ORIGINAL ARTICLE

Analgesic Efficacy of Sonar-guided Erector Spinae Plane Block versus Thoracic Paravertebral Block after open cholecystectomy: A Double-Blind Randomized Trial.

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ABSTRACT

Keywords: Anesthesia, Pain, Analgesia, Post-Operative, bupivacaine, open cholecystectomy

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Background and Aims: Erector spinae plane block (ESB) and Paravertebral block (PVB) are formats for post-operative analgesia. This study compares the analgesic effects of both after open cholecystectomy. **Methods:** fifty patients with ASA physical status I or II and ages 18 - 65 years who had open cholecystectomy surgery were randomly assigned to one of two groups: sonar guided ESB (Group 1, n = 25) or sonar guided PVB (Group 2, n = 25). After induction of general anesthesia all patients received 20 mL 0.5% bupivacaine in each technique of the study. Patients were estimated for post-operative analgesia using Visual analogue scale (VAS) at 0, 2, 4, 6, 12 and 24 h after surgery. **Results:** Post-operative VAS scores were lower in ESB at 4, 6, 12 and 24 h ($P < 0.05$). The time for first rescue analgesic requirement was significantly longer in ESB group (416 ± 68 min) than PVB group (371 ± 67 min). Regarding complications there were no significant adverse effects noted in two groups. **Conclusion:** Sonar-guided ESB reduced post-operative pain scores and prolonged the duration of analgesia compared to PVB after open cholecystectomy

INTRODUCTION

Regional anaesthesia has been believed as one of the formats for effective perioperative pain control. Regional blocks using ultrasound-guide has become a perfect supplement to general anaesthesia for extending analgesia after open cholecystectomy [1]. The advantage includes post-operative pain relief prolongation, a decrease in analgesic requirement post-operatively, a reduction in nausea and vomiting scores and probability for ambulatory discharge and hospital stay [2]. Hence, an efficient perioperative pain control of patients undergoing open cholecystectomy is fundamental. Paravertebral block when used as the sole anesthetic or with general anesthesia has been found to provide better postoperative pain relief but side effects such as vascular puncture and accidental pneumothorax are known problems [3]. In 2016 Forero et al. the first one described ESP block for managing thoracic neuropathic pain with hopeful results [4]. Erector spinae (ES) contains three layers of muscles: spinalis, longissimus and iliocostalis, which take place parallel to each other over the vertebra and expands from lower back of the skull base superiorly down to the pelvis caudally. ES facial Plane is a potential space deep to ES muscle, where the injected local anesthetic (LA) diffuses cranio-caudally up to multiple levels as the ES fascia expands from nuchal fascia cranially to the sacrum caudally (C7 - T2 cranially and L2 - L3 caudally) [5]. LA effects gate into the thoracic paravertebral space by coming the costotransverse foramina and that way blocks dorsal rami, ventral rami of spinal nerves, and rami communicants that carry sympathetic fibers. In this way the block involves somatic and visceral pain during open cholecystectomy surgery. With the present of ultrasound, novel interventions such as facial plan blocks have been come for perioperative analgesia in surgeries. Erector spinae plane block guided by ultrasound is a newer analgesic technique, in which anaesthetic agents are injected into fascial plane between transverse process and erector spinae muscle. It is reasonable to block the ventral and dorsal rami of the nerve roots depending on the site of injection andvolume of injected local anaesthetic. The drug spreads in superio-inferior way over multiple levels as the erector spinae facial plane extended from nuchal fascia cranially to the sacrum caudally [6]. Cadaveric studies have appeared that block at thoracic 5 level is adequate to have ipsilateral multidermatomal sensory block ranging from T1 to L3 [7]. This block does the purpose of a paravertebral block but erector spinae block is done without risk of pleural injury [8]. It was also wonderful and low-risk technique to improve post-operative acute pain management [9] [10]. They have an opioid-sparing effect and give early mobilization and early come out from hospital [11] [12].

PATIENT AND METHOD

This randomized, double-blind, comparative study was performed in Aswan University Hospital between October 2018 and February 2019, after obtaining an approval from the institutional Ethics Committee. Patients who underwent elective open cholecystectomy surgery were informed about the study and provided written informed consent.

The inclusion criteria were patients scheduled for open cholecystectomy surgery, ASA Physical Status I or II, age 18 - 65 years and weight 40 - 85 kg. The exclusion criteria were significant cardiac, neurological, hepatic, renal or respiratory disease, infection at the site of block, coagulopathy, and anaesthetic allergy to local anesthesia. The primary purpose of this study was to detect postoperative visual analogue scale (VAS) pain scores. The secondary targets were to determine the variation in the duration of analgesia of the two blocks and the 24h morphine consumption after surgery. The participants were randomly assigned into two groups 25 in each (ESB and, PVB) by a random sequence number produced by the computer and kept in sealed envelopes. The closed envelopes were opened on the day of surgery after induction of anaesthesia, and participants received either ESB (n = 25) or PVB (n = 25) as per the envelope. The participants were blinded, as the blocks were done after induction of general anaesthesia and blocks were done by a anesthesiologist who was not involved in patients evaluation. Before surgery, the participants received learning about the VAS pain score (0 - 10) and the technique and details of the nerve block techniques. After a 6 h fast, the patients were brought into the operation room, where an 18-gauge intravenous (IV) cannula was secured, and observations (pulse oximeter, electrocardiography and non-invasive blood pressure) were applied. General anaesthesia was done with midazolam 2 mg, fentanyl 2 mcg/kg and propofol 2.5 mg/kg treated IV, and the trachea was intubated after administering atracurium besylate 0.15 mg/kg IV for muscle relaxation. The lungs were ventilated to preserve an end-tidal carbon dioxide of 35 - 45 mmHg. Anesthesia was preserved with oxygen, and 1% isoflurane. One gram paracetamol was administered IV after induction of anaesthesia. At the end of surgery, ondansetron 4 mg was treated IV, and muscle relaxation was reversed with IV neostigmine 40 mcg/kg and atropine 1 mg. Then, the patients were transferred to post-anaesthetic care unit (PACU) for follow up.

In Group 1 (ESPB), after induction of general anaesthesia, the patient was curved to the lateral decubitus position and the surgical side superiorly [Figure 1]. After proper skin sterilization, by sonar guided with a linear probe (8 - 13 MHz) and an ultrasound machine (M-Turbo, SonoSite Inc., USA), the probe was put in a parasagittal plane over the transverse process of thoracic 4 or thoracic 5 vertebrae, approximately 2.5 cm lateral to the spinous process. Sonar guided ESP block was managed at T4 or T5 on the same surgical side using a high-frequency linear ultrasound probe. The transverse process has a square form contour as compared to rib which is rounded form contour. Then the three muscles layers or sheets with facial plane are distinguished from superficial to deep as trapezius, rhomboid major, and erector spinae with flickering pleura in between the transverse processes. The block was managed by in- plane technique using 22-gauge, 50 mm, echogenic needle was inserted in cranial-caudad orientation, and the block needle was proceeded through the trapezius, rhomboid major,and erector spinae to smoothly contact transverse process. Needle location was confirmed by hydro dissection on injecting 2 - 3 ml of normal saline. On injecting 20 ml of 0.5% bupivacaine into interfacial plane below to erector spinae, a manifest linear pattern was visualized uplifting the muscle [Figure 2 (a) and (b)].

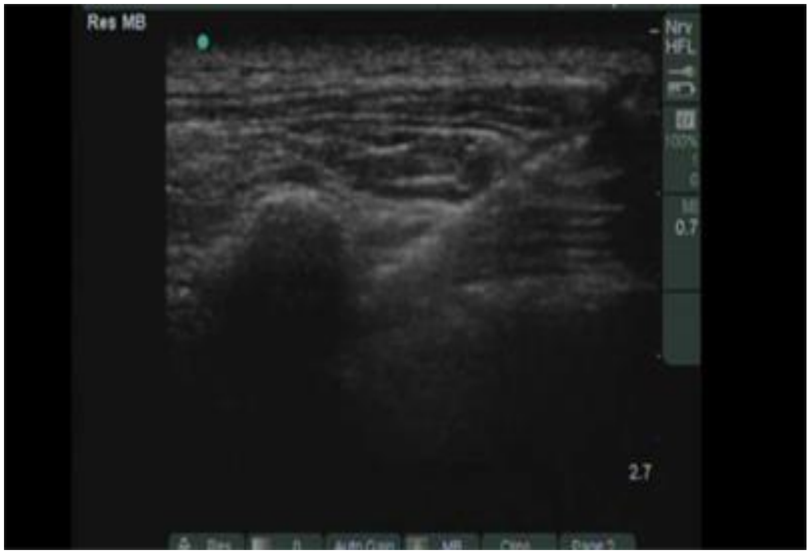
Figure 1. Patient position.

As regard the patient in Group 2 (PVB), for the ultrasound guided thoracic PVB, with the patient in the lateral decubitus position and the side of surgery was superiorly, the probe was put in a parasagittal plane over the transverse process of thoracic four and thoracic five vertebrae, almost 2.5 cm lateral to the spinous processes. The thoracic paravertebral space was distinguished as a wedge-shaped hypoechoic space between the superior costotransverse ligament and the pleura [Figure 3(a)]. After proper skin sterilization, a 22-gauge, 50 mm, echogenic needle was putted using in-plane approach from the superior side of the probe and proceeded in cranial-caudal direction and during needle progression, hydro dissection was used to determine the needle tip under ultrasound guidance, until the tip pierced the superior costotransverse ligament. The block was believed satisfactory when the pleural membrane was displaced downwards, during thistime injection of 20 ml of 0.5% bupivacaine [Figure 3(b)].

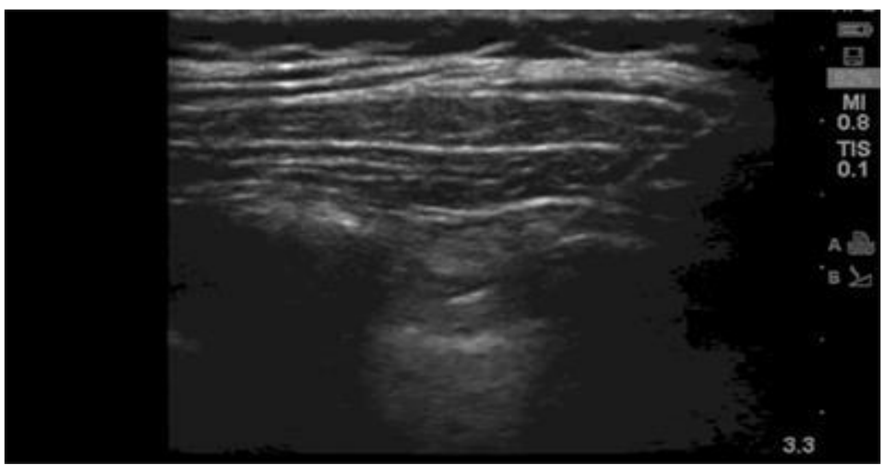
(a)

(b)

Figure 2. ESB (a) & (b).



(a)



(b)

Figure 3. PVB (a)and(b).

Vital signs (heart rate [HR], systolic, diastolic and mean blood pressure) were registered immediately before induction of anaesthesia, 10 min after induction, and then every 30 min, until the end of surgery. The patient was supposed to have pain if HR or mean arterial pressure increased >20% from baseline (at the time just before induction), sufficient anaesthetic depth by inhalation anesthesia and a bolus of 25 mcg fentanyl were treated IV if still high. In the PACU, patient-controlled analgesia (PCA) pump was connected to the patient intravenously. The pump status was morphine (1 mg per ml) bolus dose 1 mg, lockout interval 10 min and maximum dose 4 mg per hour. Pain was observed by an autonomous investigator, who was blinded, as he was not knowing of the type of block (ESB or PVB) done to the patient. Pain was estimated at 2, 4, 6, 12 and 24 h after surgery. The patient was directed to press the PCA button, whenever pain VAS ≥ 4. Duration of analgesia was from the time of administration of block to the first use of PCA by the patient, as registered by the nurse. Morphine consumption and morphine-related side effects (nausea, vomiting, respiratory depression and itching) were registered at 2, 4, 6, 12 and 24 h after surgery. Ondansetron was managed IV for nausea/vomiting and diphenhydramine was given IV for itching. One gram paracetamol was administered IV every 8 h.

Sample size and statistical analysis:

Our preparatory pilot study with ten participants in each group (ESB, PVB) showed that the duration of analgesia (mean ± standard deviation [SD]) of ESB was 45% higher than PVB (ESB, 396 ± 63; PVB, 351 ± 62 min). On this data and finding, we calculated the minimum sample size with 90% power of the study and type I error of 0.05 to be 23 patients in each study group. Allowing for withdrawal of 8% of patients, we estimated a total sample size of 25 patients for each group.

The data were analyzed using Statistical Package for the Social Sciences version 21.0 (SPSS Inc. Chicago, Illinois, USA). The categorical variables are given in numbers and percentage (%), and the continuous variables are given as mean ± SD. Normality of data was tested by Kolmogorov- Smirnov test. The quantitative variables were compared using the Unpaired t-test or Mann- Whitney test (when the data sets were not normally distributed) between the groups. The qualitative variables were compared using the Chi-square test or Fisher's exact test. $P < 0.05$ was considered statistically significant.

Result

The total number of patients registered during the study period was 50 in two groups 25 in Group 1 (ESP), 25 in Group 2 (PVB), respectively. Patients were comparable with respect to age, weight, duration of surgery and ASA status [Table 1].

Table 1. Patent demographic data

	(ESP) Group	(PVB) Group	P Value
Age	55 ± 2.9	55.1 ± 3.2	0.409
Body mass index	26.2 ± 1.8	24.8 ± 1.4	0.560
ASA Class I/II	14/11	9/16	0.409
Duration of surgery(min)	210 ± 19	206 ± 18	0.582

VAS was found to be lower in ESB group than PVB group at 2, 4, 6 and 12 h. The duration to first
rescue analgesic requirement was found to be significantly prolonged in Group 1 (ESB) (416 ± 68 min) compared to Group 2 (PVB) (371 ± 67 min) ($P < 0.001$) [Figure 4]. Total dose of morphine(mg) in ESB group were 4 ± 2, while in PVB group were 6 ± 2 ($P < 0.05$) [Table 2]. No significant complications such as vascular puncture, hypotension, pleural puncture, or pneumothorax were seen in any of the groups
Figure 4. VAS score.

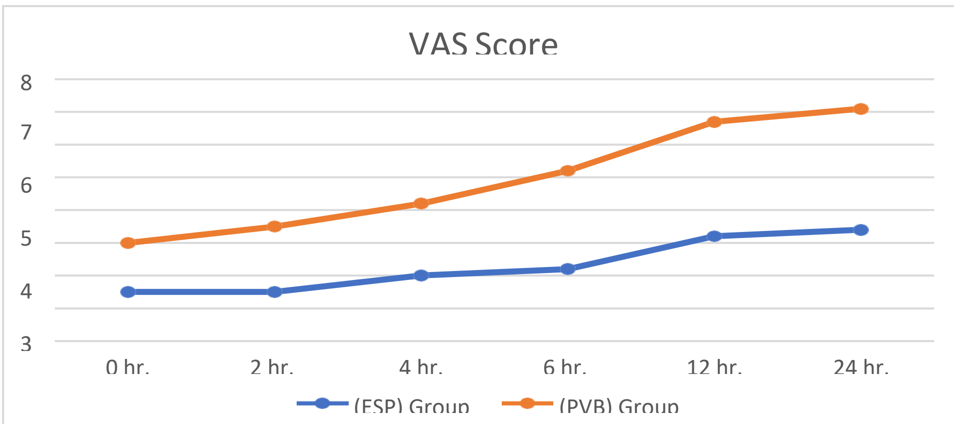


Table 2. Time to first analgesic requirement and total dose requirement

	(ESP)	(PVB)	P Value
Time to first rescued dose (min)	416 ± 68	371± 67	($P < 0.001$)
Total dose of morphine	4 ± 2	6 ± 2	($P < 0.05$)

Discussion

Different regional anaesthetic such as local wound infiltration, thoracic epidural and more recently, ultrasound-guided fascial plane blocks as thoracic paravertebral block (PVB)and erector spinae plane block (ESB) have been utilized to prolong analgesia in abdominal surgeries [13]. These procedures not only treat acute post-operative pain but also assist and prevent chronic post- surgical pain [14]. With the entrance of ultrasound in the operating theater; regional anesthetic block training has undergone a wonderful change. PVB has long been believed the gold standard procedure in patients undergoing open cholecystectomy surgery. The possible side effects and complications of PVB include pneumothorax, vascular puncture, intrathecal or epidural spread and sympathetic block leading to hemodynamic instability [15]. In open cholecystectomy surgeries,

ultrasound-guided recent interfacial plane blocks as (ESB) have been appeared which are being used as efficient alternatives to more invasive and more side effects techniques such as PVB. ESP block has elicited as an effective novel and recent regional technique with good analgesia with less opioid requirements, in addition to simplicity and safety [7] [8]. Since the description of these newer and safer interfacial plane blocks, different authors have studied their use in breast surgeries and other trunk surgeries. This randomized double-blind clinical trial compared the two main procedures of prolonged analgesia after open cholecystectomy and firm that the post- operative VAS scores were better in the (ESB) group compared to the (PVB) groups ($P < 0.05$). In addition, the duration of post-operative analgesia was significantly prolonged in the (ESB) group compared to the other group ($P < 0.001$). And also, analgesic requirement significantly lower in the (ESB) group compared to the other group ($P < 0.05$). Ultrasound-guided PVB is an excellent analgesic procedure for open cholecystectomy surgery because not only does it decrease pain but also it decreases PONV and length of hospital stay due to less morphine requirement [16]-[21]. PVB is requiring a higher degree of skill; however, the educational curve of ultrasound-guided rather declines. Moreover, a number of complications have priory been detected with PVB [3] [16].]. The local anaesthetic in PVB blocks the spinal nerves directly and expands laterally to block the intercostal nerves and expands medially into the epidural space through the intervertebral foramina and influences the sympathetic chain, leading to strong analgesia but, in ESB is indirect by this way [26] [27] [28]. The local anaesthetic can also diffuse longitudinally cranially or caudally in PVB.
This is supported by Hetta and Rezk [29] and also in ESB who compared PVB block in patients with MRM and reported complete sensory blockade over T1 - T7 dermatome levels in 100% of the patients after PVB [29]. In Hetta et al. Study also noted that the duration of analgesia of ESPB was significantly shorter compared to PVB [(median [range], 6 h [5 - 7 h] for ESPB vs. 11 h [9 - 13 h] for PVB)] by bupivacaine 25% [29]. In our study, we found a much longer duration of analgesia in groups ESB (means [±SD], [396 ± 63 min] group PVB [351 ± 62 min]). It is nice and pleasant to note that four or more intercostal spaces may be anaesthetised by a single level PVB injection, The volume of local anaesthetic is also likely an important detection of the range and duration of analgesia for ESB, and thoracic PVB. In Hetta et al. study, a more volume of bupivacaine was injected in ESB (30 ml vs. 20 ml in our study), and more efficient analgesia was detected than our study [29]. And so, ESB is a fascial block, a larger volume expected to enhance local anaesthetic spread in this technique.

In Wahba SS et al. study, after injection of 15 - 20 ml of levobupivacaine 0.25% at thoracic fourth level for PVB [30], the duration of analgesia was shorter 137.5 [115 - 165 min) than in our study (371 ± 67 min), again highlighting the influence of the local anaesthetic volume and type on duration of analgesia.
Similar to our study, Klein SM et al study found a 24 h post-operative morphine consumption higher in the ESB group compared to PVB group [1] [30]. Similar to our study, a recent study of Abdallah FW et al. also found a lowered consumption of opioids intraoperatively and postoperatively, decreased PONV and increased duration of analgesia after ambulatory breast cancer surgery [31]. In our study both ESB, PVB groups provide excellent post-operative recovery and lower the opioid requirement, as reflected by post-operative morphine consumption 4 ± 2, 6 ± 2 and 7 ± 2 mg respectively up to 24 h

postoperatively [31]. Our study results add to the limited amount of objective data available today as regarding the analgesic profile of these two new blocks after open cholecystectomy. One of the powerful of our study is the use of a standardized and fixed volume and concentration of local anaesthetic in all blocks (20 ml of 0.5% bupivacaine). Hence, our methodology has provided an equal analgesic comparison between groups as compared to other studies which administered unequal volume and/or concentration of local anesthetic
[29] [30]. Limitations in our study were also present, we could not determine on set time of block or sensory level detection because both blocks were done after induction of general anaesthesia. We do a single level injection, realizing that multiple injection procedures may provide more effective analgesia in blocks. In our study did not put a catheter to provide continuous analgesia and we could neither comment on clinical safety nor the long-term impact (as regard, development of chronic pain) of the two modalities in this small study. We conclude that ESB can thus be considered better than PVB for providing analgesia after open cholecystectomy surgery and ultrasound-guided ESP block is an excellent regional anaesthesia procedure on open cholecystectomy and has wide applications in pain relief ranging from postoperative acute pain in open cholecystectomy surgeries. We hope that in the future studies will observing the remaining issues such as the duration of analgesia with and without adjuncts and also, we hope a systematic review and meta-analyses are suggested comparing the post-operative analgesic techniques for surgery.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper

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