to define the level of intraoperative analgesia based on hemodynamic parameters (Bhattacharjee et al., 2014).

There are a few limitations to this study. The control group may have been more appropriate to perform QL block using normal saline to improve blinding, but our institution ethic board recommended that we avoid invasive intervention using the placebo. When the NRS started to increase >3, the tramadol was given by intermittent boluses 8th hourly by ward nurses, but not by PCA based on patient need. The level of sedation due to tramadol consumption was not assessed. We could not assess nausea and vomiting between the groups because antiemetics were routinely given post-operative, but we were able to eliminate bias in evaluating post-operative pain by reducing nausea and vomiting. We excluded patients with BMI >30; therefore further research of the QL block on obese patients is needed. Additional research in pre-emptive analgesia is warranted to optimise perioperative pain management following transabdominal laparoscopic surgery.

5 CONCLUSIONS

The pre-incisional bilateral QL block using 100 mg of 0.25% bupivacaine resulted in less intraoperative opioid consumption and a lower post-operative inflammatory response. It reduced the 24-hour post-operative pain intensity and additional opioid consumption following transperitoneal laparoscopic nephrectomy.

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