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HEAD AND NECK

Comparing the effects of peritonsillar infiltration of tramadol before and after the surgery on post-tonsillectomy pain

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Abstract The aim of the study was to compare the effects of peritonsillar infiltration of tramadol before and after the surgery on post-tonsillectomy pain. In this double-blinded clinical trial study, 80 children aged 5–12 years old with ASA (American Society of Anesthesiologists) class I or II undergoing tonsillectomy involved. In group A ($n=40$), after anesthesia induction and before starting the surgery, tramadol 2 mg/kg diluted in normal saline up to 2 cc total volume was injected into the tensile bed by the anesthesiologist using a 25 gauge needle. Surgery began 3 min later and the tonsils were removed using the sharp dissection method. In children of group B ($n=40$), anesthesia induction was performed. When surgery was completed, tramadol 2 mg/kg diluted in normal saline up to 2 cc total volume was injected at the site of removing each tonsil using a 25 gauge needle by the anesthesiologist. Using the CHEOPS (Children's Hospital of Eastern Ontario Pain Scale) Scale, pain recorded at different times. Patient sedation was recorded using the RAMSAY Sedation Scale. All the data were analyzed using SPSS 17 statistical software. Two groups significantly felt different pain intensities at different times following the surgery. At the three times, the mean sedation score in the group receiving tramadol infiltration before surgery was a little higher compared to the other group, but this difference was not significant ($p>0.05$). As for the relative frequency of nausea and vomiting, the difference was not significant ($p=0.793$). Request for analgesics between the groups was not significant ($p=0.556$). The mean time of the first feeding after the surgery was not significant between the groups ($p=0.062$). Surgical duration was almost the same for both groups ($p>0.05$). Systolic blood pressures (before surgery, before extubation, and after extubation) were statistically the same in both groups ($p<0.05$). Furthermore, systolic blood pressures 10, 15, and 30 min after entry into the recovery room were the same in both groups. We concluded that peritonsillar infiltration of tramadol before surgery controlled postoperative pain better from 8 h after the surgery to hospital discharge (late effect), but that local infiltration of tramadol after surgery controlled postoperative pain better up to 2 h after the operation (early effect).

Keywords Peritonsillar infiltration · Tramadol · Post-tonsillectomy pain

Introduction

The palatine tonsils are two egg-shaped tissues in the posterolateral part of the oropharynx between the anterior and posterior pillars in a space called the tonsillar sinus. Since the palatine tonsils are part of the lymphatic system that is composed of B- and T-cell organelles, they may hypertrophy following repeated viral and bacterial infections and environmental contacts including cigarette smoke, especially during childhood, and obstruct the airway in the pharyngeal region, which can cause considerable clinical

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effects considering the special anatomy of this region during childhood. Therefore, tonsillectomy is a prevalent surgical procedure during childhood with the following common indications:

- Acute recurrent tonsillitis
- Chronic tonsillitis that does not respond to treatment
- Peritonsillar abscesses
- Tonsillitis that accompanies lymph node abscesses of the neck
- Chronic oral breathing and severe snoring
- Obstructive sleep apnea or sleep disorders
- Craniofacial growth disturbance [1].

Considering the high prevalence of tonsillectomy in children, postoperative pain is one of the major complications of this surgical procedure. Duration and intensity of pain are influenced by various factors, such as the patient's perception of pain, the surgical technique, antibiotics, corticosteroids, postoperative analgesia, and preemptive analgesia [2, 3]. In previous studies, administration of narcotics was accompanied by complications including respiratory depression and suppression of cough reflex and increased postoperative nausea and vomiting, while increased postoperative bleeding and greater need for repeat surgery for establishing homeostasis followed the use of NSAIDs (nonsteroidal anti-inflammatory drug) [2, 4]. Acetaminophen and paracetamol often provide insufficient analgesia [5]. Peritonsillar infiltration of local anesthetics has been accompanied by significant complications such as two-sided vocal cord paralysis, brain stem stroke, and life-threatening deep neck abscesses (often because of deep injections with highdoses). In several studies, the effects of local infiltration of tramadol in reducing post-tonsillectomy pain were studied and confirmed [6]. Tramadol is an opiate agonist that causes analgesia one-fifth to one-tenth as strong as morphine mainly by affecting μ and, to a lesser degree, κ and σ receptors and, similar to tricyclic antidepressant drugs, through activating the process of spinal pain suppression by reducing serotonin and norepinephrine reuptake. At doses used for analgesia, tramadol causes little addiction and less respiratory depression. Moreover, it causes negligible suppression of the digestive system and has no substantial organ toxicity, but is accompanied by other side effects including nausea, vomiting, drowsiness, dizziness, perspiration, anaphylactoid reactions, increased ICP (intracranial pressure) and reduced seizure threshold Considering previous studies, a local anesthetic effect has been considered for tramadol [7]. Various studies have confirmed the effectiveness of preoperative peritonsillar injection of tramadol in controlling postoperative pain [2, 4]. However, the effects of peritonsillar injection of tramadol after the surgery on postoperative pain have not been compared with those of peritonsillar injection of tramadol before the surgery so far. Therefore, we decided to compare the effects of peritonsillar injection of tramadol before surgery on postoperative pain with those of peritonsillar injection of tramadol after surgery.

Methodology

After the Ethical Committee approval, 80 children aged 5–12 years old with ASA (American Society of Anesthesiologists) class I or II undergoing tonsillectomy involved in this double-blinded clinical trial study. Written consent was obtained from the parents of the children participating in the study. Patients with the history of allergy to drugs, history of liver, cardiac and endocrine disease and patients whose parents were uncooperative were excluded from the study. Patients were randomly divided into two 40-member groups using the random number table. All these children had fasted for 8–10 h and each received an intravenous injection of midazolam at 0.03 mg/kg before entering the operating room. After infusion with Ringer's solution at 5 cc/kg, during EKG monitoring, pulse oximetry, and blood pressure monitoring, 2 µg/kg of fentanyl was injected, and sodium thiopental at 5 mg/kg and atracurium at 0.5 mg/kg were used for induction of anesthesia. The children were then incubated after 3 min of ventilation with 100% oxygen. Anesthesia was maintained by 40% oxygen–60% N_2O and 1/2–1% isoflurane. In group A, before starting the surgery, tramadol 2 mg/kg diluted in normal saline up to 2 cc total volume (from 1 cc ampules containing 50 mg tramadol manufactured by the Exir Company in Iran) was injected into the tonsillar bed and anterior fold of each tonsil by the anesthesiologist using a 25 gauge needle. Surgery began 3 min later and the tonsils were removed using the sharp dissection method. When surgery was completed, children in group B were injected with tramadol 2 mg/kg diluted in normal saline up to 2 cc total volume (from 1 cc ampules containing 50 mg of tramadol manufactured by the Exir Company) by the anesthesiologist using a 25-gauge needle at the site of removing each tonsil. Both groups were then extubated after reversal of muscle relaxation and airway reflexes return and then transferred to recovery room. Surgical duration, anesthesia duration, recovery duration and hemodynamic variables during the operations and in recovery room were recorded. Using the CHEOPS (Children's Hospital of Eastern Ontario Pain Scale) Scale [8], pain at 10, 20, 30, and 60 min after the children entered the recovery room was recorded by the anesthesia resident unaware of the groups the children belonged to, and by the related intern at 2, 4, 6, 8, and 12 h after they entered the ward. Patient sedation was recorded using the RAMSAY Sedation Scale 15 min and 1 h after the children entered

the recovery room, and 4 h after they were transferred to the ward. In the recovery room, metoclopramide 0.2 mg/kg was prescribed and recorded in cases of severe nausea or vomiting. If the children in the recovery room felt pain with the intensity equal to or greater than 6 out of ten, intravenous fentanyl 1 µg/kg was administered and recorded. Moreover, in the ward, the time at which the first request for analgesics was made and the start of feeding liquids were recorded. All the data were collected, controlled, and entered into the computer using SPSS 17 statistical software. Statistical analysis was done using paired *t* test and results were obtained at 95% confidence limit (SPSS version 17.0). Significance was defined at $p \leq 0.05$. Data were presented as mean (SD). A priori power analysis using two-sided analysis with an error of 0.05 and a power of 0.8 showed that 80 patients (40 patients in each group) were needed for the study.

Results

After approval by ethics committee, in this double-blinded clinical trial study, eighty 5–12 years old children, ASA class I or II undergoing tonsillectomy were involved. They were randomly divided into the two 40-member groups. No significant differences in age, sex, duration of anesthesia and surgery were observed between the two groups. At the three times, the mean sedation score in the group receiving tramadol infiltration before surgery was a little higher compared to the other group, but this difference was not significant ($p > 0.05$) (Table 1). The difference in pain intensity between the two groups 10 min after the surgery was tested using the *t* test and it was found that the difference was not significant ($p = 0.161$). Ten minutes after the surgery, pain intensity was almost the same in both groups. Twenty minutes after the surgery, pain intensity in the group receiving tramadol injection before surgery was greater compared to the group receiving it after the surgery ($p = 0.000$). At 30 and 60 min and at 2 h after the surgery, pain intensity in the group receiving peritonsillar tramadol injection before the surgery was greater compared to the other group ($p < 0.05$).

Table 1 Mean of sedation in the two studied groups at various times according to Ramsy Scale

Time after surgery/group	Peritonsillar tramadol injection before surgery (*A*) ($n = 40$)		Peritonsillar tramadol injection after surgery (*B*) ($n = 40$)		*p* value
	Ramsy score	SD	Ramsy score	SD	
15 min	67/2	8/0	5/2	7/0	294/0
1 h	25/2	6/0	1/2	6/0	275/0
4 h	1/2	5/0	05/2	6/0	685/0

At 4 and 6 h after the surgery, mean pain intensities were not very different in the two groups ($p > 0.05$). However, 8 and 12 h after the surgery, and at hospital discharge, pain intensity in the group receiving peritonsillar tramadol injection before the surgery was less compared to the group receiving the injection after the surgery (for all these cases, $p = 0.000$). Therefore, up to 2 h after the surgery, pain intensity in the group that received peritonsillar infiltration before the surgery was greater compared to the group that received it after the surgery. However, at 4–6 h after the surgery, pain intensity was the same in both groups, and after that pain intensity was less in the first group compared to the second. Pain intensity at different times after the surgery in the two groups (the mutual effect) was studied using the repeated measure observation model, and the result was that pain intensities at various studied times were not the same ($p = 0.000$), and that pain intensities in the two groups were not identical either ($p = 0.012$). In other words, the two groups felt different pain intensities at different times following the surgery (Table 2).

Results showed a significant difference in pain intensity in different times between two groups by repeated measure test (*p* value = 0.000) (Fig. 1).

As for the relative frequency of nausea and vomiting, the difference was not significant ($p = 0.793$) (Table 3). The mean time of the first request for the analgesics between the groups was not significant ($p = 0.677$) (Table 4). The mean time of the first feeding after the surgery was not significant between the groups ($p = 0.062$) (Table 4). Surgical, anesthesia and recovery duration was almost the same for both groups ($p = 0.628$, $p = 0.824$, $p = 0.804$) (Table 5). Mean

Table 2 Mean pain intensity in the two studied groups at various times according to CHEOPS Scale

Time after surgery/group	Peritonsillar tramadol injection before surgery (*A*) ($n = 40$)		Peritonsillar tramadol injection after surgery (*B*) ($n = 40$)		*p* value
	Mean pain intensity	SD	Mean pain intensity	SD	
10 min	3.37	0.9	3.1	0.8	0.161
20 min	3.1	1.1	2.12	0.3	0.000
30 min	3	1.1	2.05	0.2	0.000
60 min	2.85	0.9	2.05	0.2	0.000
2 h	2.5	1.1	2	0	0.004
4 h	2.02	0.8	2	0	0.844
6 h	2.05	0.7	2	0	0.674
8 h	1.12	0.3	2	0	0.000
12 h	1.2	0.4	2	0	0.000
At hospital discharge	1.15	0.4	2	0	0.000

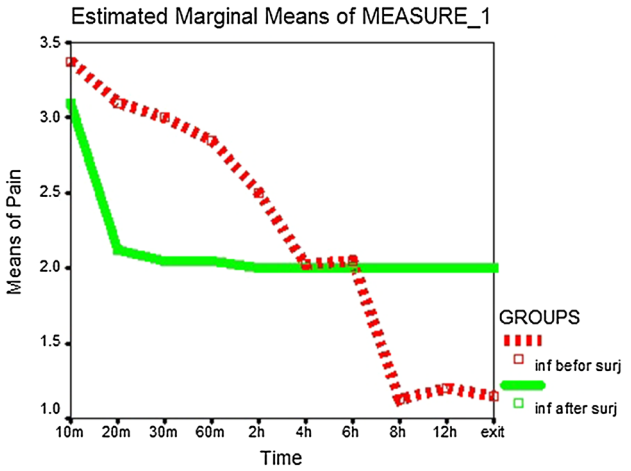

Fig. 1 Repeated measure for pain intensity in different times between two groups

Table 3 Frequency of nausea and vomiting in the two studied groups

Nausea and vomiting	Peritonsillar tramadol injection before surgery (*A*) (*n* = 40)		Peritonsillar tramadol injection after surgery (*B*) (*n* = 40)		*p* value
	Frequency of nausea and vomiting	%	Frequency of nausea and vomiting	%	
Yes	9	5/22	10	25	0.793
No	31	5/77	30	75	
Total	40	100	40	100	

Table 4 Mean time to request for the analgesics and mean time to request for the feeding in the two studied groups

Time to request/group	Peritonsillar tramadol injection before surgery (*A*) (*n* = 40)		Peritonsillar tramadol injection after surgery (*B*) (*n* = 40)		*p* value
	Mean (h)	SD	Mean (h)	SD	
To request for the feeding	48/2	6/0	72/2	6/0	062/0
To request for the analgesics	33/2	4/1	62/2	2/1	677/0

Table 5 Surgery duration in the two studied groups

Duration/group	Peritonsillar tramadol injection before surgery (*A*) (*n* = 40)		Peritonsillar tramadol injection after surgery (*B*) (*n* = 40)		*p* value
	Mean (min)	SD	Mean (min)	SD	
Surgery	35/45	4/8	25/46	1/8	628/0
Anesthesia	67/60	5/10	20/60	4/8	824/0
Recovery	57/14	3/3	75/14	3	804/0

heart beat rates in different times in both groups are listed in Table 6. Mean systolic blood pressures in different times in both groups are listed in Table 7.

Discussion

Pain resulting from tonsillectomy, which is one of the most important complaints, is mainly centered in the throat, but sometimes manifests itself as earache. Pain that is felt when chewing and swallowing food limits oral food intake and increases muscle spasms, while the natural oral flora increase and cause further inflammation and infection that lead to increased pain for the patient [2]. This pain influences the quantity of analgesics used, the length of time the patient requires care, the quality of life of the patient, and makes eating intolerable, delays the start of food intake in children, and disrupts their nutrition. Therefore, post-tonsillectomy pain control is one of the main needs of the patient in this surgery [2, 4]. Post-tonsillectomy pain is controlled in different ways including intravenous injection of various opioids, non steroid anti-inflammation drugs and steroids and suppositories, etc acetaminophen, diclofenac [3]. Local infiltration of different drugs such as various local anesthetics, narcotics, and ketamine into the tonsil and/or near the surgical site is another method of controlling this pain [2, 4]. In some studies, this injection into the tonsillar bed took place before the start of the operation, while in others it was carried out at the end of the operation. In various studies, usually two or more drugs or two or more methods of controlling post-tonsillectomy pain were studied and compared. Most studies have proved the efficiency and effectiveness of injections at the surgical site in tonsillectomy. In studies conducted by Ayatollahi et al. [9], peritonsillar injection of tramadol before surgery had good effects on post-tonsillectomy pain. In other studies also, other researchers have proved the good effect of postoperative injection of tramadol into the tonsillar bed. The effects of injections prior to the surgery can be explained by the preemptive analgesia mechanism. Moreover, the effects of postoperative injections can be attributed to the fact that the drug remains a longer time in the mucosa at the surgical site, and systemic absorption of the drug. Therefore, we decided, following the previous study, to compare tramadol infiltration after the surgery with tramadol infiltration before the surgery.

The effect of muscular tramadol was compared to that of tramadol infiltration prior to the surgery, and it was found that postoperative pain was equally controlled in both methods [2]. In another study, the effect of tramadol infiltration following the surgery was compared with that of normal saline prior to the surgery, and it was found that tramadol had good analgesic effect

Table 6 Mean heartbeat rates in the two studied groups at various times

Time of measuring heartbeat rate/group	Peritonsillar tramadol injection before the surgery (*A*) *n* = 40		Peritonsillar tramadol injection after the surgery (*B*) *n* = 40		*p* value
	Mean (heart beats per minute)	SD	Mean (heart beats per minute)	SD	
Before anesthesia	88.12	6.8	89.95	5.3	0.006
Before surgery	88.95	6.9	92.42	5.2	0.014
15 min after surgery	85.22	7	88.52	5	0.017
30 min after surgery	87.05	6.6	90	5.3	0.030
Before extubation	90.12	6.8	93.50	5.2	0.015
After extubation	101	5.1	97.42	5.2	0.003
10 min after entering the recovery room	89.10	6.9	92.47	5	0.014

Table 7 Mean systolic blood pressures in the two studied groups at various times

Time of measuring systolic blood pressures/group	Peritonsillar tramadol injection before the surgery (*A*) *n* = 40		Peritonsillar tramadol injection after the surgery (*B*) *n* = 40		*p* value
	Mean (cm Hg)	SD	Mean (cm Hg)	SD	
Before anesthesia	24/11	6/0	34/11	7/0	497/0
Before surgery	94/11	6/0	29/12	8/0	031/0
15 min after surgery	99/11	5/0	21/12	8/0	159/0
30 min after surgery	99/11	6/0	17/12	8/0	261/0
Before extubation	05/11	4/0	52/11	6/0	000/0
After extubation	7/10	8/0	34/11	1	002/0
10 min after entering the recovery room	42/11	7/0	33/11	6/0	553/0

after tonsillectomy [4]. The anesthetic effect of swapping tramadol 5% with normal saline before surgery was studied and compared in another research, and it was found to be an easy method without complications and with effective post-tonsillectomy pain control [7]. In 2009, intravenous injection and tramadol infiltration were used in a study to control pain after tonsillectomy, and peritonsillar injection was reported to be the better method [6]. In a research carried out by Ayatollahi et al. in 2012, it was observed that tramadol infiltration prior to surgery could reduce post-tonsillectomy pain better compared to Ketamine and the placebo [9]. Heiba et al. compared lidocaine, normal saline, and tramadol infiltration in three groups before tonsillectomy and noticed that, during the first 6 h after the operation, tramadol controlled pain better compared to the other two [10]. Ali et al. [11] compared the analgesic effect of infiltrated tramadol with that of oral dextromethorphan on post-tonsillectomy pain and concluded that tramadol was better.

In our research, also postoperative injection controlled pain better during the first 2 h, and this is almost in agreement with the above-mentioned study. Uysal HY et al. studied the effects of intravenous tramadol and intravenous paracetamol on post-tonsillectomy pain and stated they were equally effective in controlling pain [12]. Peritonsillar injection of ropivacaine before surgery controlled postoperative pain better than intravenous tramadol and the placebo [13]. In our research, the effects of tramadol infiltration at the end of the surgery and peritonsillar infiltration of tramadol before the surgery on post-tonsillectomy pain were compared. The differences between mean pain intensities in the groups, 10 min after the surgery were not significant; that is, 10 min after the operation pain intensity was almost the same in the two studied groups. However, 20 min after the surgery the differences in pain intensity between the two groups were significant; that is, 20 min after the operation, pain was greater in the group that received local infiltration before the surgery (group A) compared to the group that received infiltration after the surgery (group B). Moreover, 30, 60 min, and 2 h after the surgery, the group that received peritonsillar tramadol injection after the surgery felt less pain compared to the other group. Four and 6 h after the operation, average pain intensities in the two groups were not different. However, 8 and 12 h after the surgery, and at hospital discharge, mean pain intensities in the group with tramadol infiltration prior to the surgery (group A) were less compared to those in the group that received tramadol infiltration after the surgery (group B).

The conclusions to be drawn are that up to 2 h after the operation pain intensity in children who received tramadol infiltration after the operation was lower compared to the group that received tramadol infiltration before the operation and that tramadol infiltration after the surgery controlled pain better up to 2 h after the operation. At 4 and 8 h after the operation, pain intensity was the same

in the two groups, and then pain intensity was greater for group A compared to group B. Pain intensities in the two groups at different times after the surgery were studied using the repeated measures model and it was concluded that pain intensities were not the same at different times it was studied, and that pain intensity was not the same in the two groups. In other words, the two groups did not feel the same pain intensity at different times. This clearly shows the mutual effects of the time of the infiltration on post-operative pain. Average sedation in the group with tramadol infiltration prior to the surgery was a little higher compared to the other group, but this difference was not statistically significant; i.e., the time of tramadol infiltration had no effect on the degree of sedation of the patient. The relationship between the frequency of nausea and vomiting in the studied subjects was not significant; that is, there was no correlation between the time of tramadol infiltration and nausea and vomiting. The relationship between the relative frequencies of request for analgesics in the studied groups and the time of tramadol infiltration was not significant; i.e., request for analgesics was not correlated with the time of tramadol infiltration. The mean differences between the time the operation was finished and the time of the first feeding in the two studied groups were not significant; that is, the time difference between the end of the operation and the first feeding was almost the same in both groups. The mean difference between the lengths of time after the operation that the first request for analgesics was made was not significant between the two groups; i.e., the length of time after the surgery that the first request for analgesics was made was almost the same in the two groups. The mean difference between surgical durations in the two studied groups was not significant; that is, the surgical duration was almost the same in both groups and, therefore, it was not a confounding factor in our research. Moreover, the durations of anesthesia and recovery in the two groups were identical; i.e., the time of tramadol infiltration (prior to or following the surgery) had no effect on duration of recovery. The mean difference between systolic blood pressure before anesthesia in the two groups was not significant; that is, the systolic blood pressure in the two groups before the surgery was almost the same and, therefore, it was not a confounding factor in our study. Systolic blood pressures (before surgery, before extubation, and after extubation) were not the same in the two groups, but this difference was not of clinical importance. Moreover, systolic pressures 10, 15, and 30 min after entry into the recovery room were the same in the two groups. The mean differences in the number of heart beats per minute at various times were significant, but these differences were not of clinical importance.

An important point that we must add and should not be neglected is that, care managers have a critical role in controlling the postoperative pain, especially in children [14]. Different studies relating to the management of pain in children indicate that the effective management of pain requires nurses, interns and residents to:

1. Take a pain experience history from child and parent on admission,
2. assess children's pain using a valid and reliable, age-appropriate pain assessment tool,
3. take into account children's behavioral cues and physiological indicators of pain when assessing pain,
4. administer appropriate analgesic drugs,
5. use non-drug methods of pain relief,
6. involve parents in their child's pain management,
7. document pain scores and interventions,
8. re-assess pain having given time for pain-relieving interventions to take affect and, if necessary, alter the plan of care,
9. communicate with children and their parents about all aspects of pain management [15].

In this study, nurses, interns and residents applied guidelines to effective management of postoperative pain.

Conclusions

We concluded from our study that peritonsillar infiltration of tramadol before surgery controlled postoperative pain better from 8 h after the surgery to hospital discharge (late effect), but that local infiltration of tramadol after surgery controlled postoperative pain better up to 2 h after the operation (early effect).

Limitations

The small sample size is a limitation of this study.

Compliance with ethical standards

Conflict of interest Hatami Maryam declares that she has no conflict of interest. Jesmani Amin declares that he has no conflict of interest. Vaziribozorg Sedighe declares that she has no conflict of interest. Ayatollahi Vida declares that she has no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent Informed consent was obtained from all patients parents included in the study. This study approved by ethics committee of Shahid Sadoughi University of Medical Sciences.

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