

COMPARATIVE STUDY BETWEEN BUPIVACAINE INFILTRATION, TOPICAL LIDOCAINE AND INTRAVENOUS PARACETAMOL IN MANAGEMENT OF POST-TONSILLECTOMY PAIN IN CHILDREN

By

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ABSTRACT

Background: Tonsillectomy operation is a one of the most commonly performed procedures in pediatric population. Post-operative pain control in those children is very important.

Objective: To compare the efficacy of bupivacaine infiltration in gloss-tonsillar sulcus, applying a gauze soaked in lidocaine (10%) in tonsillar bed and intravenous injection of paracetamol in management of post-tonsillectomy pain in children.

Patients and Methods: Sixty kids of both sexes were included in this clinical randomized study, aged from 5 to 12 years undergoing tonsillectomy at Al-Azhar university hospitals between January 2019 and December 2019. They were randomly allocated into three equal groups: Group (A) underwent pre-operative single-point superficial infiltration of a dose of 1 mg/kg bupivacaine (0.5%) in glosso-tonsillar sulcus, Group (B) underwent post-operative application of a soaked piece of gauze in lidocaine (10%) in the tonsillar bed, and Group (C) underwent preoperative intravenous infusion of 10mg/ml paracetamol solution. They were followed up to assess the effectiveness and safety of which medication in pain management post tonsillectomy.

Results: There was no statistically significant difference between pain scores in the three groups after 30 minutes, 2 and 6 hours. There was a statistically significant difference between pain scores in the three groups after 12, 18 and 24 hours respectively. Pair-wise comparisons between the groups revealed that Group B showed the statistically significantly highest mean pain score. There was no statistically significant difference between Group A and Group C; both showed the statistically significantly lowest mean pain scores.

Conclusion: The glossopharyngeal nerve block with plain bupivacaine (0.5%) in glooso-tonsillar sulcus is a safe, effective & easily applicable method for post-tonsillectomy pain management and has a significant prolonged duration of analgesia in comparison to topical lidocaine and Intravenous paracetamol. However, paracetamol injection was more effective than lidocaine infiltration.

Keywords: Tonsillectomy, pain, bupivacaine, lidocaine, paracetamol.

INTRODUCTION

Post-operative pain management in children undergoing tonsillectomy is a very important topic. An adequate

postoperative analgesia is essential after tonsillectomy, as pain after tonsillectomy impairs swallowing with a risk of dehydration, infection and secondary

hemorrhage, and may interfere with speedy recovery and smooth convalescence. This pain has the maximum intensity immediately after operation and in the first 24 hrs (*Ahmed and Omara, 2019*).

There is a wide range of analgesic methods used for postoperative pain control in children undergoing elective tonsillectomy, and there are many cases in which the postoperative analgesic modalities have not been fully successful to treat pain effectively. Systemic analgesics and opioids provide pain relief, but also produce undesirable side effects. The alternative is to use a local anesthetic agent along with general anesthesia. Infiltration of local anesthetic agent like bupivacaine and lignocaine, have been carried out either pre or post operatively in the tonsillar fossa with conflicting results (*Debasish et al., 2018*). Peritonsillar infiltration of different types of drugs in children undergoing adenotonsillectomy has been cited many times during the past years, using local anesthetics, opioids (*Akkaya et al., 2009*), corticosteroids (*Mohamed et al., 2009*), ketamine (*Inanglou et al., 2009*), gabapentin (*Jeon et al., 2009*) and even non-pharmacologic interventions as adjuvant local analgesic compounds (*Parker et al., 2009*).

Hemorrhage, airway obstruction due to edema are the most serious complications observed post operatively after tonsillectomy. Pain is the most common complaint in early post-operative period. Pain causes anxiety and fear of swallowing with individual variations and predisposes to delayed food intake, limits respiratory effort with increased chance of

pulmonary complications and lengthens the stay in hospital (*Yucel and Ozdogan, 2020*).

The inhibition of central sensitization by local or systemic drugs is known as pre-emptive analgesia that helps to control postoperative pain. Pre-emptive analgesia has been tried with opioids, steroids, and NSAIDS as well as local anesthetics sprays and infiltration in tonsillar fossa (*Debasish et al., 2018*).

The present work aimed to compare the efficacy of bupivacaine infiltration in glosso-tonsillar sulcus, spraying of lidocaine (10%) in tonsillar bed, and intravenous injection of paracetamol in management of post-operative pain in children undergoing tonsillectomy operation.

PATIENTS AND METHODS

This clinical randomized study was carried out after local ethics committee approval and written informed consents from the parents of 60 children undergoing tonsillectomy at Al-Azhar University Hospitals between January 2019 and December 2019.

Inclusion criteria:

Age from 5-12 years and suffering from either recurrent episodes of tonsillitis ≥ 3 episodes per year in the past year, ≥ 5 episodes in the preceding 2 years or ≥ 7 episodes in the preceding 3 years.

Exclusion criteria:

Children with diabetes mellitus, cardiac, renal or liver diseases, obstructive sleep apnea syndrome, blood disease or bleeding tendency, those suspected for having hypersensitivity to the used medication, and those undergoing

simultaneous procedure in the field of surgery like adenoidectomy or tongue tie.

All patients were subjected to complete blood count (CBC), partial thromboplastin time (PTT), prothrombin time (PT), prothrombin concentration (PC) and erythrocyte sedimentation rate (ESR).

Patients were randomly allocated into 3 equal groups: Group (A) underwent pre-operative infiltration of bupivacaine, Group (B) underwent post-operative application of lidocaine, and Group (C) underwent preoperative intravenous paracetamol infusion.

The analgesia was differently applied according to the group of the patient: Group (A) underwent single-point superficial infiltration (in a depth of about 3 mm) of a dose of 1 mg/kg bupivacaine (0.5%) in glosso-tonsillar sulcus 5 minutes before tonsillectomy, Group (B) underwent application of a soaked piece of gauze (measuring about 3×3 cm) in 2 ml of lidocaine (10%) in the tonsillar bed for 3 minutes after tonsillectomy, and Group (C) underwent preoperative intravenous infusion of (10mg/ml) paracetamol solution in a dose of 15 mg/kg over at least 15 minutes, and 10 minutes prior to the procedure.

Patients were assessed for post-operative pain 30 min, 2hrs, 6hrs, 12 hrs, 18 hrs. and 24 hrs. using facial expression (Wong-Baker scale), and dysphagia in the recovery room.

The time for first request of rescue analgesia was recorded, representing the time interval between the end of the surgery and the first request of rescue analgesia. If there was any pain score more than 3 of 10 in any of the

assessments, the patient was treated with incremental rectal doses of rectal paracetamol (10 mg/kg) until the VAS score was 3. If pain persisted despite administering rectal paracetamol, intravenous pethidine with a dose of 0.4 mg/kg was administered. The whole time of surgery was recorded. The incidence of perioperative complications such as postoperative nausea and vomiting, choking, toxicity of local anesthetic, dry mouth, nasal obstruction, hoarseness of voice or foreign body sensation in the throat, dyspnea, bradycardia, were also assessed. The children were discharged from the hospital after at least 24 hours if there was no bleeding, nausea or vomiting and they were able to swallow clear fluids and their pain score was less than three.

Statistical Analysis:

All of the numerical data were explored for normality through checking the distribution of data and by using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). All data showed normal (parametric) distribution except for pain (VAS) scores data which showed non-normal (non-parametric) distribution. Data were presented in the form of mean and standard deviation (SD) values. For parametric data, one-way ANOVA test was used for comparisons between the groups. When ANOVA test was significant, Bonferroni's post-hoc test was used for pair-wise comparisons. For non-parametric data, Kruskal-Wallis test was used to compare between the three groups. Also, Friedman's test was used for studying the changes by time within every group. For pair-wise comparisons, Dunn's test was used. On the other hand, qualitative data were presented as

frequencies and percentages. Chi-square test and Fisher’s exact test were used for comparisons between the groups. The level of significance was at $P \leq 0.05$.

Statistical analysis was done with IBM SPSS program for statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS

The present study was conducted on 60 cases with equal number of cases i.e. 20 cases in each of the three groups. As regard age and sex, there was no statistically significant difference between the studied groups ($p < 0.05$) (**Table 1**). As regard heart rate, respiratory rate and

oxygen saturation, there was no statistically significant difference in all of them (P -value > 0.05 , Effect size = 0.666), (P -value > 0.05 , Effect size = 0.507), (P -value > 0.05 , Effect size = 0.860) respectively (**Table 2**).

Table (1): Mean, standard deviation (SD), frequencies (n) and results of one-way ANOVA test and Chi-square test for comparisons of demographic data in the three groups

Groups		Group A (N =20)	Group B (N =20)	Group C (N =20)	P-value
Parameters					
Age (mean ± SD)		8.0± 3.7	8.6 ± 3.8	8.0 ± 2.6	>0.05
Sex	Male	12	11	13	>0.05
	Female	8	9	7	

Table (2): Mean, standard deviation (SD), frequencies (n) and results of one-way ANOVA test for comparisons of operative data in the three groups

Groups	Group A (N =20)	Group B (N =20)	Group C (N =20)	P-value	Effect size
Parameters					
HR	92±3.2	93±2.8	93±5.2	>0.05	$f = 0.666$
RR	20±2.4	19±6.3	20±5.7	>0.05	$f = 0.507$
Oxygen saturation (%)	99±5.2	100±0	100±0	>0.05	$f = 0.860$

Also, there was no statistically significant difference as regard duration of anesthesia and duration of the surgical procedure in which (p - value =0.1430, effect size = 1.419),(p - value=.084, effect size= 1.608),respectively. According to the time for the first request of rescue

analgesia, there was statistically significant (p -value < 0.001) prolonged duration in group A in which (duration =322 ± 6.37), but in Group C (duration= 281 ± 5.8), and Group C revealed the lowest time for first rescue analgesia (duration= 236 ± 6.5) (**Table 3**).

Table (3): Mean, standard deviation (SD), frequencies (n) and results of one-way ANOVA test for comparisons of operative data in the three groups

Parameters \ Groups	Group A (N=20)	Group B (N=20)	Group C (N=20)	P-value	Effect size
Duration of anesthesia (min) (mean ± SD)	40.33 ± 3.84	39.13 ± 2.65	41.02 ± 2.34	>0.05	f= 1.419
Duration of tonsillectomy (min) (mean ± SD)	21.27 ± 4.06	20.3 ± 4.33	23.16 ± 3.72	>0.05	f= 1.608
Time to request of analgesic (min) (mean ± SD)	322 ± 6.37	236 ± 6.5	281 ± 5.8	<0.001*	f=30.874
No. of children receiving analgesics in 1st 24 hrs.	1	5	4	>0.05	v= 0.228

There was no statistically significant difference in pain scores between three groups after 30 minutes, 2 and 6 hours in which (P-value = 0.184, Effect size = 0.024), (P-value = 0.132, Effect size = 0.036) and (P-value = 0.165, Effect size = 0.028), respectively. But there was a statistically significant difference in pain scores between three groups after 12, 18 and 24 hours in which (P-value <0.001, Effect size = 0.574), (P-value <0.001, Effect size = 0.508) and (P-value <0.001,

Effect size = 0.456), respectively. Pair-wise comparisons between the groups revealed that Group B showed the statistically significantly highest (P-value <0.001) mean pain score. While comparing group A and C there was increase in pain score in group C than group A but without a statistically significant difference and both showed the statistically significant lowest mean pain scores (Table 4).

Table (4): Mean ± standard deviation (SD) and results of Kruskal-Wallis test for comparisons of pain (VAS) scores in the three groups and Friedman’s test for the changes by time within each group

Groups \ Parameters				P-value	Effect size (Eta squared)
30 min.	2.2 ± 0.52	2.4 ± 0.82	2.2 ± 0.48	>0.05	0.024
2 hrs.	2.25 ± 0.55	2.6 ± 0.88	2.35 ± 0.59	>0.05	0.036
6 hrs.	2.55 ± 0.76	2.95 ± 0.89	2.85 ± 0.67	>0.05	0.028
12 hrs.	2.65 ± 0.75	4.5 ± 0.82	2.75 ± 0.79	<0.001*	0.574
18 hrs.	2.9 ± 0.85	5.2 ± 1.00	3.05 ± 0.94	<0.001*	0.508
24 hrs.	3.15 ± 0.99	5.3 ± 0.80	3.7 ± 1.13	<0.001*	0.456
P-value	0.062	<0.001*	0.052		
Effect size (w)	0.185	0.822	0.168		

There was no statistically significant difference between severity of dysphagia in the three groups (P-value = 0.724,

Effect size = 0.180)) as showed in (Table 5).

Table (5): Frequencies, percentages (%) and results of Fisher's Exact test for comparison between severity of dysphagia in the three groups

Dysphagia \ Groups	Group A (N =20)	Group B (N =20)	Group C (N =20)	P- value	Effect size (v)
No	18 (90%)	14 (70%)	16 (80%)	>0.05	0.180
Mild	1 (5%)	2 (10%)	2 (10%)		
Moderate	1 (5%)	3 (15%)	2(10%)		
Severe	0 (0%)	1 (5%)	0 (0%)		

There was no postoperative nausea and vomiting, choking, local anesthetic

toxicity, hoarseness of voice, or foreign body sensation in the throat.

DISCUSSION

A good control of post-operative pain following tonsillectomy resulted in decreasing morbidity and increases parent satisfaction, and there are many techniques have been tried to alleviate post-operative pain following tonsillectomy with conflicting outcomes. Glossopharyngeal nerve block results in decreasing post-operative pain after tonsillectomy and decreasing analgesic consumption (*Wang et al., 2016*).

As regard age and sex, there was no statistically significant difference between the studied groups, and also there was no statistically significant difference as regard heart rate, respiratory rate, and oxygen saturation. This result came in agreement with *Vlok et al. (2017)* who reported that there was no statistically significant difference between the studied groups as regard age, sex, heart rate, respiratory rate and oxygen saturation.

The current study demonstrated that a great benefit of glossopharyngeal nerve block in patients undergoing tonsillectomy, in which it was comparing the effect of local infiltration of bupivacaine and topical lidocaine with administration of intravenous infusion of paracetamol prior to operation, showed

that there was no statistically significant difference in pain scores after 30m, 2hrs, and 6hrs. But there was a statistically significant difference in pain scores between three groups after 12, 18 and 24 hours. Pair-wise comparison between the groups revealed that Group B showed the statistically significant highest mean pain score. on comparing group A and C, there was an increase in pain score in group C than group A, but without a statistically significant difference, and both showed the statistically significant lowest mean pain scores.

This result was concomitant with *Yucel and Özdoğan (2020)* who concluded that glossopharyngeal nerve block has a practically safe and effective form of analgesia post-operatively in different times 2hrs, 4hrs, and 6hrs. and also no need for rescue analgesia over 24hrs. Also, it was similar to *Vlok et al. (2017)* where the patient had less need for analgesia. Also pain relief was of longer duration of the drug. This is explained by the phenomenon of "neuroplasticity", which proposes that pre-emptive blockade of release of nociceptive neuromediators which may contribute to the elimination of hyper-excitable state responsible for maintenance of postoperative pain. Therefore, one may speculate that the

prolonged analgesia was attributed to successful blockade of these nociceptive impulses by the use of local anesthetic preoperatively (*Ju et al., 2013*).

There is a meta-analysis of seven randomized controlled trials evaluating perioperative bupivacaine infiltration for pain relief following adeno-tonsillectomy which revealed that bupivacaine infiltration in the peritonsillar region is a safe and effective during post-operative period (*Vlok et al., 2017*). *Stelter et al. (2009)* and *Maryam et al. (2017)* reported that post-tonsillectomy infiltration with local anesthetic is superior to pre-incisional infiltration.

Zhang et al. (2014), in their randomized double-blinded study, reported that pre-incisional local anesthetic infiltration in children presented for tonsillectomy significantly decreased post tonsillectomy pain, and helped in better recovery of activities.

In the current study, there was no postoperative nausea and vomiting, choking, local anesthetic toxicity, hoarseness of voice, or foreign body sensation in the throat and this result was concomitant with *Yucel and Özdoğan (2020)* reported that topical application of both lignocaine and bupivacaine spraying was safe and simple to be performed.

Intravenous infusion of paracetamol prior to operation also has a good analgesic effect in which pain score at 30m, 2h, 6h, and 12h had no statistically significant difference, but it was founded that there was statistically Significant increase in pain score at 18h , and 24 h in comparison with group and this result was concomitant with *Salonen et al. (2009)* who reported that Intra venous

paracetamol decreases the need to opioid doses after adeno-tonsillectomy but they combined it with ketoprofen and administer two drugs at the end of operation.

In contrast to the current finding, *Dahi-Taleghani et al. (2011)* demonstrated that there is no difference between peritonsillar infiltrations of bupivacaine compared with rectal acetaminophen suppositories in children undergoing adeno-tonsillectomy. This disagreement may be due to the high dose of paracetamol (30mg/kg), and the use of peritonsillar infiltration technique.

CONCLUSION

The glossopharyngeal nerve block with plain bupivacaine (0.5%) in glosso-tonsillar sulcus was a safe, effective, and easily applicable method for post-tonsillectomy pain management, and has a significant prolonged duration of analgesia in comparison to topical lidocaine and Intravenous paracetamol. Paracetamol injection is also an effective method for pain management in tonsillectomy especially in early post-operative period with fewer side effects than lidocaine infiltration.

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دراسة مقارنة بين حقن عقار البيوبيفاكين والليدوكاين الموضعي وعقار الباراسيتامول الوريدي في مناجزة ألم ما بعد عملية استئصال اللوزتين في الأطفال

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خلفية البحث: تعد عملية استئصال اللوزتين من أكثر العمليات التي يخضع لها الأطفال والتي تسبب ألمًا قد يكون في بعض الأحيان شديد جدًا أو غير محتمل. لذلك، فاعن معالجة هذا الألم من أهم أسباب تقليل مضاعفات العملية وقد استخدمت في ذلك طرق عديدة والكثير من الأدوية مثل المسكنات و المخدرات سواءً كانت موضعية أو عامة.

الهدف من البحث: مقارنة تأثير الحقن الموضعي لعقار البيوبيفاكين والليدوكاين الموضعي بتركيز 10% والحقن الوريدي لعقار الباراسيتامول في معالجة ألم ما بعد عملية استئصال اللوزتين في الأطفال.

المرضى و طرق البحث: تم إجراء هذه الدراسة على ستين من المرضى مقسمين عشوائيا بالتساوى بين ثلاث مجموعات، وقد تم حقن عقار البيوبيفاكين في التلم اللساني اللوزي قبل عملية استئصال اللوزتين في المجموعة الأولى، كما تم وضع شاشة صغيرة مباللة بعقار الليدوكاين في مكان اللوزتين بعد استئصالهما في المجموعة الثانية وفي المجموعة الثالثة تم حقن الأطفال وريديا بعقار الباراسيتامول قبل العملية، وتم بعد ذلك متابعة هؤلاء الأطفال لتقييم تأثير كل عقار في التحكم في ألم ما بعد استئصال اللوزتين ومدى أمانه.

نتائج البحث: لا يوجد فارق إحصائي معتبر بين المجموعات الثلاث فيما يخص درجة الألم بعد نصف ساعة و ساعتين وست ساعات، ولكن كان هناك فارقاً إحصائياً معتبراً بين المجموعات الثلاث فيما يخص درجة الألم بعد اثني عشر وثمان عشر وأربع وعشرين ساعة حيث كانت درجة الألم الأعلى في المجموعة الثانية والأدنى كانت في المجموعة الأولى و الثالثة.

الاستنتاج: أثبتت هذه الدراسة فعالية وأمان وسهولة تطبيق حقن عقار البيوبيفاكين الموضعي وكذلك طول مفعوله عن الطرق الأخرى المستخدمة في الدراسة.