

## The Efficacy of Ropivacaine 0.5% in Transversus Abdominis Plane Block to Relieve the Postoperative Pain of Female Laparoscopic Surgery Grade II

### Abstract

**Background:** The aim of this study was determination of the effect of the transversus abdominis plane block (TAP block) with ropivacaine 0.5% in relieving postoperative pain after laparoscopic gynecologic surgery. **Materials and Methods:** The population of the double-blinded clinical trial study included 200 women candidates for elective laparoscopic gynecologic surgery who referred to Al-Zahra and Beheshti hospitals in Isfahan during 2016–2018. In the TAP block group in addition to standard general anesthesia, an anesthetic drug Ropivacaine (Naropin, 0.5%) was injected at a dose of 0.5 mg/kg between transverse abdominal muscle and internal oblique muscle fascia. And in control group just received standard general anesthesia. Hence, the severity of pain and nausea and vomiting is recorded at the time of recovery, at 30 min, 2, 4, 6, 12, and 48 h after the surgery. **Results:** The results of this study showed that in all periods of time (30 min, 2, 4, 6, 12, 24, 36, and 48 h after the surgery), mean pain score in TAP block group was lower than control group ( $P < 0.001$ ). Hence that, in the 48 h after the surgery, the pain score in the TAP block group with a mean of  $0.46 \pm 0.50$  was significantly lower than the control group with a mean of  $1.06 \pm 0.68$  ( $P < 0.001$ ). Nausea and vomiting between the two groups were no significant differences. There was no decrease in narcotic use or length of stay among those who received the TAP block. **Conclusions:** TAP block with ropivacaine 0.5% had a significant role in reducing postoperative pain of laparoscopic surgery.

**Keywords:** Laparoscopy, Pain, Ropivacaine, Surgery, Transversus Abdominis

### Introduction

Postoperative pain as a major difficulty in surgical procedures may affect the condition of patients dramatically.<sup>[1]</sup> Despite using drug therapies to prevent and manage pain, the prevalence of postoperative pain (80%) have exceeded expectations.<sup>[2]</sup> The alleviation of postoperative pain not only may result in an increase in the level of comfort and relaxation and improvement speed-up but also a faster return to routines, reduction in length of stay, less complications, and lower cost of treatment.<sup>[3,4]</sup>

In Iran, one of the most common surgeries is surgical procedures for women (such as laparoscopy, myomectomy, and hysterectomy). Like other surgical operations, postoperative pain is of the most common complaints from patients in these cases, and it may affect their quality of life and satisfaction.<sup>[5]</sup> Herein, inadequate pain management not only may increase

mortality, disability, length of stay, and related costs but also the occurrence of the immune system, circulation, and respiratory systems malfunctions as well as sleep disorders, fatigue, and parasympathetic nerve stimulation.<sup>[6]</sup>

The change in the surgical procedure, the use of anesthetic drugs, high-dose opioids and/or epidurals and Nonsteroidal Anti Inflammatory Drug (NSAID)s are common strategies.<sup>[7]</sup> Along with advances in radiology and ultrasonography, surgeons welcomed the transversus abdominis plane (TAP) block as an efficient approach. For the first time, Rafi described an anatomical landmark to use TAP on the body surface in 2001. The TAP block provides analgesia through blockage of the 7<sup>th</sup>–11<sup>th</sup> intercostal (T7–T11), subcostal (T12) nerves as well as ilioinguinal/iliohypogastric nerves.<sup>[8]</sup> The technique is implemented by injection of local anesthetic between the internal oblique and transverse abdominis muscles. Formerly, the triangle of Petit

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on the body was utilized, but nowadays, TAP block is performed by ultrasonography.<sup>[9]</sup> TAP block has been identified as a helpful component in various surgical procedures for women (such as hysterectomy, colectomy, and appendectomy), and efficacy of the approach has been evaluated through a variety of clinical trials.<sup>[10-12]</sup> However, these studies have reported different results in the case of pain management by TAP. It is recognized as an inefficient approach<sup>[13,14]</sup> in some studies but efficient in some others.<sup>[15]</sup> Herein, there were studies suggesting independent investigations to assess the efficacy of the approach for any kind of abdominal surgeries.<sup>[16]</sup>

On the other hand, perhaps a faster efficacy of ropivacaine as an amide local anesthetic compared to bupivacaine in motor block<sup>[17]</sup> could provide an alternative approach to treatment process optimization. In the field of obstetric surgery, several randomized studies have suggested a shorter duration of motor block by using intrathecal ropivacaine compared to bupivacaine.<sup>[18-20]</sup> Thus, ropivacaine as a local anesthetic may lead to more efficient consequences as well.

However, considering controversial results in studies and high prevalence of surgeries for women in Iran as well as the importance of postoperative pain, the current study is aimed to evaluate the efficacy of ropivacaine 0.5% in TAP to relieve related postoperative pain of laparoscopic surgery in women.

## Materials and Methods

### Study design and population

The population of this double-blinded clinical trial (IRCT20190204042618N3) included women, candidates for female surgeries (including ovarian cystectomy, ectopic pregnancy, and diagnosis of infertility), presented at Al-Zahra and Beheshti hospitals from 2016 to 2018. To determine a sample size of 100 for each group, we used the sampling formulae of means comparison (IC = 95%, power of test = 80%) and for the reduction in pain in these two groups, means and standard errors were, respectively,  $\mu_1 = 1.5, \delta_1 = 1.8$  and  $\mu_2 = 0.9, \delta_2 = 2$  (13).

Being a candidate for female surgeries (including ovarian cystectomy, ectopic pregnancy, and diagnosis of infertility) in the form of laparoscopy, and being consent to participate in the study were inclusion criteria and allergies to the agents used in the study (such as ropivacaine, morphine, and diclofenac), no adverse reactions to opioids were exclusion criteria.

The study was approved by the ethical committee of Isfahan University of Medical University (code: IR.MUI.REC.1396.913). Afterward, 200 eligible patients were recruited to the study using simple randomization. The written informed consent was obtained from all participants. Next, using Random Allocation software, we randomly

assigned them to two groups of ropivacaine 0.5% receivers with/without TAP block. Before surgical procedures, we recorded baseline clinical information of patients.

### Technique of transversus abdominis plane block

TAP block was performed before the surgical procedure. With local anesthesia and a 22G needle, the solution was injected. Due to the full thickness of the abdominal wall (fascia, muscle, and peritoneum) and the presence of Petit's triangle, we introduce a solution using the method called "loss of resistance." After lying down (supine position), the patient, the investigator located in front of injection site. Hence, the iliac crest was touchable from anterior to the posterior region and to a place connected to latissimus dorsi. Petit's triangle has been located among three portions of the anterior edge of latissimus dorsi, posterior edge of external oblique muscle, and iliac crest. The skin of Petit's triangle was selected to puncture by the needle in the right angle toward the coronal plane and the needle moved forward. The movement will face with two resistances: fascia of external abdominal oblique muscle and internal oblique muscle. To test, the 1 ml solution was injected after reaching the injection site. If any resistance at injection, we replaced the needle. Otherwise, ropivacaine 0.5 mg/kg was injected as anesthetic. The vital signs and condition of the patient was considered at the injection process. The process was repeated for the second group as well and also, TAP block did not use in the control group.

It is noticeable that all patients were visited by a gynecologist recording the indication of the surgery at visit time. The patient undergoing female surgery by an expert surgeon underwent a standard general anesthesia before.

After using the above-mentioned technique, patients were transferred to Recovery section and afterward, to related departments.

### Data collection and outcome

Clinical characteristics of patients including blood pressure (systole and diastole), heart rate, oxygen saturation (%) (SPO2) before and after anesthesia, before and after blowing gas in laparoscopy, before injection of drug (TAP block) and 10, 20, and 30 min after injection, were measured and recorded. Furthermore, the severity of pain and occurrence of nausea and vomiting were recorded immediately after entrance to recovery ward and 30 min, 2, 4, 6, 12, 24, 36, and 48 h after surgery.

To measure the severity of pain, we used Visual Analog Scale (VAS) (from 0: no pain to 10: maximal pain intensity). If required and no reduction in pain (>3), we administered peptidine and diclofenac suppository.

The nausea was rated from 0 to 3 (0: no nausea, 1: mild, 2: moderate, 3: severe). If nausea was severe and/or vomiting was annoying, we administered anti-nausea drugs and recorded the dosage.

### Statistical analysis

Finally, collected data were analyzed using the SPSS.22 (SPSS. Inc., Chicago, Ill., USA). For descriptive analysis, we benefited from *n* (%) or mean ± standard deviation. Considering the results of Kolmogorov–Smirnov test that indicated the normal distribution of data, using independent samples *t*-test and repeat measure ANOVA were used to compare the mean of quantitative variables between two groups and the mean of quantitative variables over 48 h after the surgery in each group, respectively. However, to adjust the effects of other medications used for pain relief and nausea/vomiting management, Univariate analysis test was used. Furthermore, Fisher’s exact test was used to compare two groups of the study in qualitative data. Significance level of <0.05 was considered in all analyses.

### Results

Of 200 women undergoing laparoscopy (Grade II), 100 women were in case group (treated with TAP block with ropivacaine 0.05%) (mean age = 33.61 ± 0.76 years) and 100 women were in control group (mean age = 34.24 ± 4.06 years). There was no significant difference between groups in this regard (*P* > 0.05) [Table 1].

On the other hand, in patients there was no significant difference among mean clinical factors such as systolic/diastolic blood pressure, heart rate, and SO<sub>2</sub> in patients before and after anesthesia, before and after gas blowing and before and after injection of drug (ropivacaine or placebo) (*P* > 0.05). Furthermore, over time, the changes in these factors were not substantial (*P* > 0.05) [Table 2].

The evaluation of mean scores of patients’ pain after the surgery showed that immediately and after entrance to the recovery ward, mean score of patients’ pain in case group (mean score = 5.00 ± 0.83) was significantly lower than that of control group (mean score = 6.92 ± 0.96) (*P* < 0.001). Moreover, in all periods of time (30 min, 2, 4, 6, 12, 24, 36, and 48 h after the surgery), mean score of pain in cases was lower than controls too (*P* < 0.001). Furthermore, reduction in mean scores in each group separately was significant. In other words, in both groups 48 h after the surgery, pain of patients showed a significant reduction (*P* < 0.001). It should be noted that frequencies of using peptidine and diclofenac suppository in case group (42% and 70%, respectively) are significantly lower than those in control group (89% and 96%, respectively). Hence, when the values were adjusted

for additional administered drugs and after re-evaluation of pain intensities in patients, it clarified that pain of patients in case group was significantly lower than that in control group (*P* < 0.001) [Table 3 and Figure 1].

Finally, the evaluation of nausea and vomiting in both groups showed that mean scores of nausea (ranged 0–3) at entrance to recovery ward and 30 min after the surgery and from 2 to 48 h after the surgery in cases were slightly higher than those in controls. However, this change was not significant statistically (*P* > 0.05). It is considerable that anti-nausea drugs were administered for 76% of patients in control group but 28% of patients in case group. Therefore, there was a significant difference between groups in this respect (*P* < 0.001). In other words, it may be concluded that the need for anti-nausea drugs was substantially higher in controls than that in cases. Hence, it led to a higher intensities of nausea and vomiting in cases at 2, 4, 6, and 12 h after the surgery than those in controls at the same times but afterward, conditions of both groups were the same (*P* > 0.05) [Table 4].

### Discussion

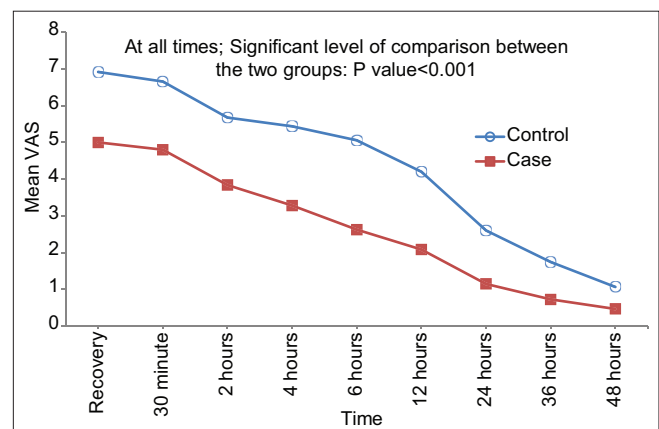
The current study showed a significant reduction in pain intensity in both groups of treatments with and without TAP block, 48 h after the surgery. However, reduction in pain intensity in the group treated with ropivacaine 5% and TAP block was considerably faster and with more desired results than that in the group treated with ropivacaine 5% but without TAP block. Hence, in the former group, pain intensity diminished within 2 h and reached a value of <4 but latter group experienced this amount of reduction after 24 h. It is of interest that using TAP block did not lead to any significant difference in clinical factors (such as blood pressure, heart rate, SPO<sub>2</sub>, and so on) compared to the treatment without TAP block. In other words, TAP block approach could lead to pain management in patients without any significant change in their clinical factors.

To limit uses of opioids and pain killers in pain management, researchers consistently seek for alternative

**Table 1: Demographic characteristics of patients**

Characteristics	Control (n=100)	Case (n=100)	P
Age (year)	34.24±4.06	33.61±0.76	0.341*
BMI (kg/m <sup>2</sup> )	26.21±6.56	27.36±6.01	0.875*
Past medical history (%)	6 (6)	5 (5)	0.767**

\*Using independent sample test for mean age and BMI comparing two groups, \*\*Using Fisher’s exact test for the frequency distribution past medical history of comparing two groups. BMI: Body mass index



**Figure 1: Linear chart means pain score between two groups**

**Table 2: Comparison of mean clinical parameters between two groups**

Variables	Time	Control (n=100)	Case (n=100)	P*
SBP	Before anesthesia	116.08±10.86	119.06±12.01	0.067
	After anesthesia	116.14±11.58	140.02±16.96	0.163
	Before gas blowing	115.82±12.28	114.56±11.31	0.451
	After gas blowing	112.52±12.45	114.16±11.97	0.343
	Before injection	114.54±15.38	116.02±17.01	0.519
	10 min after injection	113.56±12.10	114.40±12.60	0.069
	20 min after injection	112.40±12.84	113.96±12.21	0.382
	30 min after injection	111.71±10.63	112.39±13.26	0.697
	P**		0.130	0.115
DBP	Before anesthesia	68.62±8.24	70.08±8.91	0.230
	After anesthesia	68.84±8.54	68.64±8.47	0.868
	Before gas blowing	67.98±7.51	68.54±8.34	0.618
	After gas blowing	67.20±7.39	68.80±8.54	0.502
	Before injection	78.56±8.86	85.12±11.03	0.647
	10 min after injection	65.14±7.64	67.78±10.73	0.046
	20 min after injection	66.16±7.70	66.88±8.74	0.540
	30 min after injection	66.73±7.20	68.96±10.37	0.086
	P**		0.153	0.158
HR	Before anesthesia	85.32±10.60	84.76±10.59	0.709
	After anesthesia	86.54±11.25	85.98±11.29	0.726
	Before gas blowing	86.74±11.31	84.60±10.68	0.170
	After gas blowing	86.90±10.64	84.60±10.03	0.117
	Before injection	86.62±11.13	84.14±9.69	0.095
	10 min after injection	86.04±10.87	83.04±14.26	0.051
	20 min after injection	86.50±10.38	83.61±10.34	0.026
	30 min after injection	86.94±10.28	82.78±14.88	0.970
	P**		0.210	0.243
SPO <sub>2</sub>	Before anesthesia	99.04±1.30	98.66±1.85	0.073
	After anesthesia	98.84±1.34	98.44±1.63	0.060
	Before gas blowing	98.72±1.06	96.66±12.69	0.107
	After gas blowing	98.46±1.56	98.32±1.59	0.530
	Before injection	98.56±1.56	98.36±1.86	0.411
	10 min after injection	98.50±1.59	98.22±1.86	0.254
	20 min after injection	98.42±2.07	98.52±1.62	0.704
	30 min after injection	98.35±2.01	96.44±14.27	0.191
	P**		0.860	0.490

\*Using independent sample test for mean variables comparing two groups, \*\*Used of repeat measure analysis test for mean variables comparing during time each groups. SBP: Systolic blood pressure, DBP: Diastolic blood pressure, SPO<sub>2</sub>: Oxygen saturation, HR: Heart rate

approaches to manage postoperative pain. Thus, approaches such as TAP block with a variety of medications were examined to restrict uses of other pain killers to a minimal point. In the current study, two additional administered drugs as pain killers were peptidine and diclofenac suppository. The frequencies of using peptidine and diclofenac suppository were >80% in controls but 42% and 70%, respectively, in cases. The reduction in pain was adjusted for additional drugs which can be mentioned as a noticeable point of the study. Re-assessment of results suggested a substantial efficacy of using TAP block with ropivacaine in pain management.

This is in line with recent evidence in the literature, which generally showed a reduction in pain scores and opioid requirements with TAP blockade.<sup>[12,21-23]</sup>

Contrary to the current study, Griffiths *et al.* showed no significant reduction in pain scores in patients undergoing major gynecological cancer surgery divided into two groups of with and without TAP block.<sup>[14]</sup> Furthermore, Kane *et al.* showed that TAP block did not improve postoperative VAS pain scores following laparoscopic hysterectomy, nor did it decrease narcotic pain medication use. There was no decrease in narcotic use or length of stay among those who received the TAP block.<sup>[24]</sup>

Although many previous studies have evaluated the efficacy of TAP block with medications such as bupivacaine (0.2%, 0.5%), lidocaine (0.2%), levobupivacaine (0.5%), ropivacaine (1%, 0.75%, 0.5%, 0.25%, and 0.2%) and normal saline in postoperative pain management. These



**Table 3: Comparison means pain score between two groups**

VAS	Control (n=100)	Case (n=100)	P*	P**
At entrance to recovery ward	6.92±0.96	5.00±0.83	<0.001	<0.001
30 min after the surgery	6.66±0.99	4.80±0.88	<0.001	<0.001
2 h after the surgery	5.68±0.93	3.84±1.01	<0.001	<0.001
4 h after the surgery	5.44±0.97	3.28±1.10	<0.001	<0.001
6 h after the surgery	5.06±1.26	2.62±1.36	<0.001	<0.001
12 h after the surgery	4.20±1.21	2.08±1.27	<0.001	<0.001
24 h after the surgery	2.60±1.22	1.14±0.88	<0.001	<0.001
36 h after the surgery	1.74±0.96	0.72±0.67	<0.001	<0.001
48 h after the surgery	1.06±0.68	0.46±0.50	<0.001	<0.001
P***	<0.001	<0.001		

\*Using independent sample test for mean VAS comparing two groups, \*\*Using Univariate analysis test for mean VAS comparing two groups with adjusted of the use of additional drugs (Pethidine and Diclophenac), age, BMI, \*\*\*Used of repeat measure analysis test for mean VAS comparing during time each groups. VAS: Visual analog scale, BMI: Body mass index

**Table 4: Comparison means nausea score between two groups**

Nausea score	Control (n=100)	Case (n=100)	P*	P**
At entrance to recovery ward	1.68±0.67	1.84±0.73	0.973	0.877
30 min after the surgery	1.50±0.69	1.71±0.92	0.899	0.899
2 h after the surgery	1.00±0.38	1.09±0.47	0.469	0.041
4 h after the surgery	0.80±0.58	0.98±0.56	0.699	0.026
6 h after the surgery	0.52±0.62	0.72±0.67	0.762	0.029
12 h after the surgery	0.27±0.46	0.47±0.45	0.642	0.002
24 h after the surgery	0.14±0.35	0.24±0.45	0.685	0.866
36 h after the surgery	0.07±0.26	0.12±0.27	0.565	0.735
48 h after the surgery	0.06±0.24	0.08±0.24	0.767	0.467
P***	<0.001	<0.001		

\*Using independent sample test for mean nausea score comparing two groups, \*\*Using Univariate analysis test for mean nausea score comparing two groups with adjusted of the use of anti-nausea medicine, age, BMI, \*\*\*Using repeat measure analysis test for mean nausea score comparing during time each groups. BMI: Body mass index

studies showed that generally TAP block had a significant effect on pain relief and limited uses of other opioids such as morphine, diclofenac, and peptidine.<sup>[15,25-27]</sup> It seems that most of them suggest a positive efficacy of bupivacaine with TAP block in postoperative pain management but the lack of strong evidence on the efficacy of ropivacaine in this respect is obvious.

On the one hand, Mohamed study suggested a similar positive effects of TAP block with ropivacaine 0.2% and 0.5% in managing the pain caused after cesarean delivery.<sup>[28]</sup> On the other hand, De Oliveira *et al.* (2014) evaluated the efficacy of TAP block with ropivacaine 0.25% and 0.5% in managing the pain caused after laparoscopic hysterectomy. Their findings suggested that the treatment with ropivacaine 0.5% was more efficient in managing the pain than that

with ropivacaine 0.25%.<sup>[15]</sup> The contradictory results of studies in this respect require further studies. Hence, the current study evaluated the efficacy of ropivacaine with TAP block to relieve the postoperative pain of laparoscopic surgery in women which resulted in positive efficacy of the approach.

Furthermore, the incidence of complications such as nausea and vomiting in cases and controls were 28% and 76%. The evaluation of these complications in both groups showed that within 30 min after the surgery, there was no significant difference between groups but after 2–12 h, intensities of nausea and vomiting in TAP block + ropivacaine receivers was less than controls. However, 12 h after the surgery, the conditions of both groups were similar in intensities of these complications. It should be stated that the intensities of these complications within 2–12 h in both groups reach a score of <1. It means that in general, their intensities were not considerable and after 48 h, these complications were resolved in both groups.

In agreement with the current study, Griffiths *et al.* showed that there was no significant difference between ropivacaine users and controls in the incidence of complications such as nausea, vomiting, and pruritis.<sup>[14]</sup>

Furthermore, many literature suggested that The TAP block did not have any negative effects or increase in postoperative complications other than the increased operating room time. The potential for improved pain and quality of recovery (not having nausea and vomiting) with its use in multiple procedures has been previously demonstrated, so the continued practice in some cases is reasonable.<sup>[29,30]</sup>

It is important to note here that due to the different pain thresholds in individuals and differences in pain expression; its control was beyond the control of the researcher and the limitation of the present study is considered. In contrast, the control of other confounding factors such as the use of additional drugs (pethidine and diclophenac), age, body mass index to reduce pain and show the effect of this drug is one of the strengths of this study.

## Conclusions

According to the results of the study, TAP block with ropivacaine 0.5% can play a significant role in fast and proper reduction in postoperative pain of laparoscopic surgery grade II in women. In addition to a limited uses of opioids in pain management, this approach can be accompanied with no substantial complications.

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## Conflicts of interest

There are no conflicts of interest.

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