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Research Paper

Analgesic effects of TAP block among open appendectomy patients and the need of postoperative pethidine for Pain Management: A randomised controlled trial

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ABSTRACT

Background: The transversus abdominis plane (TAP) block is an effective method to reduce postoperative pain and need of analgesics following abdominal surgeries.
Objective: The aim of this study is to evaluate the effects of Marcaine (0.5% bupivacaine) TAP block on postoperative pain, patient recovery and the need of pethidine as an analgesic, following open appendectomy.
Method: In this randomized blinded study, 96 patients undergoing open appendectomy were randomly divided into two equal groups of 48 patients. Group A received 20 cc of Marcaine (0.5% bupivacaine) under ultrasound guidance as TAP block and group B received 20 cc of normal saline as a control group. Under general anesthesia, patients underwent open appendectomy. The visual analogue scale (VAS) was used to measure postoperative pain along with the patient's need of pethidine, patient's satisfaction, duration of hospitalization, complications and recovery time (time to resume walking).
Result: The two groups were had no statistically significant difference in terms of age, sex and BMI, $P < 0.99$, respectively. After adjusting the duration of the surgery and incision size, the duration of hospitalization, time of resume walking, patient satisfaction based on postoperative pain and the need of pethidine at 1, 3, 6, 12, 24 and 48 h were significantly different in the two groups, $P < 0.001$. Additionally, postoperative complications were not significantly different among the two groups.
Conclusion: The results of the study indicate that TAP block before open appendectomy with Marcaine (0.5% bupivacaine) is effective to manage postoperative pain and is associated reduced need of post-operative analgesia and hospitalization.

1. Introduction

Acute appendicitis is one of the most common emergencies globally in children and adults. Open appendectomy has been surgical standard since the past century [1]. Postoperative pain following the surgery is associated with prolonged hospitalization duration [2,3]. Opioids are usually prescribed for the management of postoperative pain, nonetheless, a number of side effects such as respiratory distress, nausea and vomiting, gastrointestinal disorder, dizziness and urinary retention are associated with opioids [4,5]. Non-narcotic analgesic methods are therefore needed to reduce postoperative pain among the patients [6,7]. Local anesthesia inducing nerve blocks are recently well-known for the management of postoperative pain [8,9].

The transversus abdominis plane (TAP) block is practiced that includes administration of local anesthesia into the TAP of the abdominal wall [10,11]. The procedure is evident to reduce post-operative pain and need of analgesics in appendectomy patients [12,13]. It can be performed by injecting anesthetic agents in the triangle of Petit or mid-axillary line, depending on the type of the surgery [14]. Ultrasonographic guidance for injection TAP block has improved the accuracy of the procedure and reduced the complications [15]. A number of systematic reviews have reported the efficacy of TAP block for various abdominal procedures [16,17]. A recent study by Bayindir, Ozcan [18] reported that the use of TAP block for open appendectomy is associated with more wound infiltration and reduced postoperative pain score [19,20].

The aim of this study is to evaluate the effects of TAP Blocks with Marcaine (0.5% bupivacaine) on postoperative pain, need of

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analgesia and recovery of the patients undergoing open appendectomy at our center.

2. Methods

This, prospective randomized controlled based on CONSORT guideline [21], study was conducted at (XXXX). Patients undergoing open appendectomy meeting ASA class I and II criteria were enrolled in this study. Written consent was obtained from all the patients and details of the study were explained to all. Patients with right lower quadrant or periumbilical pain rotating to right lower quadrant, nausea and/or vomiting, fever >38 °C, leukocytosis >10,000 mL and tenderness with the age >15 years were included in the study.

Patients with the duration of symptoms >5 days, absence of clinical findings of appendicitis, palpable mass on physical examination suspected for appendiceal abscess and presented with history of cirrhosis or hematological disorders, allergic to or contraindicated for general anesthesia or Marcaine, pregnancy, psychiatric disorders and those who did not consent to participate were excluded from the study.

Patients were randomly divided into two groups, A and B using stratified random allocation method. Anesthesiologist randomly picked a card for each patient, marked A or B (Marcaine or normal saline) and was unaware of the code. TAP block was performed under ultrasound guidance. 20 cc of Marcaine (0.5% bupivacaine) was administered in group A (intervention group) and group B (control group) received 20 cc normal saline. Demographic details and vital signs were logged for all the patients in a questionnaire. All the patients underwent general anesthesia with propofol 1.5–2.5 mg/kg, fentanyl 0.05–0.35 mg and a single dose of atracurium for tracheal intubation.

The linear probe of ultrasound (M-Turbo ultrasound system WA, USA) covered with sterile sheath was placed over right side and moved from medial to lateral for the identification of three muscle plane between costal margin and iliac crest. A spinal needle (22G) was used to inject 20 mL Marcaine and normal saline in group A and B, respectively.

Open appendectomy was performed using McBurney muscle-splitting with an incision of 1.5 inches in the right lower quadrant. A double ligation of the appendiceal stump was conducted using an absorbable suture. The abdomen and pelvis were watered with normal saline solution. The skin sutures were performed with 3-0 nylon. The study was approved by the (XXX).

2.1. Pain measurement

After the patients were transferred to general ward in stabilized and conscious condition, Visual analog scale (VAS) was used to calculate pain, on which left extreme is 0 point, indicating no pain and right extreme is marked 10 indicating worst pain. Patients' satisfaction was the end point of VAS score. The need of pethidine for the management of pain was also measured at 1,3,6,12,24,48 h after surgery by a blinded evaluator. During this period, complications such as dizziness and nausea and vomiting were recorded in both the groups. The patients were prescribed pethidine if the severity of pain was above 3.

The data was computerized and analyzed statistically using SPSSv21. Frequency distribution tables, mean indices, standard deviation, median, and quadratic range were used to describe the data. For comparison, independent *t*-test or Mann-Whitney test, chi-square test, Turkey and Sidak and repeated measure ANOVA was used. Covariance analysis was also required in some cases. GEE (generalized estimation equation) was used to measure the likelihood estimation. Statistical significance was determined at the level of 0.05.

3. Results

Group A and B were equally divided into 48 patients, each. Overall, the average age of the patients studied was 30.22 ± 10.25 years (15–59 years) and the average BMI was 25.35 ± 2.16 kg/m^2 (19.02–30.22 kg/m^2).

3.1. Outcomes of the demographic data among the two groups

The two groups, test and control, were compared in terms of gender, age group and BMI. The results of Fisher's exact test showed that there was no significant statistical difference between the two groups in terms of gender, age and body mass index P > 0.999, respectively, Table 1.

The two groups were compared for the length of the incision site, the duration of surgery, the type of postoperative diagnosis and the type of surgical incision. Based on the independent *t*-test, there was a significant difference between the two groups in terms of the length of the incision site (P = 0.047), where the incision size was 4.60 ± 0.68 cm in group A and in group B was 4.88 ± 0.64 cm. The duration of the surgery was statistically significant between the two groups, P = 0.153, Table 2. In both the groups, 100% patients were diagnosed with acute appendicitis.

Independent *t*-test was used to compare the two groups in terms of quantitative answers and Fisher's exact test was used to compare qualitative answers.

** Because the comparison of the two groups in terms of the length of the incision site and the duration of surgery yielded significant or near-significant results, the variables were used for multivariate modeling.

3.2. Comparison of postoperative variables in the two groups

The marginal model and logit link function using GEE approach was used to model correlated data (postoperative variables).

Based on the generalized linear model and adjusting the duration of surgery and the length of the incision site, there was a statistically significant difference between the two groups in terms of the duration of the hospitalization (P < 0.001); which was 41.45 h in group A and 47.30 h in group B. Similarly, the time to resume walking among the two groups was also statistically significant p < 0.001, which was 15.65 in group A and 22.85 h in group B, Table 3.

The generalized linear model with the cumulative distribution function was used where the duration of the operation and the length of the incision were adjusted to evaluate the patient satisfaction based on VAS score.

There was a statistically significant difference between the two groups in terms of patient satisfaction. The patient satisfaction in was about 25.23 times higher in group A than the control group (P < 0.001 and CI: 9.06–70.23, %95) (Tables 4 and 5).

According to Fisher's exact test, there was no statistically significant difference between the two groups in terms of nausea P > 0.999. The incidence of nausea was about 4.2% (2 cases) in both the groups.

In addition, there was no significant difference between the two groups in terms of vertigo (P = 0.362); however, the incidence of vertigo in the control group was higher than the group A, 8.3% (4 patients) vs 1.2% (1 patient).

The occurrence of ileus was not significantly different in the two groups, p = 0.117; however, the incidence of Ileus in the group A

Table 1
Distribution of the two groups in terms of age, gender and BMI.

Variable	Group	Test group		Control group		P-Value
		Number	Percentage	Number	Percentage	
Gender	Female	32	66.7%	32	66.7%	P > 0.99
	Male	16	33.3%	16	33.3%	
Age group	Less than 20 years	11	22.9%	11	22.9%	P > 0.99
	Older than 20 years	37	77.1%	37	77.1%	
BMI	Less than 25	19	39.6%	19	39.6%	P > 0.99
	Greater than 25	29	60.4%	29	60.4%	

Table 2
Comparison of two groups of test and control in terms of some features related to surgery.

Variable	Category	Control		Test		p-value
Intake medication (cc)	–	1.50398	13.6875	1.54584	13.6875	>0.999
Cutting lenghth surgery (cm)	–	0.63998	4.8750	.67602	4.6042	0.047
Duration of operation (min)	–	10.68571	54.1667	10.56683	51.0417	0.153
Type of postoperative diagnosis	Acute appendicitis	100.0%	48	100.0%	48	–
	Others	0.0%	0	0.0%	0	
Postoperative wound condition	Close	100.0%	48	100.0%	48	–
	Open	0.0%	0	0.0%	0	
Surgical incision type	McBurney's point	97.9%	47	97.9%	47	>0.999
	Others	2.1%	1	2.1%	1	

Table 3
Comparison of two groups of test and control in terms of hospital stay and walking time and patient movement.

Variable	Control group			Test group			p-value
	Adjusted mean	Standard deviation	Mean	Adjusted mean	I Standard deviation	Mean	
Hospital stay time (hours)	47.30	2.33021	47.5385	41.45	6.45633	41.6842	<0.001
Time to start walking and moving the patient (hour)	22.85	2.48798	23.0769	15.65	4.83494	15.4286	<0.001

Table 4
Comparison of two groups of test and control in terms of satisfaction with postoperative pain relief.

Satisfaction with postoperative pain relief	Control group		Intervention group		p-value
	Percent	Frequency	Percent	Frequency	
Very less	6.3%	3	0.0%	0	<0.001
Rather less	33.3%	16	6.3%	3	
Normal	47.9%	23	12.5%	6	
Rather much	12.5%	6	35.4%	17	
Very much	0.0%	0	45.8%	22	

Table 5
Modeling the effect of the drug received on the level of satisfaction with postoperative pain (after adjusting the effect of the duration of surgery and the length of the incision site).

Variable	Correlation coefficient	Standard error	p-value	Odds ratio	Confidence interval	
					Upper bound	Lower bound
Test group	3.228	0.5223	0.000	25.228	70.225	9.063
Control group	Ref	–	–	–	–	–
Duration of operation	−0.006	0.0186	0.763	0.959	1.031	0.959
Cutting lenghth surgery	−0.242	0.3135	0.440	0.425	1.451	0.425

was higher than the group B, 8.3% (4 patients) vs 0.0% (0 cases) (Table 6).

Fisher's precise test was used to compare the two groups, and due to the small number of reported complications, it was not possible to model and adjust the effects of the duration of surgery and the length of the incision site on these complications.

3.3. Pethidine requirement in the two groups

The marginal model was used by GEE method and link function where the duration of the operation and the length of the incision site was adjusted.

As seen from Fig. 1, postoperative time duration and the need of pethidine was significantly correlated, $p < 0.001$. The need of

Table 6
Comparison of two groups of test and control in terms of some surgical complications.

Variable	Category	Control group		Test group		p-value
		Percentage	Frequency	Percentage	Frequency	
Nausea	No	95.8%	46	95.8%	46	>0.999
	Yes	4.2%	2	4.2%	2	
Dizziness	No	91.7%	44	97.9%	47	0.362
	Yes	8.3%	4	2.1%	1	
Ileus	No	91.7%	44	100.0%	48	0.117
	Yes	8.3%	4	0.0%	0	

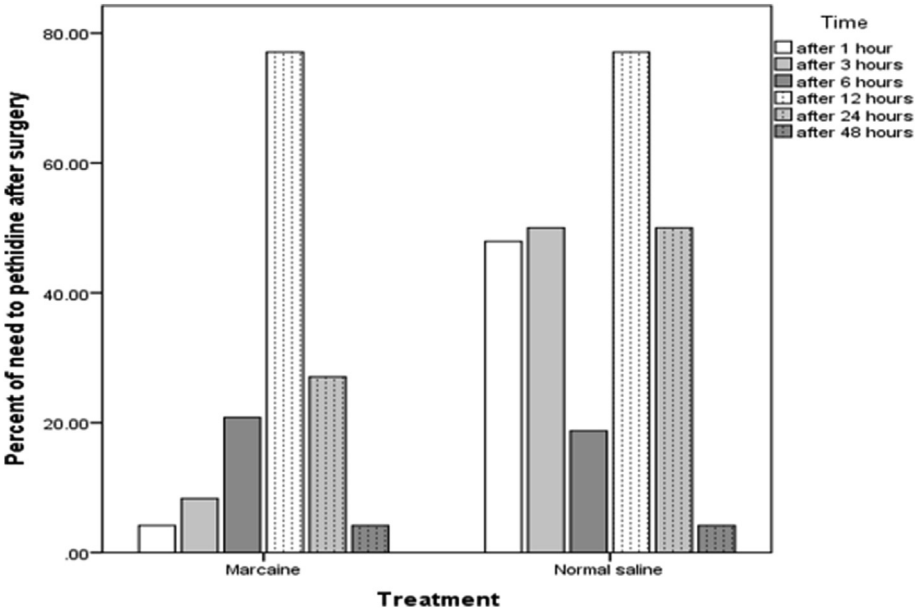

Fig. 1. Compares the two test and control groups in terms of post-operative Pethidine requirement.

pethidine in relative to the postoperative duration showed the following relationship:

The relative odds of pethidine requirement in the control group compared to the intervention group = Exp (0.0261-1.1805 x time) for time = 1.

In the above relationship, it was concluded that at the end of the first hour after the surgery, the relative odds of the patient's need for pethidine in the control group was about 3.172 times more than intervention group.

Similarly, for t = 3, the odds of pethidine requirement in the control group was 3.011 times more. For t = 6, 12, 24 and 48, the outcomes of this function were 2.784, 2.380, 1.740 and 0.93, respectively. At t = 48, the odds of pethidine requirement in control group reduced by 7%.

4. Discussion

The results from our study demonstrated that TAP block with Marcaine (0.5% bupivacaine) is associated with a significant reduction in the postoperative need of pethidine, postoperative pain and hospitalization duration, $P < 0.05$. The TAP group of the study was not associated with significantly increased incidence of side effects, $P > 0.05$.

A study by Batko et al. examined effects TAP block for open appendectomy on 90 children and found that using TAP block reduced the length of hospital stay ($P = 0.045$). These findings are consistent from those reported from our study.

In a study by Sandeman DJ et al., conducted on 93 children TAP Block reported no higher clinical benefits than local anesthesia in patients undergoing laparoscopic appendectomy, in terms of time, pain, anesthesia, and length of hospital stay [22]. These findings are inconsistent with our study [23]. Seyedhejazi, Motarabbesoun [24] conducted a study in Tabriz, Iran on 40 pediatric patients undergoing appendectomy who were provided with TAP block using 0.25% bupivacaine. The study concluded that TAP block did not significantly reduce postoperative pain in TAP group, as compared to the control group. These discrepancies could be related with the dose of the block, skills of the surgeons and statistical variations. Furthermore, pain tolerance is positively associated with advanced age and ethnic difference can also differ pain sensitivity [25,26] that can indicate greater satisfaction in our intervention group.

In a study by Cho, Kim [27] 22 patients undergoing open appendectomy were provided with ultrasound guided TAP block using 20 mL of 0.5% levobupivacaine were compared with those provided standard care (n = 22). The results from the study reported that TAP block was associated with a significant reduction in verbal numerical rating pain scores, which is consistent with our findings and those provided by Alvi, Hussain [28]. However, the study did not report any difference in term of analgesic demand among the two group, which was reduced in our intervention group. Ghisi, Fanelli [29] conducted a study on 52 patients and reported that TAP block is not associated with reduced postoperative morphine consumption following total laparoscopic hysterectomy. The study also concluded that TAP block does not affect 2-minutues walking time, numerical pain rating score and

postoperative nausea and vomiting. These results are also not in line with our study. The contrasts among the two studies could be the due to the differences in the sample size, preoperative pain threshold of the patients, surgeon's skills and pain measurement methods. A recent study by Hernandez, Finnesgard [30] including 960 appendicitis patients reported that TAP block for laparoscopic appendectomy among patients with low-grade appendicitis is associated with reduced intake of morphine and shorter hospitalization. Similarly, Patel, Gandhi [31] reported that the need of diclofenac after TAP block (n = 30) with 20 mL ropivacaine (0.5%) leads to a significant reduction in VAS pain score, compared to the control group (n = 30). Additionally, our study also reports greater patients' satisfaction in the intervention group as a result of reduction in pain and reduced need of analgesic (pethidine). Other studies have also shown significant satisfaction in terms of pain relief. Parents and children have also expressed satisfaction with the usage of TAP block among pediatrics following abdominal surgery [32–35], which is also consistent with our findings. Baaj, Alsatli [36] reported that TAP block among 40 cesarean section patient leads to reduced postoperative pain and greater patients' satisfaction. These findings are parallel with our results. McDonnell, O'Donnell [37] also reported the similar outcome in 32 appendectomy patient receiving TAP block.

In both the groups, the incidence of nausea, vertigo and ileus was not statistically different from our results. In a study, Niraj, Searle [38] reported that among 52 adult patients, ultrasound-guided TAP block in appendectomy is associated with a significant reduction in the postoperative need of morphine, reduces postoperative pain and does not lead to postoperative complications such as post-operative nausea and vomiting. These findings are similar to those reported from our study; however, duration of surgery was significantly shorter in TAP block group in our study whereas, this study did not report any significant difference as compared to the control. The incidence of side effects is low-to-no with TAP block [39]. Bryskin et al. reported among 45 children aged 1–9, the prevalence of nausea in the TAP block group as very low, which can be adjusted with a reduction in use of narcotics [40]. These findings were also confirmed from the study by Srivastava et al. Other studies have also reported that the side effects after TAP block are insignificant or uncomplicated [41].

Our study is based on a small sample size and the outcomes are from a single center. Demographic variation and patients' pain tolerance can alter these outcomes. Large-scale studies including more parameters can provide better conclusion.

5. Conclusion

The result of our study confirms that TAP block is associated with the reduced need of postoperative analgesics and hospitalization and increased patient satisfaction among patients undergoing open appendectomy. Additionally, no significant complications or side effects are reported with the usage of TAP block.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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Author contribution

Dr. Mohammad Kazem shahmoradi: conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Dr. Gholamreza Besharatifar: Designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript.

Dr. Hamid Reza Taheri: Coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content.

Conflict of interest statement

The authors deny any conflict of interest in any terms or by any means during the study.

Guarantor

Mohammad Kazem Shahmoradi.

Research registration number

Name of the registry: Lorestan University of Medical Sciences.

Unique Identifying number or registration ID: (IR.LUMS.REC.1397.133).

Hyperlink to the registration (must be publicly accessible): http://ethics.research.ac.ir/ProposalViewEn.php?id=38148.

Human and animal rights

No animals were used in this research. All human research procedures followed were in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

Consent for publication

Informed consent was obtained from each participant.

Availability of data and materials

All relevant data and materials are provided with in manuscript.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2020.11.015.

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