Original paper

Peritonsillar Infiltration with Tramadol or Bupivacaine to Relief Post-Tonsillectomy Pain in Children

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Abstract

Background: Tonsillectomy is one of the most frequently performed surgical interventions in children. Pain control for pediatric' patients undergoing tonsillectomy remains problematic.
Objectives: To investigate the effects of peritonsillar infiltration of tramadol or bupivacaine in reducing post-tonsillectomy pain in children.
Patients and methods: A Quasi-interventional study. One hundred fifty children aged 5–15 years were enrolled, who were scheduled for elective tonsillectomy or adenotonsillectomy at the ENT department. Patients were allocated randomly into three groups with 50 patients in each. Group A received peritonsillar infiltration of tramadol, group B received peritonsillar infiltration of 5ml of 2% Bupivacaine. While equal quantities of isotonic saline were used for infiltration in the control group (C). No significant difference between the groups in relation to age, gender, weight, type of surgery, and duration of the operation. Peritonsillar infiltration was performed after tonsillectomy in all groups, but before tracheal extubation. The visual analog scale (VAS) was used to measure and compare postoperative pain for the three groups.
Results: The tramadol group shows a significantly lower pain score in the early postoperative hours compared to the bupivacaine and control groups. Further, the bupivacaine group shows significantly lower pain scores compared to the control group within the first hour postoperatively. No significant difference was found between the groups in regards nausea and vomiting side effects.
Conclusions: Peritonsillar tramadol infiltration offers greater control for post-tonsillectomy pain than bupivacaine or placebo in the early postoperative period. With no obvious side effects. Bupivacaine was superior to placebo in reducing early postoperative pain.
Keywords: Tonsillectomy, Postoperative pain, Tramadol, Bupivacaine

Introduction

Tonsillectomy is a common surgical procedure performed to children and it is associated with presumed pain. This pain not only harms the well-being of the patient, but it can also hinder swallowing, contributing to a higher risk of secondary infection, bleeding and dehydration [1,2].
Optimal pain control regimens following pediatric tonsillectomy continue to be a challenge for both anesthesiologists and otorhinolaryngologists. Thus, different methods have been studied and used to reduce pain, including improved intraoperative anesthetic pain relief regimens. In surgery, local anesthetics have traditionally been used to decrease postoperative discomfort hence the demand for analgesics. [3,4].
Although numerous researches has documented the use of peritonsillar infiltration

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of local anesthetics and/or locally acting analgesic medicines to alleviate post-tonsillectomy pain, with varying outcomes in areas of effectiveness and duration of analgesia. However, pain control remains problematic and there is no standard analgesic protocol [5,6].

Bupivacaine (Marcaine) is a long-acting local anaesthetic that adequately decreases pain following surgery. It is used as a topical analgesic widely. In terms of construction, it is similar to lidocaine, except for an amine group of butylpyridine. Bupivacaine had been utilized for infiltration anaesthesia, nerve blocks, epidural, and caudal anaesthesia. Because of its rapid onset of action and prolonged duration, bupivacaine is gaining popularity as an effective method for pain control after tonsillectomy, where its half-life is 4–7 hours [7-9].

Tramadol is a centrally acting analgesic medication, which is structurally related to codeine and morphine its effectiveness equals that of morphine. Tramadol is available in various compositions, with monoaminergic reuptake inhibitory and opioid receptor agonist function. Its prescription is widening globally as an alternate to high-affinity opioid treatment, for treating acute and chronic pain [10,11].

As an analgesic, tramadol effects require approximately one hour to take effect and 2 to 4 hours to peak with direct-release formula through oral administration. Tramadol induces analgesic effects through a variety of different targets on the noradrenergic system, serotoninergic system, and opioid receptor system. Moreover to its systemic action, both laboratory and clinical trials have demonstrated the local anesthetic role of tramadol on peripheral nerves [12-14].

This study aims to investigate the effects of a multimodal analgesic regimen including peritonsillar infiltration of tramadol or bupivacaine in reducing post-tonsillectomy pain in children

Patients and methods

A quasi-interventional study was conducted over a period from December 1, 2018, to December 31, 2019, at the department of otorhinolaryngology in AL- Hussein Teaching Hospital in Karbala. A total of 150 children aged 5–15 years who were scheduled for elective tonsillectomy or adenotonsillectomy hypertrophy with obstructive symptoms and recurrent tonsillitis had been included in the research. Children with a history of unilateral peritonsillar abscess, known hypersensitivity to medication drugs, history of heart, kidney, lung, or liver diseases were excluded from the study. Also if they used any medications that interact with bupivacaine or tramadol. Or the current regular use of a systemic steroid or non-steroidal anti-inflammatory drugs.

Ethical approval for the study was obtained from the research ethics committee in Karbala Health Directorate. Further, informed consent was obtained from the guardians of all children after the explanation of the objectives of the study and operational procedure, and the guardians were not aware on the type of intervention their kid will take.

The children were randomly divided into 3 groups with consideration of age and gender of the children. Each group includes 50 child patients. Children in the three groups were matched for age, gender, weight, and type of surgery (tonsillectomy or adenotonsillectomy). In addition, no significant difference between each two of the three groups for age, gender, weight, and type of surgery was noted as shown in table 1. And even the duration of operations show no significant difference between the mean duration between each 2 groups.

All group members receive continuous standard monitoring and same adequate premedication (Atropine 0.01mg/kg. Dexamethasone 0.1mg/kg) and analgesia ketamine (1.5mg/kg). Induction with intravenous propofol (1mg/kg) sevoflurane and suxamethonium (1mg/kg). The intubation

done, and after deep anesthesia full relaxation.

Group A received tramadol (2mg/kg), Group B received a peritonsillar injection of bupivacaine (1mg/kg). While Group C was the control group that received an equivalent volume of normal saline. These drugs were given as a single injection before general anesthesia, while Group C received normal saline pre-operatively. Maintenance was performed by isoflurane and esmeron 0.5 mg/kg upon recovery and reversal was given then extubation was done. Anesthesia was given by the same anesthetist while the surgery was carried out by different surgeons. However, surgeons follow the same procedure with intense dissection without an electrical cutter.

The post-surgery pain sensation of the children in each group was assessed using the 10-points visual analog scale (VAS) score. On a scale of zero to 10, the VAS is rated (0: no pain, 10: worst pain imaginable) (15). The pain score evaluation was performed by the anesthetist and an anesthetist assistant who was trained on the instrument utilization, and after assure standardization of their recorded measures. The pain was evaluated for each patient at 15, 30, 45, 60, 120, 180, and 240 minutes where the patients are ready for discharge from the post-anesthesia care unit.

Further, families were orally informed that they can give the children oral analgesic syrup (paracetamol or ibuprofen syrup) which could be offered to the children as required starting from one hour after being discharge to the post-anesthesia care unit.

Data were entered and analyzed using statistical package for social science (SPSS) program version 21. Qualitative data were expressed as frequency (numbers) (N) and percentages (%). Quantitative data were expressed as a minimum (Min.), Maximum (Max.), mean, and standard deviation (SD). Chi- square or Student's t-test was used accordingly for statistical analysis. A p-value of < 0.05 was assumed to be significant statistically.

Results

The children age ranged from 7–13 years with a mean ± SD for age was 8.97 ± 1.61 years, and for the duration of surgery was 25.14 ± 4.44 minutes, and for the weight was 27.54 ± 13.77 kg, respectively. Male forms 98 (65.3%) of the total sample. While 90 (60%) of patients had tonsillectomy and 60 (40%) of them had adenotonsillectomy. The groups does not differ regarding age, gender, type of surgery, child weight, and duration of surgery in terms of statistical significance ($P > 0.05$), as shown in table 1.

Using the VAS pain scores, the severity of pain in the three groups was assessed by specific time intervals at 15, 30, 45, and 60 minutes and after 2, 3, 4, and 5 hours after the surgery.

The tramadol group had a significantly lower pain scores than the control group in the immediately after surgery until 120 min ($P < 0.05$), while the opposite appeared after the 5th hour shown in table 2.

Moreover, the mean pain scores of the tramadol group were significantly lower than the bupivacaine group at 15 minutes till the 4th hour after surgery ($p < 0.01$), as shown in table 3.

Further, the scores of pain in the bupivacaine group were significantly lower than the control group at 45 and 60 minutes while the opposite appeared at 3-5 hours where the control group showed significantly lower scores of pain ($p < 0.05$) as shown in table 4.

Almost all participants had taken the oral analgesic solution; most of the children in the control group take it much earlier between the first and second hours. While the tramadol group take it lately whilst the bupivacaine group had taken it in between.

No significant adverse drug reaction was noticed in the three groups.

However, postoperative nausea and vomiting were slightly higher among group A who receive tramadol. However, no significant difference was noted in comparison

to the other two groups group (P > 0.05) as shown in table 5.

Discussion

Relieving of pain and hindering of popular side effects after tonsillectomy is an important area of postoperative care. Typical analgesics should be effective, safe, and easily administrable.

Table1. Descriptive characteristics of children in the three study groups.

Variable	Group A (n = 50)	Group B (n = 50)	Group C (n = 50)	P value
Age (years) Mean ± SD*	8.67 ± 1.31	9.18 ± 1.79	9.11 ± 1.74	> 0.05**
Gender (Male/Female)***	34/16	29/21	35/15	> 0.05**
The type of surgery (Tonsillectomy/Adenotonsillectomy *	31/19	30/20	29/31	> 0.05**
Weight (kg) Mean ± SD*	26.61 ± 12.38	27.2 ± 16.98	28.81 ± 13.95	> 0.05**
The duration of surgery (minutes) Mean ± SD *	24.29 ± 4.8	25.01 ± 3.73	26.03 ± 4.78	> 0.05**

* The t-test was used to compare between means in each 2 two groups
** The p value was > 0.05 between each two of the three groups
*** chi-square test was used to compare between each two groups

Table 2. The postoperative pain intensity level between the tramadol group and control group

Time (Minutes)	Tramadol Group (A) Pain (Mean ± SD)	Control Group (C) Pain (Mean ± SD)	P value
15	7.20 ±1.61	9.78 ± 1.30	< 0.001
30	6.44 ± 1.94	8.80 ± 0.81	< 0.001
45	5.60 ± 1.47	8.40 ± 0.57	< 0.001
60	4.40 ± 0.57	8.0 ± 0.64	< 0.001
120	3.61 ± 1.51	5.67 ± 1.40	< 0.001
180	3.01 ± 1.16	3.20 ± 0.76	0.334
240	2.05 ± 1.27	2.01 ± 1.16	0.870
300	2.80 ± 0.73	0.84 ± 1.28	< 0.001

Table 3. The postoperative pain intensity level between the tramadol group and the Bupivacaine group

Time (Minutes)	Tramadol Group (A) Pain (Mean ± SD)	Bupivacaine Group (B) Pain (Mean ± SD)	P value
15	7.20 ±1.61	9.60 ± 0.80	< 0.001
30	6.44 ± 1.94	8.80 ± 0.98	< 0.001
45	5.60 ± 1.47	7.60 ± 0.57	< 0.001
60	4.40 ± 0.57	6.80 ± 0.80	< 0.001
120	3.61 ± 1.51	5.58 ± 0.93	< 0.001
180	3.01 ± 1.16	4.96 ± 0.73	< 0.001
240	2.05 ± 1.27	3.20 ± 1.39	< 0.001
300	2.80 ± 0.73	3.02 ± 0.76	0.141

Table 4. The postoperative pain intensity level between the bupivacaine group and control group

Time (Minutes)	Bupivacaine Group (B) Pain (Mean ± SD)	Control Group (C) Pain (Mean ± SD)	P value
15	9.60 ± 0.80	9.78 ± 1.30	0.406
30	8.80 ± 0.98	8.80 ± 0.81	0.912
45	7.60 ± 0.57	8.40 ± 0.57	< 0.001
60	6.80 ± 0.80	8.0 ± 0.64	< 0.001
120	5.58 ± 0.93	5.67 ± 1.40	0.705
180	4.96 ± 0.73	3.20 ± 0.76	< 0.001
240	3.20 ± 1.39	2.01 ± 1.16	< 0.001
300	3.02 ± 0.76	0.84 ± 1.28	< 0.001

Table 5. Postoperative nausea and vomiting in the 3 groups of patients

Side effect		Group A	Group B	Group C	P value
vomiting	Yes	16	10	12	> 0.05*
	No	34	40	38	
Nausea	Yes	12	10	8	> 0.05*
	No	38	40	42	

* The chi-square test is applied for analysis. No significant difference between each two groups (P value > 0.05).

As well as that it does not inhibit respiration. However, the local anaesthetic infiltration role in controlling of post-tonsillectomy pain has been debatable as no specific analgesic treatment protocol exists [2,16-18].

In this study, the preemptive effect of tramadol or bupivacaine on post adenotonsillectomy was compared.

The results showed that peritonsillar infiltration of tramadol has significantly lowered the postoperative pain in children compared to the placebo group within the first 2 hours after surgery. This was similar to other studies that reported the same findings [8,19,22]. However, another study did not approve this result and reported that peritonsillar tramadol infiltration in children undergoing adenotonsillectomy was not better than placebo in minimizing the pain after surgery [23]. Further, children received tramadol infiltration showed statistically significant lower pain scores in comparison to those who received bupivacaine infiltration all over the first 4 hours post-operation, and these findings are similar to other studies [8,24].

The bupivacaine infiltration group showed lower pain scores compared to the control group within the first postoperative hour and it was statistically significant at 45 and 60 minutes. And this agreed with other studies that suggested that pain control by the infiltration of bupivacaine was obviously effected after the first hour [25-29]. However, another study did not confirm these findings [30].

The statistically significant lower scores of pain in the group of control than the tramadol group at 5 hours and with bupivacaine after 3 hours was probably due to the earlier use of oral analgesia after surgery or even to higher dosage or frequent use of the oral analgesics.

No noticeable difference was observed between the groups in terms of nausea and vomiting side effects. However, it was slightly higher among the tramadol group. And this agreed with other studies [18,21,25]. While, another study showed that tramadol increased the risk of nausea and vomiting after surgery [23].

Conclusion

Peritonsillar infiltration of tramadol has greater control of pain after tonsillectomy than bupivacaine or placebo in the immediate postoperative period, with trivial nausea and vomiting side effects. Further, the bupivacaine infiltration experienced a significantly milder pain in the first hour comparing with the control. Future studies with a combination of medication are recommended.

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