Original Article

Analgesic efficacy of trocar sites local anesthetic infiltration with and without transversus abdominis plane block after laparoscopic hysterectomy: a randomized trial

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Received December 2, 2015; Accepted March 2, 2016; Epub March 15, 2016; Published March 30, 2016

Abstract: Background: In gynecologic laparoscopic procedures, both the transversus abdominis plane (TAP) block and local analgesic (LA) infiltration of trocar insertion sites were suggested as components of multimodal approach for postoperative analgesia, and their effects were controversial. However, there is limited data comparing the combination of these 2 approaches and either regimen alone. Material and methods: Seventy-one women who underwent laparoscopic hysterectomy were randomly divided into 2 groups: the TAP group (n = 35, performed with TAP block after tracheal intubation) and the control group (n = 36). All subjects had trocar sites LA infiltration before closure of trocar incision sites and multimodal analgesia postoperatively. A numeric rating scale (NRS) was used to evaluate the pain relief and to record additional analgesic usage; other outcomes such as length of stay, adverse effects, and satisfaction scores were also assessed. Results: The 2 groups had comparable demographic information. Patients in the TAP group had significantly lower NRS compared with those in the control group (P<0.05); reduced postoperative analgesics requirement was also shown (parecoxib requirement of 60-80 mg: 11 cases vs. 34 cases, P<0.01; sufentanil supplementation: 3 case vs. 10 cases, P<0.05). In addition, satisfaction scores were significantly more satisfactory in the TAP block group (Z = 1.61, P<0.01) and comparable results were shown in length of stay and adverse effects between the 2 groups (P>0.05). Conclusion: After laparoscopic hysterectomy, conjunction of TAP block and trocar sites LA infiltration may be a better analgesic regimen compared to the latter alone.

Keywords: Laparoscopic hysterectomy, local analgesic, analgesia

Introduction

It is generally accepted that laparoscopic approach has been a highlight of modern developments in gynecologic surgery. Compared to traditional laparotomy, laparoscopic surgery has the advantages of minimal invasion, less postoperative pain, and reduced perioperative morbidity [1, 2]. However, postoperative pain is still the main factor hindering overall patient rehabilitation after laparoscopic procedures [3, 4].

For postoperative analgesia of laparoscopic hysterectomy, the multimodal approach has drawn more attention. Except for patient-controlled analgesia (PCA), as a simple and practical approach, the efficacy of trocar sites local anesthetic (LA) infiltration during gynecological

laparoscopic procedure is debatable, with both positive [5, 6] and negative [7, 8] results reported. Recently, transversus abdominis plane (TAP) block has been a growing more popular as an effective strategy for pain management after laparoscopic surgeries [9, 10]; however, Champaneria et al mentioned that use of TAP block should not be routine [11]; in other trials, comparable analgesic results were shown between these 2 interventions after laparoscopic surgery [12, 13]; even a systematic review has concluded that understanding of TAP block is limited, as well as its role in contemporary use [14].

Based on previous trials, we hypothesized that a combination of the TAP block and trocar insertion sites LA infiltration would be a better analgesic alternative over the latter alone following

Table 1. Ramsay sedation scale

Rating	Level
1	Patient is anxious and agitated, restless, or both
2	Patient is cooperative, oriented, and tranquil
3	Patient responds to commands only
4	Patient shows a brisk response to light or loud auditory stimulus
5	Patient shows a sluggish response to loud auditory stimuli
6	Patient exhibits no response

laparoscopic hysterectomy. In this prospective, randomized study, their effects on postoperative additional analgesic consumption, pain relief, and other outcomes were investigated.

Material and methods

Patients grouping

From November 2013 to November 2014, with approval of Clinical Research Ethics Committee of the Second Hospital of Lanzhou University (No. 2013092), 71 women scheduled for laparoscopic hysterectomy with benign lesions were enrolled and analyzed; total laparoscopic abdominal hysterectomy (TLH) and laparoscopically-assisted vaginal hysterectomy (LAVT) were all elective procedures. Written informed consent was obtained from all patients and they received instructed on the analgesic maneuver and numeric rating scale (in the NRS, "0" signifies no pain, and "10" signifies the worst pain imaginable).

Patients with preoperative analgesic usage were excluded from the study due to potential impact on postoperative analgesia requirement, as well as for those who presented with body mass index (BMI) greater than 30, coagulopathy, contraindication to peripheral nerve block, and allergy to any drugs.

Before surgery, under computer generation, a lay assistant provided the randomized assignment in a sealed envelope, and patients were divided into the TAP group (performed with TAP block) and the control group. Patients and post-operative assessors were blinded to the intervention protocol, while members of the anesthesia and surgery team were not blinded.

Processing and records

Premedication and anesthetic procedures were consistent in all patients. After entering the operating room, standard monitoring and the bispectral index (BIS) monitoring were applied,

followed by preoxygenation with 100% oxygen. General anesthesia was induced with sufentanil 0.3 to 0.5 µg/kg and propofol 2 mg/kg through peripheral venous catheter, and rocuronium 0.6 to 1 mg/kg was used to facilitate tracheal intubation.

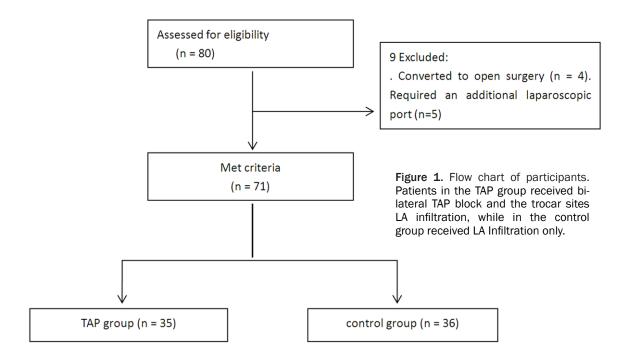
When the vital signs were stable after intubation, patients in

the TAP group received bilateral TAP block. Anesthesiologists experienced with the technique performed the operation under ultrasound guidance. Briefly, a high-frequency (5-13 MHz) ultrasound probe (SonoSite M-Turbo®, SonoSite, USA) was placed traversely between the iliac crest and the subcostal margin, at the level of the anterior axillary line, identifying the external oblique, internal oblique, and transversus abdominis muscle. A Pajunk 19G, 100-mm needle (Medizinth Chnologle, Geisingen, Germany) was inserted within the plane of the ultrasound beam and anterior to the probe, locating at the neuro-fascial plane between the internal oblique and the transversus abdominis muscle. After confirmation by negative aspiration, 15 ml of ropivacaine 0.375% was injected incrementally under ultrasound visualization. Contralateral block was accomplished in the same maneuver and total volume was 30 ml of ropivacaine 0.375% per patient.

All patients received a standard laparoscopic procedure consisting of 4 port incisions at or below the umbilicus (T10 dermatome): 1 periumbilical balloon trocar incision, 2 accessory ports inserted into the right lower quadrant and left lower quadrant, and 1 accessory port in the suprapubic region.

Maintenance of anesthesia was provided with 1.5 to 2.5% sevoflurane, 1.5 to 3.0 ug/kg/min of remifentanil, and additional bolus of rocuronium if needed. The BIS value was adjusted between 40 and 60 intraoperatively. At the end of surgery, neuromuscular blockade was reversed by neostigmine and atropine (usually neostigmine 1 mg and atropine 0.5 mg if no contradictions).

For all patients in the 2 groups, LA infiltration was performed by skilled anesthesiologists prior to the closure of trocar incision sites. Incisions 8 mm or greater were injected with 7 ml of ropivacaine 0.375% and incisions 5 mm



or less were infiltrated with 3 ml of ropivacaine 0.375%, mean volume 20 ml, and a full-thickness local injection through all preperitoneal layers was administered to all patients.

After the operation, intravenous (IV) analgesic regimens for patients were roughly equivalent. Non-steroidal analgesic was given unless contraindicated; the routine process was IV injection of parecoxib 40 mg before transferring to the postoperative care unit (PACU). For those who required additional analgesia, repeated doses of 20-40 mg parecoxib were given and total dose was less than 80 mg within 24 hours. If the analgesic efficiency was still poor, 5 to 10 µg sufentanil was IV injected slowly. No PCA was used in this study.

Postoperative use of analgesics regimens was recorded. NRS was evaluated by the PACU and floor nurses (time to arrive at PACU began as time "0" for pain assessment, followed by 30 and 60 min, and 4, 8, 12, and 24 h). After 24 h, satisfaction scores were evaluated by the floor nurses with a 4-point rating scale (excellent = 3, good = 2, fair = 1, and poor = 0). Other data were collected from the medical records: operative time, which contained duration for performance of the TAP block or LA infiltration, because exact time interval for LA administration had not be specifically recorded; incidence of adverse events, including postoperative nausea and vomiting (PONV), respiratory distress,

and injuries related to respective interventions; the Ramsay sedation scale was used to determine the sedation degrees [15], incidence of score beyond 2 to 4 was considered abnormal (**Table 1**); finally, length of stay was obtained from all patients.

Statistical analysis

Based on previous assumptions to estimate the sample size, a mean difference between the 2 treatment groups of 2 NRS pain score points was deemed clinically relevant, and the standard deviation was expected to be 2.5 in this study. A sample size of 29 participants in each group provided 86% statistical power to obtain a mean difference of 2 NRS pain scores points between the 2 treatment groups at any period of time using a 2-sided test, having a significance level of 0.05. Anticipating a 20% dropout rate, at least 35 subjects per group were enrolled.

Statistical analysis was performed using the Statistical Package for Social Sciences (version 20.0 for Windows; SPSS Inc, Chicago, IL, USA). Normality of distributions was tested with Kolmogorov-Smirnov test; Quantitative data are presented as mean and standard deviation (SD), and categorical data are presented as numbers or percentage. Differences in quantitative data (age, BMI, operative time, length of stay) were analyzed with the *t*-test. Analysis of

Table 2. Comparison of demographic data

	TAP group n = 35	control group n = 36	P-value
Age (years)	43.11±4.33	42.28±4.10	0.41
BMI (kg/m [2])	22.32±4.07	22.52±4.70	0.85
ASA class (I/II)	23/12	23/13	0.87
Surgical history	8	15	0.09
Operative time (min)	85.49±20.67	86.25±22.05	0.88
Type of operation (TLH/LAVH)	24/11	27/9	0.55

Results are expressed as means \pm SD or numbers of patients. Patients in the TAP group received bilateral TAP block and the trocar sites LA infiltration, while in the control group performed LA Infiltration only.

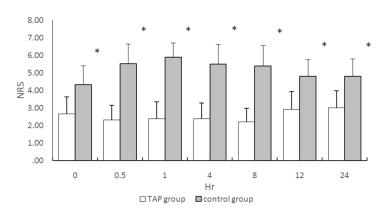


Figure 2. Comparison of pain scores over time on NAS. Results are expressed as means ± SD. Patients in the TAP group received bilateral TAP block and trocar sites LA infiltration, while the control group received LA Infiltration only. *P<0.05, compared with TAP group.

variance (ANOVA) with repeated measures was used to compare the pain scores of 2 groups. Categorical data (ASA class, surgical history, type of operation, incidence of adverse effects) were analyzed with chi-square test. Ranked data (parecoxib consumption and satisfaction scores) were analyzed with Wilcoxon rank sum test. P<0.05 was considered statistically significant for all 2-sided statistical tests.

Results

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Initially, a total of 80 patients were enrolled into this study; 5 in the TAP group and 4 in the control group did not complete the study. Intraoperative convention to a laparotomy was 2 per group; 3 in the TAP group and 2 in the control group required an additional laparoscopic port (**Figure 1**).

The 2 groups were comparable with respect to age, BMI, ASA status, surgical history, type of operation (TLH or LAVH), and operative time (Table 2).

For postoperative NRS evaluation at given time points, the patients in the TAP group presented significantly lower pain scores than those in the control group (P<0.05, **Figure 2**).

Postoperative additional analgesic use was significantly lower in patients in the TAP group (Table 3). Parecoxib consumption was described by the constituent of ratio, and in the TAP group, 24 required 40 mg, 10 required 60 mg, and 1 required 80 mg, respectively; in the control group, 2 required 40 mg, 16 required mg, and 18 required 80 mg, respectively (P<0.01). For opioids consumption, 3 in the TAP group and 8 in the control group received the same dose of sufentanil (5 µg), and 2 in the control group were at the dose of 10 μ g (P = 0.036).

Satisfaction scores (**Table 4**) were higher in the TAP group compared to those in the control group (Z value was 1.61, P<0.01).

No significant difference was found for length of stay or adverse events (**Table 3**). No cases of vis-

ceral injury or hemorrhage were associated with the bilateral TAP block.

Discussion

The results of this study show that the TAP block was associated with lower additional analgesics requirement and lower pain scores in patients undergoing laparoscopic hysterectomy. In addition, patients in the 2 groups showed similar length of stay and incidence of adverse effects. Multimodal analgesia may have more influence on laparoscopic surgery, with a trend towards the reduction of postoperative opioids.

Previous studies revealed that length of stay and opioids usage could be reduced in TLH compared with abdominal and vaginal hysterectomy [16, 17]. For length of stay, many factors contribute to the findings, such as age, surgical technique, and postoperative analgesia. Generally, minimal invasive technique has positive impact on the overall rehabilitation. In a

Table 3. Comparison of length of stay, additional analgesic usage and adverse effects

	TAP group n = 35	control group n = 36	P-value
Length of stay (days)	4.63±1.08	4.32±0.90	0.20
Parecoxib			
40 mg	24	2	<0.01
60 mg	10	16	
80 mg	1	18	
Sufentanil	3	10	0.036
Incidence of adverse events			
PONV	3	4	1.000
Abnormal sedation	0	2	

Results are expressed as means \pm SD or numbers of patients. Patients in the TAP group received bilateral TAP block and the trocar sites LA infiltration, while in the control group were performed with LA infiltration only.

Table 4. Comparison of satisfaction scores

	TAP group n = 35	control group n = 36	Z value	<i>P</i> -value
Excellent	12 (34.3)	3 (8.3)	1.61	<0.01
Good	14 (40.0)	10 (27.8)		
Fair	9 (25.7)	23 (63.9)		
Poor	0 (0)	0 (0)		

The data are presented as numbers of patients (%). Patients in the TAP group received bilateral TAP block and trocar sites LA infiltration, while the control group received LA Infiltration only.

retrospective review, a TAP block in women undergoing TLH resulted in significantly shorter length of stay [18]; reinforced analgesic efficiency of the TAP block (both posterior and subcostal TAP blocks were applied) might account for it. Our study found that length of stay was comparable between the 2 groups, and a similar result was shown in other prospective trials involving LA administration [7, 12]. More prospective trials containing a blank control group are warranted.

From this study, efficiency of ultrasound-guided TAP block was judged mainly from the reduction of additional analgesics usage and the better result of NRS, which was similar to results of previous studies [9, 10, 18]. Additionally, a considerable numbers of patients receiving the TAP block gave better satisfaction scores. In consideration of admission passage, the posterior approach of the TAP block was used [12, 13]. However, the best admission passage is still debatable. In a meta-analysis, the "poste-

rior" block technique was used for injections within the triangle of Petit, and the "lateral" approach was used close to the "posterior" injection (as we used) [19]. A cadaveric study revealed that different approaches led to different nerve involvement [20]. Another cadaveric study showed that, between the iliac crest and the subcostal margin, it might involve T10-L1 nerve roots by ultrasound-guided TAP injection [21]. These results need to be verified.

For pain relief, trocar insertion sites LA infiltration and the TAP block both aims to control somatic pain from trocar incisions in the anterior abdominal wall. The source of postoperative pain can be more than 1 anatomical struc-

ture, which is described as somatic pain (superficial pain) and visceral pain (deep pain) [22]; there is no evidence of the analgesic efficiency of TAP block for visceral pain related to surgical trauma. Based on the evaluation of pain in the present study, we think distinctive description for the 2 types of pain may be difficult due to the residual general anesthesia and influence of additional analgesics. Interestingly, the TAP block after laparoscopic procedures did not always lead to favorable outcome. A study by Kane et al concluded that, by using the TAP block, neither lower pain scores nor reduced opioids usage were evident after laparoscopic hysterectomy [23]. De Oliveira Jr et al reported that several factors contributed to their outcome, including the variation of surgical procedures and participation of obese patients [9]. Efficacy of LA infiltration in this study was consistent with previous findings for gynecologic laparoscopy [7, 8]. From this trial, the combination of TAP block and LA infiltration led to the best outcome. We suggest that double peripheral nerve blocks effectively prevented the transmission of sensorial messages to advanced nerve centers.

Time-related factors were also taken into consideration in this study and the 2 kinds of LA inventions used in this trial were based on previous experience. It was suggested that preoperative TAP block could have greater effect on postoperative analgesia. Performance of TAP block between induction and operation was reported in many clinical studies [9, 13, 24], and point-in-time of LA infiltration was also vari-

able by operators' experience [7, 8, 13]. Considering the full-thickness injection and slowdown of LA degradation, infiltration before the closure of trocar insertion sites may be more effective for pain management. There are currently no data to confirm the true action time for the TAP block or LA infiltration. To explain the superiority of the TAP group, another reason may be the anatomical structure of the transversus abdominis muscle, which is likely to have few blood vessels, so the clearance of LA may be delayed and persistent time for TAP block can reach 36 to 48 hours [25]. In total operative time, in spite of different surgical periods of time for respective LA administration, only an insignificant difference was found between the 2 groups.

In addition, many puncture-related injuries have been reported with the TAP block [26, 27] and no cases of visceral injury or hemorrhage were found in this study. With assistance of ultrasonography, effectiveness and accuracy of the TAP block have been dramatically improved to that of "pop" technique, referring to the anatomic landmark. A larger volume of ropivacaine was used in the TAP group than in the control group; whether this could result in better analgesic efficacy remains to be elucidated. In previous controlled studies, equivalent [12] and non-equivalent dose of LA [13, 18] by use of these 2 interventions were both reported and no dose-related relationship was confirmed. Recently, Griffiths et al reported that the systemic absorption of LA after ultrasound-guided TAP block and ropivacaine at 3 mg/kg was thought be potentially neurotoxic [28]. This should remind us of the safety of peripheral nerve block. Few cases of adverse events were shown in the 2 groups; the relatively lower consumption of opioids might be a contributing factor.

This study had a few limitations. For patients in the TAP group, sensory level of the TAP block could not be tested after induction, and incidence of block failure was unknown, so we judged its efficacy by NRS and additional analgesics usage. Furthermore, during the postoperative period, consumption of non-steroidal analgesic could lead to reduced opioids usage; as a result, an equivalent effect of non-steroidal analgesic to opioid was hard to detect. Finally, in the main outcomes between the 2 groups, the lack of a blank control group limits ability to draw firm conclusions.

In conclusion, combined use of the TAP block and LA infiltration can effectively reduce post-operative analgesics usage and enhance the satisfaction of patients after laparoscopic hysterectomy. In contrast, general outcome of trocar sites LA infiltration is limited. Further prospective trials are warranted to verify their utility while carrying out multimodal analgesia.

Acknowledgements

The authors would like to thank Dr. Yonggang Peng from the University of Florida for his assistance in revising the draft of this paper.

Disclosure of conflict of interest

None.

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