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Local infiltration versus laparoscopic-guided transverse abdominis plane block in laparoscopic cholecystectomy: double-blinded randomized control trial

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Abstract

Background Transverse abdominal plane block (TAP) is a new technique of regional block described to reduce postoperative pain in laparoscopic cholecystectomy (LC). Recent reports describe an easy technique to deliver local anesthetic agent under laparoscopic guidance.

Methods This randomized control trial was designed to compare the effectiveness of additional laparoscopic-guided TAP block against the standard full thickness port site infiltration. 45 patients were randomized in to each arm after excluding emergency LC, conversions, ones with coagulopathy, pregnancy and allergy to local anesthetics. All cases were four ports LC. Interventions—Both groups received standard port site infiltration with 3–5 ml of 0.25% bupivacaine. The test group received additional laparoscopic-guided TAP block with 20 ml of 0.25% bupivacaine subcostally, between the anterior axillary and mid clavicular lines. As outcome measures the pain score, opioid requirement, episodes of nausea and vomiting and time to mobilize was measured at 6 hourly intervals.

Results The two groups were comparable in the age, gender, body mass index, indication for cholecystectomy difficulty index and surgery duration. The pain score at 6 h ($P=0.043$) and opioid requirement at 6 h ($P=0.026$) was higher in the TAP group. These were similar in subsequent assessments. Other secondary outcomes were similar in the two groups.

Conclusion Laparoscopic-guided transverses abdominis plane block using plain bupivacaine does not give an additional pain relief or other favorable outcomes. It can worsen the pain scores. Pre registration: The trial was registered in Sri Lanka clinical trial registry—SLCTR/2016/011 (http://www.slctr.lk/trials/357)

Keywords Cholecystectomy/laparoscopic · Analgesics · Post-operative/prevention · Randomized control trial · Nerve blocks

Laparoscopic cholecystectomy is the treatment of choice for symptomatic gallstone disease. It is increasingly becoming popular as a day procedure, reducing the cost of surgery and the workload on the health care system [1–4]. Effective pain relief sparing opioids is one of the key factors allowing early discharge. Pain after laparoscopic cholecystectomy arises as a visceral pain due to trauma of gallbladder resection and partial pain due to incision in the abdominal wall. The incisional pain predominates over the visceral pain in the first 24 h [5, 6]. Apart from standard post-operative analgesics, local port site infiltration of anesthetic drug has been the standard practice [7].

Transverse abdominal plane block (TAP) is a new technique of regional block described initially for lower abdominal procedures. It was introduced as a blind procedure and

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later became popular as an ultrasound (US)-guided procedure [5, 8]. The plane between the transverse abdominis muscle and the internal oblique muscle is infiltrated with a considerable volume of Bupivacaine. The effectiveness of TAP block has been studied in laparoscopic cholecystectomy extensively [7, 9, 10]. Recent reports describes a technique to deliver the local anesthetic agent under laparoscopic guidance [11, 12]. This technique has advantages over ultrasound-guided procedure. It is a simple procedure that does not need the skill to handle the ultrasound scan and saves time. It also prevents intra peritoneal injections. The procedure takes less than 30 s to complete. It has been the standard practice in our unit since 1 year before the study.

This randomized control trial was designed to compare the effectiveness of additional laparoscopic-guided TAP block with the standard full thickness port site infiltration during uncomplicated laparoscopic cholecystectomy.

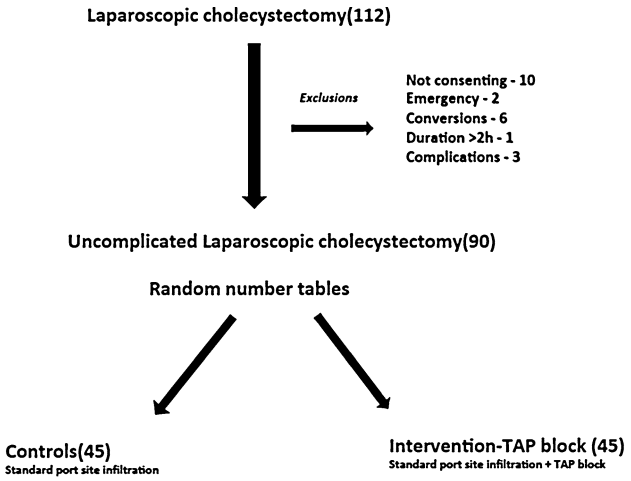

Fig. 1 The study design

Methodology

This trial is a double blind randomized controlled study, which was conducted in a single surgical unit. Trial was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. The institutional review board (IRB) at university of Kelaniya Faculty of Medicine approved the trial and it was registered in the Sri Lanka clinical trial registry (SLCTR/ 2016/011).

Sample size and inclusion criteria

Considering the previous data, 50% of patients who underwent laparoscopic cholecystectomy in our unit had received 5 mg of subcutaneous Morphine for postoperative pain relief during first 24 h. It was hypothesized that laparoscopic TAP block gives superior pain relief after laparoscopic cholecystectomy. For the anticipated reduction of postoperative analgesic requirement up to 20%, 45 patients for each arm was required to have 80% power at P value < 0.01. Patients who underwent elective laparoscopic cholecystectomy were selected for the study. Those who underwent emergency laparoscopic cholecystectomy, conversions to open cholecystectomy, coagulopathy, pregnancy, allergy to local anesthetic agents were considered as exclusion criteria (Fig. 1).

Randomization and blinding

Patients were allocated to two groups using random number tables and the randomization was done immediately before the surgery. Two surgeons working in two separate theatre lists operated the patients. When the surgeon 'A' performed the surgery, surgeon 'B' placed the ports and delivered the TAP block depending on the randomization and handed over the patient for surgeon 'A'. The patients' management and discharge decisions were taken by surgeon 'A' who was not aware about the patients group. A data collector who was not aware about the patients group collected data.

Clinical management

The laparoscopic cholecystectomy was performed with 10 mm umbilical port, 10 mm epigastric port, two 5 mm ports in right hypochondrium and iliac fossa. Procedure was standardized with the use of the same anesthetic, intraoperative and postoperative techniques in the two groups except for the additional transverse abdominis plane block with 20 ml of 0.25% bupivacaine in the intervention group. 22 G Needle was introduced subcostally between the anterior axillary and mid clavicular lines on the right side. Infiltration into the correct plane was confirmed by visualizing the needle traversing the extra-peritoneal space without penetration of the parietal peritoneum. The needle was then withdrawn and infiltration was commenced. Confirmation of the corrected plan was highlighted by the presence of Doyle's bulge which is covered by the fibers of the thin transversus abdominis muscle [11]. Both groups received standard port site infiltration with 3–5 ml of 0.25% bupivacaine.

The postoperative analgesics were given according to a protocol. A separate medical officer who was blinded on the groups did the in ward management. A standard data collection form was used for data collection. Patients were evaluated every 6 hourly until discharge. Post-operative pain at rest was assessed using 10-point visual analog pain scale. The requirements for the opioid analgesics (S/C morphine 0.1 mg/kg) were recorded as a total dose at each point. Duration of immobilization, postoperative vomiting, duration of hospital stay were the other parameters assessed. Data were entered to a SPSS database immediately following the data

collection. The statistical analysis was done using SPSS statistical software with significance set at *P* value less than 0.05.

Results

A total of 90 patients were included to the study with forty-five patients each to the intervention and control groups. Median age of the study population was 50 years (range 19–80) and 72.2% were females. Majority (67.1%) were ASA 1 patients and rest being ASA 2 patients. The median body mass index (BMI) was 25.34 kg/m^2 (range 14.6–33.3). The indication for laparoscopic cholecystectomy was biliary colic in 61.4%, cholecystitis in 18.2 and 20.5% accounted for miscellaneous conditions. The median operating time was 60 min (range 20–135).

Table 1 Baseline characteristics of the study population

	TAP block given (Intervention)	TAP block not given (Control)	*P* value
Male female ratio	0.214	0.333	0.244
Age	51(19–80)	47(23–72)	0.288
Indication			
Biliary colic	65.2%	57.1%	
Cholecystitis	10.9%	26.2%	0.155
Other	23.9%	16.7%	
ASA	1(1–2)	1(1–2)	0.473
Body mass index	25.15(16–33)	25.68(14.6–30.4)	0.904
Operating time	60(30–120)	60(20–135)	0.528
Difficulty index	4(0–7)	4(1–9)	0.637

The baseline characteristics of the control group and the intervention group were similar (Table 1). There was no difference in the male to female ratio ($P = 0.244$), the median age ($P = 0.288$), the indication for surgery ($P = 0.155$), the ASA grade ($P = 0.473$), the BMI ($P = 0.904$), operating time ($P = 0.528$), and the difficulty index ($P = 0.637$).

When the visual analog scale pain scores were compared at six hourly intervals, the pain score at 6 h was higher among the patients who received the TAP block ($P = 0.043$). Thereafter, the six hourly pain scores were not significantly different between the two groups until the discharge (Fig. 2). Similarly, there was a statistically significant difference in the opioid requirement at 6 h between the two groups ($P = 0.026$) with 89% of patients in TAP group compared to 68% in control group requiring opioids for pain control. There after the opioid requirement was similar among the groups (Table 2).

There was no difference in the secondary efficacy variables between the two groups (Table 3). The total hospital stay ($P = 0.470$), the number of vomiting episodes ($P = 0.859$) and the percentage of patients mobilized at six hourly intervals ($P = 0.883$) were similar between the two groups.

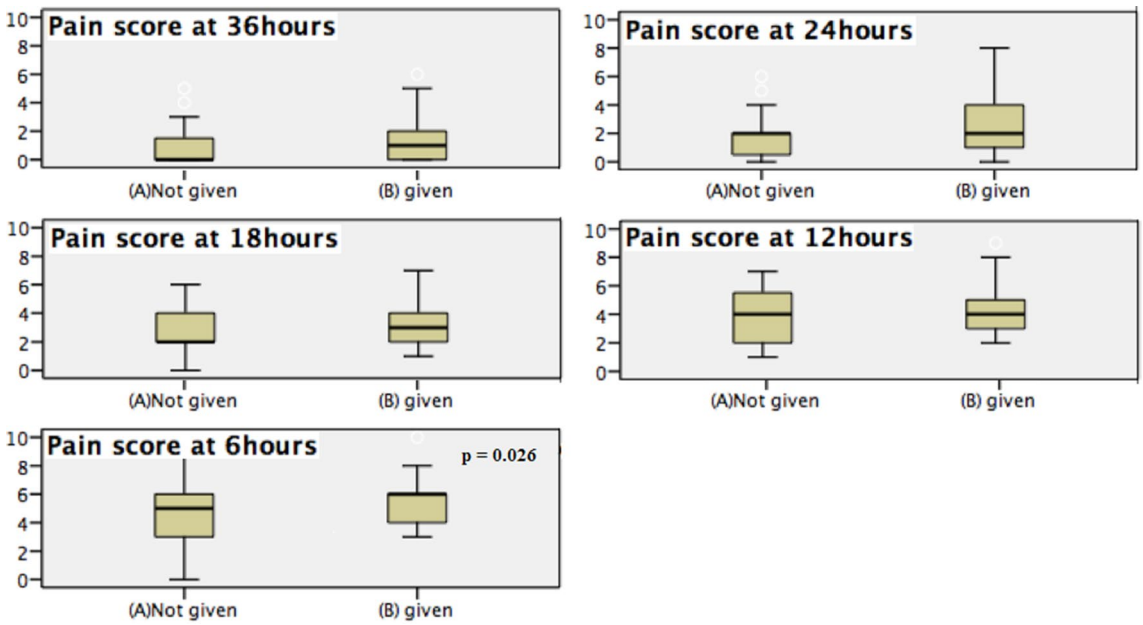

Fig. 2 The distribution of 6 hourly pain scores in the two groups

Table 2 Primary efficacy variables

	TAP block given (Intervention)	TAP block not given (Control)	*P* value
Pain score			
6 h	6(2–10)	5(0–9)	0.043
12 h	4(2–9)	4(1–7)	0.587
18 h	3(0–7)	2(0–6)	0.135
24 h	2(0–8)	2(0–6)	0.188
36 h	1(0–6)	0(0–5)	0.093
Opioid requirement (Number of doses)			
6 h	1(0–1)	1(0–1)	0.021
12 h	0(0–6)	0(0–6)	0.414
18 h	0(0–3)	0(0–2)	0.715
24 h	0(0–4)	0(0–2)	0.267
36 h	0(0–4)	0(0–2)	0.671

Table 3 Secondary efficacy variables

	TAP block given (Intervention)	TAP block not given (Control)	*P* value
Hospital stay	48 h (24–72)	48 h (24–72)	$P=0.470$
Vomiting episodes	0(0–4)	0(0–2)	$P=0.859$
Percentage of patients mobilized			
6 h	11.4%	7.5%	$P=0.883$
12 h	22.7%	33.3%	
18 h	69.8%	77.5%	
24 h	100%	100%	

Discussion

The results show that laparoscopic transverse abdominis plane block in addition to local port site infiltration had higher pain scores at 6 h. The pain scores at 12, 18, and 24 h were similar. Secondary outcomes, vomiting, time to mobilize from the bed, and the hospital stay, were similar between the two groups.

Most of the previous studies published compare TAP block with placebo, port site infiltration or no local infiltration [5, 13]. Local post site infiltration is a simple well-established mode of pain relief [5]. We believe that any other mode of pain relief that is tested should show additional effect to port site infiltration.

An interesting observation made in this study is the increased pain score at 6 h in the TAP group. McDermott et.al looked at the accuracy of plane of delivery after anatomical landmark guided lateral TAP bock [14]. The study showed that drug was delivered in to the correct plane only in 23% of the times. 18% of the cases had drug delivered in to the peritoneal cavity. Laparoscopic-guided technique is semi-blind procedure. It is likely to negate sub-cutaneous or intra-peritoneal injection. However injection in to internal oblique or transverse abdominis muscle can happen inadvertently. Injection of a volume of 20 ml can act as a significant stimulator of visceral pain [15, 16] specially when the effect of bupivacaine weans off. There are many other studies in literature comparing TAP block with a placebo [5]. In these studies, a significant volume of saline was used as the control. As we have observed in our study, this can also act as a confounding factor that negatively affects the control group.

The site of local infiltration also needs to be taken in to consideration. In a cadaveric study by Tran et.al, Aniline dye was injected as posterior TAP block in to the cadavers under ultrasound guidance [17]. It was shown that the nerves stained were below T 10 up to L1 and only 50% of the T10 nerves were involved. The subcostal block given between anterior axillary and mid-clavicular line is unlikely to cover the T 10 area.

TAP block was initially introduced in open abdominal procedures [13]. In others, it was used for long laparoscopic procedures with larger tissue dissection [18, 19]. In our study, we have excluded complicated cases. Our median operating time was 60 min. Often laparoscopic cholecystectomy is a short surgery with limited tissue dissection. The efficacy of full thickness local port site infiltration is well established mode and has become a routine practice [6]. It is combined with standard analgesia in many centers in day case cholecystectomy [1]. Currant standard practice seems to be giving optimum pain relief in this context, and additional blocks do not provide better pain outcome and can even make the pain scores worse.

The methodology of studies in TAP blocks for laparoscopic cholecystectomy is highly heterogeneous. Whether to use anterior approach or subcostal block, whether to use ultrasound or laparoscopic guidance, the control that is used and the number of quadrants that needs to be anesthetized are some of the unclear areas [5, 13, 20]. The results of these are also heterogeneous. Tolchard et. al came to the conclusion that the subcostal transverses abdominis plane block provided superior postoperative analgesia [21]. Oritz et.al in another randomized study came to the conclusion that bilateral ultrasound-guided TAP block is equivalent to local anesthetic infiltration of trocar insertion sites for overall postoperative pain relief [20]. In most of the studies showing a benefit, it was seen only within first 6 h and subtle. Some have reported a benefit at 1 and 3 h [22]. The reliability of pain assessment in this immediate post-operative period is questionable. Some of the studies reported better scores only during movement and cough [14].

The main reason for the negative findings of the study was probably the inappropriate plane of administration of local anesthetic agent and its shorter duration of action. This

highlights the difficulty in accurately accessing the correct plane during the semi-blind laparoscopic-guided procedure. In order to overcome this, prior training of surgeons with ultrasound guidance to enter in to the correct plane could have increased the accuracy of delivery. However, such training during actual clinical practice is impractical. In contrast to plain bupivacaine that was used in this trial, liposomal bupivacaine has extended release action up to 72 h of duration. This, though not widely available, may have far-reaching and significant impact in clinical practice as local infiltrating agent [23].

In conclusion, laparoscopic-guided transversus abdominis plane block does not give an additional pain relief or other favorable outcomes compared to standard port site infiltration of local anesthetic agents in straightforward laparoscopic cholecystectomy. In fact, it can worsen the pain scores.

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Compliance with ethical standards

Disclosures Rohan C Siriwardana, Sumudu K Kumarage, Bhagya M Gunathilake, Suchintha Thilakarathne, and Jeevani S Wijesinghe have no conflicts of interest or financial ties to disclose.

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