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Comparison of Topical Bupivacaine, Peritonsillar Dexamethasone Infiltration or Topical Bupivacaine Plus Intravenous Dexamethasone for Post-Adenotonsillectomy Pain Control

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ABSTRACT

Background: About all patients who have had tonsillectomies report experiencing post-operative pain, which often lasts for about a week. Opioids still play a part in post-tonsillectomy pain management despite the absence of codeine, as some children may not have enough pain relief from acetaminophen and ibuprofen alone. Dexamethasone treatment following adult tonsillectomy is the subject of multiple randomized controlled trials.

Objective: The aim of the current study was to evaluate controlling post adenotonsillectomy pain with topical bupivacaine, peritonsillar dexamethasone infiltration or topical bupivacaine plus intravenous dexamethasone.

Patients and methods: A randomized controlled clinical trial was conducted at Zagazig University Hospitals. The study duration was 6 months. Patients were randomly allocated to three equal groups; Group B (topical bupivacaine), Group D (dexamethasone infiltration) and Group BD (topical bupivacaine plus intravenous dexamethasone).

Results: For changes in Multidimensional Assessment of Pain (MAP) scale, like FLACC, initial request for analgesia, first oral intake, and overall quantity of analgesia in the five hours before to discharge, there was a statistically significant difference between the study groups. Demographic information, the length of the surgery, the duration of the anesthesia, and variations in SPO2 did not statistically differ across the study groups. **Conclusion**: Topical bupivacaine plus intravenous dexamethasone is more effective for controlling post-operative adenotonsillectomy pain than topical bupivacaine or peritonsillar dexamethasone infiltration.

Keywords: Adenotonsillectomy, Bupivacaine, Dexamethasone, Clinical Trials, Zagazig University.

INTRODUCTION

One of the most often performed surgical operations on children is a tonsillectomy [(1)]. Recurrent throat infections and sleep disordered breathing (SDB) are the two conditions that lead to surgery the most commonly, and both can have a substantial impact on a child's health and quality of life (QoL) [(2)].

Though tonsillectomy has been commonly performed for many years, complications are still encountered [(3)]. It should not be viewed as minor or routine surgery that is relatively devoid of complication [(4)]. Although anesthesia and surgical methods have improved, post-tonsillectomy pain is still a significant clinical concern for patients, families, and doctors [(5)].

Almost all patients who have had a tonsillectomy report experiencing post-operative pain, which can last for about a week [(1)]. It could be caused by the patient's positioning, such as when utilizing a mouth retractor (e.g., Boyle–Davis mouth gag).

Stretching of the temporomandibular joint, pressure and venous congestion of the tongue, postoperative edema, and pain could all occur from this [(6)]. After a tonsillectomy, pain is thought to be brought on by a confluence of nerve end injury, inflammation, and pharyngeal muscle spasm [(7)]. Since postoperative opioids have been reported to aggravate nausea while offering little analgesic benefit, many otolaryngologists advise against them due to the high rate of nausea and vomiting following tonsillectomy [(8)]. Opioids still play a part in post-tonsillectomy pain management despite codeine's exclusion, as certain children may not have enough pain relief from acetaminophen and ibuprofen alone [(1)].

Despite evidence that non-steroidal anti-inflammatory drugs (NSAIDs) are effective in reducing postoperative pain in children; doctors have administered these medications with caution due to concerns of higher bleeding rates [(9)]. Several randomized controlled clinical trials are examining the effectiveness of post-tonsillectomy dexamethasone in humans. However, the outcomes of these studies were inconsistent, with some showing a therapeutic benefit from giving patients perioperative dexamethasone and others not [(10,11)]. A local anesthetic (LA) injection, which is frequently administered prior to procedures to minimize pain stimulation during the surgery, has been shown to be beneficial in several trials [(12)]. Local infiltration analgesia (LIA) has shown to be effective in lowering the risk of postoperative nausea and vomiting (PONV) and the need for postoperative opioid medication during a number of surgical procedures [(13)]. Local anesthetic bupivacaine belongs to the chemical family of amino amides. Using local anesthetics, such as infiltration, nerve blocks, epidurals, and intrathecal anesthesia, is advised. Using it topically or slipping into the workplace space has two options [(14)] because of its prolonged action period; bupivacaine is a recommended local anesthetic [(15)].

The aim of the current study was to evaluate controlling post adenotonsillectomy pain with topical bupivacaine, peritonsillar dexamethasone infiltration or topical bupivacaine plus intravenous dexamethasone.

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PATIENTS AND METHODS

A randomized controlled clinical trial was conducted at Zagazig University Hospitals. The study duration was 6 months.

Inclusion criteria were parents or first-degree relative acceptance, patient aged 5-10 years, both sexes, physical status ASA class I and II, Body Mass Index (BMI) is neither more in value than 85% (i.e., Obese) nor below the value in 5th % (underweight) of the children in the same age and gender, and type of operation elective adenotonsillectomy under general anesthesia.

Patients were randomly allocated to three equal groups; Group B with 18 patients (topical bupivacaine), Group D with 18 patients (dexamethasone infiltration) and Group BD with 18 patients (topical bupivacaine plus intravenous dexamethasone).

Preoperative preparation:

All participating patients were evaluated preoperatively during their preoperative preparation. The goal and endpoints of the study was discussed with the parents/guardians of the patients and written informed consent from the parents /guardians was taken. Physical examination of participants included vital signs (base line values), cardiac, and chest examinations. Participants with acute or chronic cardiac or chest diseases were excluded. Routine laboratory investigations were reviewed, Patients was kept fasting 6 hours for solid food, and 2 hours for clear fluids. No premedication was given before operation.

Intraoperative: Standard monitors were linked to the patients after pre-operative evaluation, including pulse oximetry, non-invasive blood pressure, and ECG, and baseline parameters were recorded; Peripheral oxygen saturation, mean arterial pressure and heart rate.

Ethics Approval:

This study was ethically approved by the Institutional Review Board of the Faculty of Medicine, Zagazig University (Reference number #9572-12-6-2022). Written informed consent was obtained from all parents/guardians. This study was executed according to the code of ethics of the World Medical Association (Declaration of Helsinki) for studies on humans.

Statistical Analysis

The collected data were introduced and statistically analyzed by utilizing the Statistical Package for Social Sciences (SPSS) version 22.0 for windows. Qualitative data were defined as numbers and percentages. Chi-Square test was used for comparison between categorical variables. Normal distribution of variables was described as mean and standard deviation (SD), and one-way ANOVA test was used for comparison between groups. P-value ≤0.05 was considered to be statistically significant.

RESULTS

Table 1 demonstrated how similar the study groups were in terms of age, gender, weight, height, BMI, and ASA I/II.

Table (1): Comparison between demographic data among the three studied groups.

Groups	Group B n= 18	Group D n= 18	Group BD n= 18	F/ X^2	P-value
Age (years) Mean ± SD	7.6 ± 2.2	7.3 ± 2.1	7.4 ± 2.4	0.62	0.54
M/F n	11/7	8/10	9/9	1.04	0.59
Weight (kg)	16.4 ± 3.8	15.6 ± 3.5	15.7 ± 3.4	0.16	0.84
Height (cm^2)	130 ± 8.8	132 ± 6.9	131.7 ± 8	0.53	0.59
BMI (Kg/m^2)	8.9 ± 1.6	8.4 ± 1	8.55 ± 1	0.85	0.43
ASA I/II	13/5	14/4	16/1	1.6	0.44

Data are expressed as Mean ± Standard Deviation (SD). n= group number and patient numbers. F= one-way ANOVA test. X^2= Chi square test. P>0.05= non-significant difference. P<0.05= significant difference. M= male. F= Female.

Table 2 showed that there were no significant difference between groups as regards duration of anesthesia and duration of surgery (P>0.05).

Table (2): Comparison between duration of anesthesia and duration of surgery among the 3 studied groups.

Groups	Group B n=18	Group D n=18	Group BD n= 18	F	P-value
Duration of anesthesia (min) Mean ± SD	46.1 ± 6.3	50 ± 7.2	49 ± 7.1	1.5	0.21
Duration of surgery (min) Mean ±SD	39.9 ± 6.1	36.9 ± 4.5	39.4 ± 3.6	1.8	0.16

Data are expressed as Mean ± Standard Deviation (SD). n= group number. F= one-way ANOVA test. P>0.05= non-significant difference. P<0.05 =significant difference.

Table 3 showed that the HR was comparable between Group B and Group D at different times of recording. While, there were significant decrease in heart rate in Group BD from time 15 min post intubation up to 5 hours after extubation, when compared with either Group B or Group D (P<0.001).

Table (3): Comparison of changes in HR among three study groups at different time.

Groups	Group B n= 18	Group D n= 18	Group BD n= 18	F	P-value
Pre induction	101 ± 5.5	101.9 ± 7.9	100.8 ± 5.7	0.1	0.81
5 min. post intubation	105 ± 6.1	106.1 ± 9	104.5 ± 5.9	0.2	0.81
15 min. post intubation	104.8 ± 8	103.1 ± 9	91.7 ± 5.5	14.8	<0.001*
During Packing or infiltration	105.4 ± 8.7	104.5 ± 8.3	90.3 ± 5.7	21.2	<0.001**
Before extubation	104.9 ± 8.3	105.5 ± 8.8	93.0 ± 6.6	13.2	<0.001*
10 min. post extubation	105.7 ± 7.3	102.4 ± 10	90.8 ± 5.2	17.3	<0.001**
20 min. post extubation	103.8 ± 10	102.5 ± 11.4	87.7 ± 5.2	16.2	<0.001**
40 min. post extubation	99.3 ± 9.2	98.2 ± 8.5	85.2 ± 4.9	18.3	<0.001**
1hr after extubation	99.7 ± 9	94.6 ± 7.3	82.8 ± 5.4	24.6	<0.001**
2hr after extubation	96.1 ± 6.6	93.2 ± 8.1	80.9 ± 5.7	24.3	<0.001**
3hr after extubation	93.1 ± 6.1	92 ± 6.6	80 ± 4.5	27.7	<0.001**
4hr after extubation	88.7 ± 9.7	91.5 ± 7.6	79 ± 4.2	13.8	<0.001**
5hr after extubation	90.4 ± 9.2	90.7 ± 8.4	76.8 ± 4.5	19.4	<0.001**

Data are expressed as Mean ± Standard Deviation (SD). n= group number. F= one-way ANOVA test. P>0.05= non-significant difference. P<0.05= significant difference.

Table 4 showed that Multidimensional Assessment of Pain (MAP) scale were comparable between Group B and Group D at the different times of recording. While there were significant decrease in MAP in Group BD at the times of (During packing or infiltration, before extubation, 10 min. post extubation, 20 min. post extubation, 40 min. post extubation and 1 hour after extubation) (P<0.001), when compared with Group B and Group D.

Table (4): Comparison of changes in MAP among the three studied groups at different times.

Groups	Group B n= 18	Group D n= 18	Group BD n= 18	F	P-value
Pre induction	86.6 ± 1.0	86.5 ± 4.6	87.5 ± 4.4	0.38	0.68
5 min. post intubation	85.3 ± 2.6	88.6 ± 3.7	83.4 ± 3.9	2.7	0.07
15 min. post intubation	84.8 ± 2.6	86.4 ± 3.4	84 ± 4.1	1.55	0.22
During Packing or infiltration	85.1 ± 2.3	84.8 ± 2.3	75.3 ± 3.4	47.9	<0.001**
Before extubation	85.2 ± 3.1	84.3 ± 3.3	76.9 ± 3	32.1	<0.001**
10 min. post extubation	84.6 ± 2.8	85.5 ± 3.6	76.7 ± 3	20.0	<0.001**
20 min. post extubation	88.6 ± 1.5	86.1 ± 2.9	76.7 ± 2.8	8.5	<0.001**
40 min. post extubation	87.9 ± 2	84.6 ± 3.8	77 ± 1.5	9.2	<0.001**
1hr after extubation	88 ± 1.6	87.8 ± 2.3	76.2 ± 1.4	9.8	<0.001**
2hr after extubation	77.2 ± 2.4	79 ± 2.4	76.7 ± 3.8	2.6	0.07
3hr after extubation	77.9 ± 3.6	77.3 ± 2.5	75.9 ± 4.95	0.3	0.2
4hr after extubation	75.8 ± 6.7	75.1 ± 3.7	73.6 ± 4.6	0.85	0.43
5hr after extubation	76.1 ± 3.6	75.5 ± 2.5	73.8 ± 4.3	2.2	0.11

Data are expressed as Mean ± Standard Deviation (SD). n= group number. F= one-way ANOVA test. P>0.05= non-significant difference. P<0.05= significant difference.

Table 5 showed that the pain score was significantly decreased in Group BD when compared with other groups at different times of recording (P<0.001), while the difference between Groups B and D were non-significant (P>0.005).

Table (5): Changes in pain score (**FLACC**) among studied groups.

Groups	Group B n= 18	Group D n= 18	Group BD n= 18	F	P-value
T_{15}	2.1 ± 0.75	2.3 ± 0.5	1.3 ± 0.5	14.2	<0.001**
T_{30}	2.7 ± 0.5	3.2 ± 0.5	2.1 ± 0.7	18.0	<0.001**
T_{45}	3.5 ± 0.5	3.6 ± 0.5	3 ± 0.6	5.0	<0.01*
T_{1h}	4.6 ± 0.5	5.3 ± 0.5	3.7 ± 0.6	43.0	<0.001**
T_{2h}	4.8 ± 0.6	5.9 ± 0.6	4.4 ± 0.5	41.9	<0.001**
T_{3h}	5.5 ± 0.5	6.3 ± 0.6	4.9 ± 0.7	26.7	<0.001**
T_{4h}	5.67 ± 0.5	6 ± 0.9	4.7 ± 0.5	18.8	<0.001**
T_{5h}	5.72 ± 0.6	6 ± 1.0	4.8 ± 0.7	11.8	<0.001**

Data are expressed as Mean ± Standard Deviation (SD). n= group number. F= one-way ANOVA test. P>0.05= non-significant difference. P<0.05= significant difference.

Table 6 showed that Groups B and BD had longer times before their initial request for analgesia than Group D, with Group BD having a longer period (P<0.001) than Group B. The time of first oral intake was significantly lower in Groups B and BD than in Group D (P<0.001). Moreover, the table demonstrated a significantly lower overall quantity of analgesia in Groups B and BD than in Group D (P<0.001).

Table (6): Comparison between Time of 1st request analgesia and Time of 1st oral intake and total amount of analgesia in 5h hours before discharge.

Groups	Group B n= 18	Group D n= 18	Group BD n= 18	F	P-value
Time of 1st request analgesia (min)	90.4 ± 29.8	45 ± 15.3	130.8 ± 20.2	64.03	<0.001*
Time of 1st oral intake (hour)	2.3 ± 0.4	3.5 ± 0.6	2.1 ± 0.4	52.6	<0.001*
Total amount of analgesia in 5h (mg)	190.6 ± 35.7	250.2 ± 29.5	170.3 ± 30.4	98.1	<0.001*

Data are expressed as Mean ± Standard Deviation (SD). n= group number. F= one-way ANOVA test. P>0.05= non-significant difference. P<0.05= significant difference.

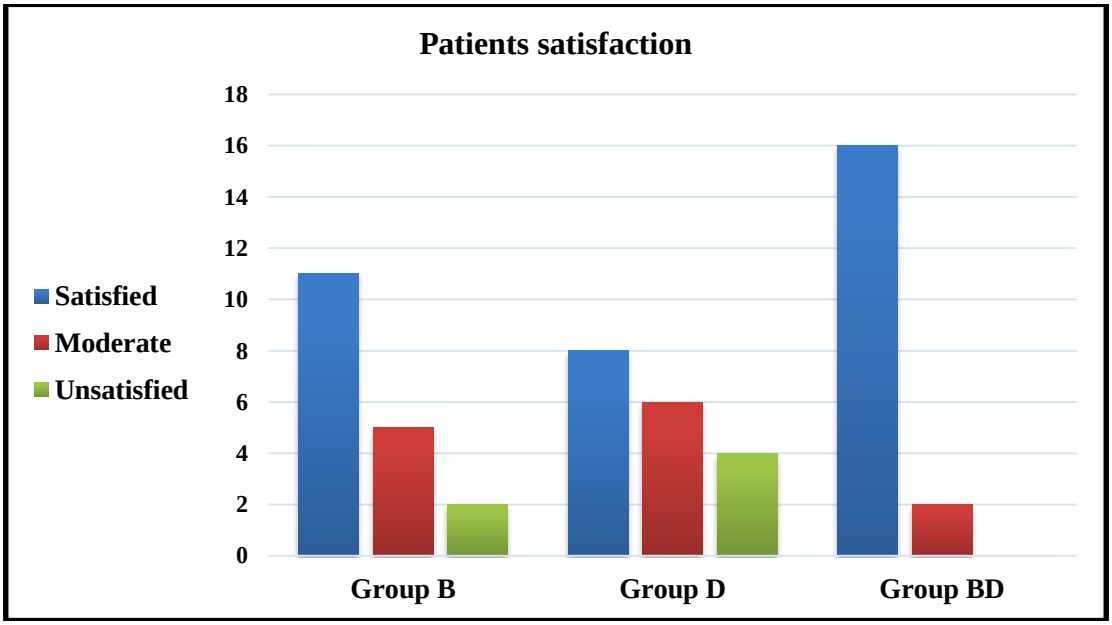

Figure (1): Comparison between three studied groups regarding patient's satisfaction.

DISCUSSION

The study groups in our study had similar age, gender, weight, height, BMI, and ASA I/II values. Our results were in line with **Khan's study [16].**

It demonstrated the use of a non-probability practical technique to choose 60 people of both sexes between the ages of 5 and 15 who met the criteria for tonsillectomy. They were divided equally into two groups of 30, each getting 30 patients. Bupivacaine was administered to the tonsils in Group A, whereas Dexamethasone was administered to the tonsils in Group B.

In Group A (bupivacaine), the mean age was 10.20 years with a 2.94 SD, and in Group B (dexamethasone), it was 11.13 (SD 2.86) years.

The proportion of male patients in groups A and B was 70% and 63.3%, respectively, however there was no statistically significant difference between the two groups. The results of the analysis showed that there was no discernible difference in the length of anesthesia or the duration of the surgery between the groups (P>0.05). A total 140 kids underwent their initial examinations between November 2018 and June 2019, as **per Kang's [17]** findings from our study. Due to turbinoplasty or the implantation of a breathing tube contemporaneous with an adenotonsillectomy, 17 kids were disqualified.

Dexamethasone (n= 60) or the control group (n= 63) were randomly given to one of the two groups of children (n= 123). They found that the difference in operation time between the two groups was not statistically significant (P=0.763).

According to the results of the current investigation, the HR between Group B and Group D at various recording times was comparable in terms of vital indicators. When compared to either Group B or Group D, the heart rate in group (BD) significantly decreased from 15 minutes after intubation to 5 hours following extubation (P<0.001). At the various recording times, MAP was comparable between Group B and Group D. When compared to Group B and Group D, there was a significant decrease in MAP in Group BD at the times of packing or infiltration, before extubation, 10 minutes after extubation, 20 minutes after extubation, 40 minutes after extubation, and 1 hour after extubation (P<0.001). The studied groups were equivalent with regard to SPO2 at various recording times.

However, in the study of **Ahmed *et al*. [18]** between January and December of this year, 60 children between the ages of 5 and 12 underwent tonsillectomy surgeries at the facilities affiliated with Al-Azhar University. They were divided into 3 equal groups at random: After surgery, Groups A and B received an application of gauze soaked in 10% lidocaine to the tonsillar bed, whereas Groups C received an intravenous infusion of a 10 mg/ml paracetamol solution. Preoperative single-point superficial infiltration of the glosso-tonsillar sulcus with bupivacaine at a dose of 1 mg/kg (0.5%) was performed in Group C. Heart rate, respiratory rate, and oxygen saturation didn't differ in a way that was statistically significant (P>0.05), respectively. According to our findings, Group BD experienced a considerably lower pain score than the other groups at various recording times (P<0.001), whereas Groups B and D experienced a non-significant difference (P>0.05).

Our findings concurred with **Kilinc's [19]** study, which found no statistically significant difference in pain scores between the bupivacaine-only group and the control group until the seventh postoperative day. In terms of its capacity to lessen early and late post-tonsillectomy discomfort, they found that peritonsillary infiltration with dexamethasone-bupivacaine was superior to bupivacaine alone and the control group. Early pain relief was anticipated as a result of the local anesthetic injection to the surgical region. However, the results for the long-term pain reduction may be due to the early pain alleviation that improves early and sufficient oral intake for the young patients. The corticosteroid's anti-inflammatory actions at the surgical site, which deliver long-lasting pain relief, could represent another underlying mechanism. While, in the study of **Khan [16]** at 24 hours, Group A's mean post-tonsillectomy VAS was 6.73 (SD 1.44), while Group B's was 5.93 (SD 1.26) (P=0.025).

Mean post-tonsillectomy VAS was 5.60 (SD 1.25) in Group A and 4.37 (SD 1.03) in Group B at 48 hours (P<0.001). On the seventh day following tonsillectomy, Mean VAS was 3.27 (SD 0.74) in Group A and 2.30 (SD 0.79 SD) in Group B (P<0.001). Furthermore, **Hosseini [20]** demonstrated that the bupivacaine group's postoperative pain was greatly reduced 240 and 360 minutes after surgery.

The current study's findings showed that Groups B and BD had considerably longer waiting times (P-value <0.001) before their initial requests for analgesia than Group D, and Group BD had a longer waiting time (P<0.001) before their first requests than Group B. The period of first oral intake is significantly shorter in Groups B and BD compared to Group D (P<0.001). Moreover, Groups B and BD show much less overall analgesia compared to Group D (P<0.001).

Ju *et al*. [21] finding that total fentanyl intake was considerably lower in Group RD than Group R supported our findings [50.9 (SD 9.3) vs. 103.9 (SD 11.5) g, P<0.001]. Group RD required considerably less time to complete the first oral intake and the first water request [40 min (Range 27-64) vs. 64 min (Range 43-89); P<0.001] and [54 min (Range 40-91) vs. 85 min (Range 67-127); P<0.001]. The rate of oral consumption increased significantly.

CONCLUSION

Topical bupivacaine plus intravenous dexamethasone is more effective for controlling post-operative adenotonsillectomy pain than topical bupivacaine or peritonsillar dexamethasone infiltration.

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