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Original Research Article

Efficacy of local infiltration tramadol (transversus abdominis plane block technique) versus preemptive intravenous tramadol on postoperative pain after open appendectomy: a prospective randomized controlled trial

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ABSTRACT

Background: Acute postoperative pain, if mismanaged, leads to increased morbidity and mortality. Effective perioperative analgesia is crucial to prevent persistent pain. In abdominal surgeries, endogenous opioids are released, and tramadol, a weak synthetic opioid, has demonstrated effective analgesic properties. Recent studies suggest tramadol's mechanism involves blocking voltage-dependent sodium channels, which increases extracellular calcium and affects peripheral nerves. This suggests tramadol has both systemic and local anesthetic effects.
Methods: A prospective, randomized, double-blind study was conducted on 32 patients (ages 18–60) diagnosed with acute appendicitis who underwent open appendectomy under general anesthesia. Participants were randomly assigned to two groups: group 1 received normal saline with tramadol infiltration for transversus abdominis plane (TAP) block (n=16), and group 2 received preemptive intravenous tramadol with TAP normal saline infiltration (n=16). Pain was assessed using the visual analogue scale (VAS) at various postoperative intervals. Opioid consumption was monitored through patient-controlled analgesia (PCA), and intraoperative data, complications, and hospital stay were recorded.
Results: Demographic data were similar between groups. The primary outcome showed a significant reduction in postoperative pain (VAS score) at 0 hours (p=0.031) for the tramadol TAP group, with a 1-point reduction in pain over 24 hours compared to the intravenous group. Secondary outcomes indicated reduced opioid consumption, with no significant differences in complications (nausea/vomiting, infection, hospital stay).
Conclusions: Local tramadol combined with TAP block is an effective alternative for postoperative pain relief after open appendectomy, reducing opioid consumption without additional complications.

Keywords: Tramadol, Transversus abdominal plane block, Open appendectomy, Postoperative pain

INTRODUCTION

Acute appendicitis remains one of the most common surgical conditions with a lifetime cumulative incidence of approximately 9% and appendectomy for appendicitis is the most common surgical procedure in abdominal surgery.[1-6] In general, 7% of the entire population undergoes an appendectomy.[7] Even though this is a minor procedure, patients seem to have long periods of convalescence after surgery due to postoperative pain.[8] Acute postoperative pain misappropriated management is associated with Increased morbidity and mortality.[9] A more effective perioperative analgesic is important for the prevention of progression and persistent pain. Approximately 30-40% of patients undergoing abdominal surgery experience moderate to severe pain.[10] To reduce

postoperative pain, a variety of methods and medications are used. Intraoperative and intraoperative multimodal pain management techniques may reduce the incidence of acute pain and other related complications.[11] Local anesthesia provides an advantage in the control of intraoperative and postoperative pain with minimal systemic side effect.[12]

Conventional local anesthesia consists of three common elements: an aromatic ring, an amino group and an ester or amide bond. When injected, local anesthetics bind to the open form of the Na+ channel from the cytoplasmic side of the neuronal membrane, preventing the depolarization and the propagation of the signal. Local anesthetics can be injected either at the surgical site (subcutaneous, submucosal, intra-articular) or at the nerves that innervate the surgical site region (plexus block, plane block).[13]

Abdominal field block has been extensively used as they are mostly unchallenging technique. Innervation of the anterolateral abdominal wall arises from the anterior rami of spinal nerve (T7 to T11), the subcostal nerve (T12) and the iliohypogastric and ilioinguinal nerve (L1). This block is indicated for any lower abdominal surgery including appendectomy. The description of the landmark technique for performing transversus abdominis plane (TAP) block is enter the lumbar triangle of Petit to deposit local anesthetic between the internal oblique and transversus abdominis muscle. In open appendectomy, surgeon can access for injected local anesthesia targeting to spinal nerve in this plane.[14-16]

In the acute phase of abdominal surgeries resulted in the release of endogenous opioids and increase in opioid levels in blood, which counteracts the noxious stimulus and pain. Circulating levels of Beta-endorphin are significantly elevated.[17-20] In review, beta-endorphins are proteins that in response to physiologic stressors such as pain. They function through various mechanisms in both the central and peripheral nervous system to relieve pain when bound to their mu-opioid receptors.[21] Opioid medications function by mimicking natural endorphins, competing for receptor binding.

The use of systemic opioids alone is not enough to postoperative analgesic effect. It can be associated with side effects such as nausea, vomiting, constipation, itching, and respiratory and cardiac suppression.[21,22] In addition, non-steroidal anti-inflammatory drugs (NSAIDs) may cause skin reactions, and renal (analgesic nephropathy) and digestive (peptic ulcers and their effects) complications.

Therefore, it is attempting to relieve post-operative pain by using more accessible and cheaper methods, and of course with less side effect. Local injection techniques are one of those methods. Tramadol is a weak synthetic opioid with an effective analgesic result. According to studies, Tramadol modifieds both local and systemic effect. An important mechanism is blocking voltage-gated sodium channels (NaV 1.2), increasing the concentration of extracellular calcium and raising the activation threshold of voltage-dependent channels that similar to lidocaine mechanism.[24,25] Compared with local anesthetics, tramadol seems to have fewer side effects, good efficacy and safety and used it such as injected intradermally and injected for tooth extraction.[26,27] According to these reports, tramadol has both a systemic and local anesthetic effect.

In food and drug administration (FDA) suggest using tramadol in patients above 18 years old. The European medicines agency (EMA) does not mention contraindications in children, but recommend observing the clinical of opioid toxicity.[28-30] The maximum dose of tramadol is 400 mg/day.[31,32] The objective of study is to review and compare the outcome of local administration of tramadol applied with transversus abdominal plane block technique with preemptive intravenous tramadol in reducing postoperative pain in open appendectomy.

METHODS

The trial was approved and registered with the Institutional Review Committee of Police General Hospital, Central Research Ethics Committee (CREC). The study was designed to randomize, double-blinded, single centre prospective study.

This study was performed in Police General hospital, Bangkok, Thailand between December 2021 and October 2022.

Inclusion criteria

All patients aged between 18 to 60 years old with a preoperative and postoperative diagnosis of acute appendicitis who undergo open appendectomy under general anaesthesia.

Exclusion criteria

For one of the following reasons American associations of anesthesiologist (ASA) classification above 3. Allergy to tramadol or opioid derivatives. Unable follow instructions to evaluate pain score. Patient with history of chronic pain/ long term opioid used. Contraindication to general anaesthesia such as malignant hyperthermia or airborne disease. Patients who undergo appendectomy with delay suture

Thirty-two patients were registered for this study. All patients were informed and assigned into research groups after completing the consent letter. They were randomly divided into two groups within an allocated program.

Group 1 normal saline injection and transversus abdominis plane block technique with tramadol infiltration (16 patients) and group 2 the preemptive

intravenous tramadol and transversus abdominis plane normal saline infiltration (16 patients). After patients in the operation room. General anaesthesia was starting with preoxygenation. Intravenous anaesthesia was injected (In this study used only propofol and fentanyl) and intubated. The first syringe contained 10 ml of the drug which was injected slowly (group 1=normal saline10 ml, group 2=tramadol1mg/kg diluted to 10 ml) 15 minutes prior to surgery.

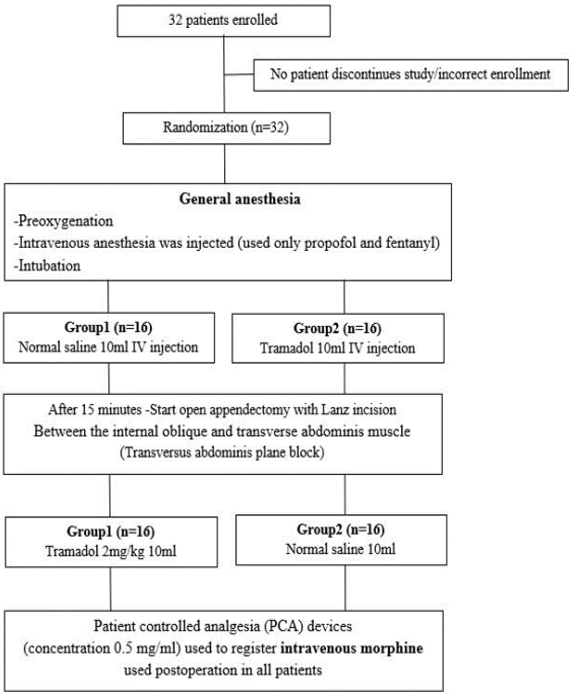

Figure 1: Study flow diagram.

The second syringe containing 10 ml of medication was injected between the internal oblique and transverse abdominis muscle targeting the spinal nerve in this plane. (group 1=tramadol 2 mg/kg diluted to 10 ml, group 2=normal saline 10 ml). The syringes in each solution were coded and indiscriminate to the investigator and subjects.

Following induction of general anaesthesia, additional agents are needed for maintenance. In the study, fentanyl was used only for the maintenance phase. The incision in this study used only Lanz incision and injected each 2ml at the medial and lateral site of the incision, and 3ml at upper and lower site of the incision between the internal oblique and transverse abdominis muscle (transverses abdominis plane block). Pain score was assessed by patients with visual analogue scale at rest and activity during the first day after operation (at immediate, 1,6,12 and 24-hour post operation).

Patient controlled analgesia (PCA) devices (concentration 0.5 mg/ml) used to register intravenous morphine used post operation. Intraoperative finding, operative time, blood loss, length of hospital stays and complications such as nausea/vomiting, surgical site infection were recorded

Data analysis

The sample size required for the study and data is collected and analyzed using statistical software (SPSS Statistical Package for the Social Sciences). A sample size of 32 patients provides 80% power of the test with an alpha of 0.05.

In descriptive statistics, data are analyzed in Means, SD, and median. In the statistical analysis, an independent T-test for mean differences and Chi-square for frequencies were used to draw a comparison between the two groups. Continuous data such as age, body mass index (BMI), and postoperative intravenous morphine are analyzed with an independent T-test. Categorical data such as sex and underlying disease are analyzed with the Chi-square test. A 2 sides p value below 0.05 were considered statistically significant.

RESULTS

A total of 32 patients were enrolled in this study from a single center and were randomly assigned to a treatment group. No patients withdrew consent or rejected treatment, resulting in a complete sample of 32 patients for final analysis (Figure 1). Baseline characteristics were not significant difference between two groups (Table 1). The median age was 37 years (36.9 ±12.1in group1 and 37.2 ±16.1 in group2). The mean body mass index (BMI) not significant different between the two groups (21.9±3.8 in group1 and 24.3±3.5 in group 2). There was no statistically significant difference in Alvarado scores between the groups. In group 2, two patients presented with additional underlying medical conditions. One patient was found to have glucose-6-phosphate dehydrogenase (G6PD) deficiency, while the other patient had well-controlled asthma.

The preoperative pain level was evaluated in both resting and active states and no statistically significant difference was observed between the two groups (p value=0.062, 0.061). There was no significant difference in operative time (minutes), intraoperative blood loss (milliliters), or delay in wound closure among patients between the two groups (Table 2).

The primary outcome of this study indicated that the administration of tramadol locally resulted in a significant decrease in postoperative pain by approximately 2 points of visual analogue scale at immediate post operation (at 0-hour, p=0.031) Additionally, within the first 24 hours post operation, there was a mean difference of 1 point in visual analog scale scores between the local tramadol group and the group receiving preemptive intravenous tramadol (Table 3). The secondary outcome of this study showed a decrease in postoperative opioid consumption in the local

tramadol administration group (3.4±2.2 mg in group1 and 5.8±4.7 in group 2, p value=0.077) (Table 4). There were no reported incidences of complications, including nausea/vomiting, respiratory depression, and surgical site infection, in either group. There was no statistically significant difference in the length of hospital stay between the two groups (63.9±23.4 hours in group 1 and 69.6±24.3 hours in group 2, p value=0.510)

Table 1: Demographic data.

	Group 1 (n=16)	Group 2 (n=16)	P value
Age (in years)	36.9 ±12.1	37.2±16.1	0.961
BMI (kg/m^2)	21.9±3.8	24.3±3.5	0.069
Underlying disease, N (%)	3 (18.75)	3 (18.75)	
Hypertension	3	2	
Diabetes	2	2	
Dyslipidemia	2	1	
other	-	2	
As a classification, N (%)			
Class 1	13 (81.25)	11(68.75)	
Class 2	3 (18.75)	4 (25.00)	
Class 3	0 (0)	1 (6.25)	
Alvarado score	6.6±1.4	6.7±1.7	0.912

Results are given as mean± standard deviation or as number (%).

Table 2: Preoperative and intra operative variables.

	Group 1 (n=16)	Group 2 (n=16)	P value
Appendicitis types, N (%)			
Acute inflammatory appendicitis	6(37.50)	7(43.75)	
Acute suppurative appendicitis	4(25.00)	3(18.75)	
Gangrenous appendicitis	4(25.00)	4(25.00)	
Ruptured appendicitis	2(12.50)	2(12.50)	
Intra operative blood loss (ml)	12.6±11.4	10.9±5.8	0.602
Operative time(minutes)	78.9±25.5	73.6±12.7	0.456
Length of stay (hours)	63.9±23.4	69.6±24.3	0.51
Pre-operative visual analog scale			
Resting	5.2± 1.7	6.1± 1.1	0.062
Activity	6.3± 1.8	7.3± 1.1	0.061

Results are given as mean± standard deviation or as number (%).

Table 3: Comparison of pain visual analog scale.

	Group 1 (n=16)	Group 2 (n=16)	P value
Immediate postoperative			
Resting	4.3±2.7	6.1±1.8	0.031
Activity	5.1±2.6	6.9±2.0	0.031
Postoperative 1 hour			
Resting	4.1±2.1	5.3±1.7	0.096
Activity	5.3±2.4	6.0±1.7	0.378
Postoperative 6 hour			
Resting	3.8±2.2	4.5±1.3	0.274
Activity	4.6±2.3	5.3±1.8	0.358
Postoperative 12 hour			
Resting	3.5±2.3	4.1±1.3	0.400
Activity	4.4±2.7	5.1±1.9	0.424
Postoperative 24 hour			
Resting	3.3±2.6	4.2±1.8	0.283
Activity	4.0±2.6	5.1±2.0	0.183

As mean±standard deviation.

Table 4: comparison of postoperative morphine consumption.

	Group 1 (n=16)	Group 2 (n=16)	P value
Postoperative morphine consumption (mg)	3.4±2.2	5.8±4.7	0.077
Postoperative morphine consumption per kilograms (mg/kg)	0.062±0.039	0.088±0.071	0.208

Results are given as mean±standard deviation.

DISCUSSION

The results of this study suggest that local administration of tramadol may be an effective alternative to preemptive intravenous tramadol in reducing postoperative pain. The primary outcome measure, as measured by the visual analog scale, indicated a statistically significant decrease in pain scores at immediate post operation in the local tramadol group with a mean difference of 2 points (P=0.031) compared to the group receiving preemptive intravenous tramadol. Furthermore, within the first 24 hours post operation, there was a mean difference of 1 point in visual analog scale scores between the two groups. The secondary outcome measure of postoperative opioid consumption also revealed a decrease in the local tramadol administration group, with a mean difference of 1.4 mg.

This suggests that local administration of tramadol may also lead to a reduction in opioid consumption and the associated risks such as respiratory depression, nausea, and vomiting. No incidences of complications including nausea/vomiting, respiratory depression, and surgical site infection were reported in either group. Additionally, there was no statistically significant difference in the length of hospital stay between the two groups. Pang et al, demonstrated the effectiveness of local tramadol administration intradermal injection, with a decrease in response to pinprick sensation similar to that of lidocaine.[37] The pH values of the drug solutions were measured, with a value of 6.5 for tramadol, 6.0 for 1% lidocaine and 6.7 for normal saline. These results parallel the study with minimal reaction reported at the tramadol injection sites. The study by Vahabi et al, compared the local anesthetic effect of tramadol and lidocaine when administered in subcutaneously in minor surgeries such as lipoma excision or revision scar.[39] The study found no significant difference in postoperative pain between the two groups.

Mohammad Ali et al, evaluated the effectiveness of local infiltration of tramadol (2 mg/kg) compared to bupivacaine in providing somatic wound pain relief during cesarean sections. Results indicate that local infiltration of tramadol was effective in reducing somatic wound pain without significant complications.[40] Tramadol is structurally related to codeine, i.e., methylmorphine.[33,34] From the in vitro study by Gilly et al, showed the local anesthetic effects of morphine. An in vivo study by Erciyes et al, suggested that morphine affected the peripheral nerves directly. A local analgesic effect in tramadol was suggested.[35-37]

The limitations of this study include a small sample size, which may have affected the generalizability of the results. Additionally, the surgeon's experience level may have been a confounding variable as they were surgical residents in their first to third year of training. The pain score measure relied on the patients' own self-assessment which may introduce a bias.

Further research with larger sample sizes and more comprehensive control for confounding variables is needed to confirm the findings of this study.

CONCLUSION

Local tramadol with transversus abdominis plane block technique is an alternative for postoperative pain reduction after open appendectomy and decrease postoperative opioid consumption compared with intravenous tramadol without any complications.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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