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Comparison of Postoperative Pain and Duration of Analgesia Between Peritonsillar Preincisional Infiltrations with Bupivacaine versus Bupivacaine-dexamethasone in Children undergoing Tonsillectomy

Bashir Garba Aljannare¹, Hamza Aliyu² and Abdullahi Khalid³

¹Department of Anaesthesiology and Intensive Care, Usmanu Danfodiyo University Teaching Hospital, Sokoto State, Nigeria.

² Department of Anaesthesia, Federal Teaching Hospital Katsina, Katsina State, Nigeria.

³Department of Surgery, TETFU Centre of Excellence in Urology and Nephrology, Usmanu Danfodiyo University Teaching Hospital, Sokoto State, Nigeria.

Corresponding author:

Bashir Garba Aljannare

Department of Anaesthesiology and Intensive Care,
Usmanu Danfodiyo University Teaching Hospital,
Sokoto State, Nigeria.

Email: bashiraljannare@yahoo.com

GSM: +2348032311354

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Website

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Introduction

Tonsillectomy is defined as the surgical removal of the palatine tonsil. It involves dissecting the peritonsillar space between the tonsillar capsule and the muscular wall.¹ It is carried out as an inpatient procedure, and the main concern of the operation is the risk of post-tonsillectomy bleeding and postoperative pain.² A study from Tanzania on the survey of tonsillectomy care patterns reported 34.6% of the otorhinolaryngologists to have never performed day-case tonsillectomy, while 65.4% sometimes performed day-case tonsillectomy.³ In Nigeria, patients are sometimes operated on as day cases after careful selection and evaluation, while other surgeons perform the tonsillectomy procedure as an inpatient.⁴ Managing post-tonsillectomy pain remains a challenge for both the Anaesthetist and the Surgeon. This is because inadequate pain management often leads to exaggerated sympathetic activity, which increases heart rate, blood pressure, cardiac output, and cardiac work. It may lead to delays in discharge from the hospital, nausea and vomiting, dehydration, unplanned readmission, and infection.^{5,6} Different techniques have been developed for use during and after the surgery to reduce post-tonsillectomy pain, these include: injection of the tonsillar region with bupivacaine with or without steroids, bupivacaine with epinephrine. Other methods are lidocaine tonsillar injection, use of intravenous opioids, NSAIDs, ketamine tonsillar injections, and topical application of bupivacaine with or without adjuncts, among others.^{7,8} These techniques have shown positive outcomes in a randomised trial.^{7,8} Opioids, steroids, non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and the surface application of local anaesthetics are traditionally used to treat post-tonsillectomy pain over time. However, opioids can

Abstract

Background: Tonsillectomy is one of the most common surgeries performed in pediatric Otorhinolaryngology. The main morbidity of the surgery is postoperative pain, which is treated by systemic analgesics. This study aims to compare the analgesic effects of bupivacaine and bupivacaine-dexamethasone for peritonsillar infiltration before surgical incision during tonsillectomy, as postoperative analgesia.

Methods: Sixty-four patients scheduled for tonsillectomy who met the eligibility criteria were recruited into the study and were randomly allocated into groups A and B. Group A received bupivacaine 15 mg (3 ml) plus 3 ml of normal saline to make up to 6 ml. Group B – received bupivacaine 15 mg (3 ml) plus 4 mg (1 ml) dexamethasone plus 2 ml of normal saline to make up to 6 ml. The postoperative visual analogue score (VAS) and the duration of analgesia were assessed.

Results: The data were analysed using SPSS version 25.0. The VAS and analgesia duration between the two groups were compared using the unpaired Student's t-test, whereas quantitative variables were compared using the chi-square test. The postoperative VAS was significantly lower in group A than in group B at 0, 2nd, 4th, 8th, 12th, and 24th hours ($p < 0.001$). The duration of analgesia was longer in group A (855 ± 83.4 minutes) than in group B (502.5 ± 348.1 minutes). This difference was statistically significant ($p < 0.001$).

Conclusion: Peritonsillar injection of 15 mg bupivacaine plus 4 mg dexamethasone before tonsillectomy provides improved pain relief and prolongs analgesia duration after tonsillectomy in children.

Keywords: Postoperative Pain, Duration of Analgesia, Peritonsillar, Infiltrations, Bupivacaine, Dexamethasone, Tonsillectomy.

cause adverse effects such as sedation, nausea and vomiting, pruritus, urinary retention, respiratory depression, and overdose.⁹ Research conducted at Usmanu Danfodio University Teaching Hospital in Sokoto, Nigeria, demonstrated a favourable result following topical application of bupivacaine in post-tonsillectomy pain.¹⁰ However, the effect was for two hours postoperatively after the topical application of the local anaesthetics.¹⁰ The duration of action of the local anaesthetics used limited the effectiveness of the intervention. Hence, the purpose of this study is to determine whether the addition of dexamethasone to bupivacaine during peritonsillar infiltration provides better and longer postoperative analgesia after tonsillectomy. Although similar studies have been published in Asia and Europe (11 and 12), no African study has evaluated peri-incisional peritonsillar infiltration of a bupivacaine-dexamethasone mixture versus bupivacaine alone; hence, this is the justification for this study.

Materials and Methods

The study was a double-blinded, randomised controlled trial for children scheduled for elective tonsillectomy in Usmanu Danfodiyo University Teaching Hospital. It was conducted within seven (7) months, from August 2023 to February 2024. After obtaining approval from the Ethics and Research Committee of the Hospital (NHERC/30/012/2019).

All ASA I and II patients aged 7 to 15 years scheduled for elective tonsillectomy and who consented to participate in the study were included. The following were excluded from the



study: patients with proven or suspected allergy to local anaesthetics, and patients with a peritonsillar abscess or a suspected tonsillar tumour. Other patients were those who weighed less than 20 kg, patients with severe systemic disease and patients who were unable to understand the Visual Analogue Score (VAS)

All patients who met the inclusion criteria were randomly assigned to two groups, A and B, each with 32 patients, using the sealed-envelope technique. It is a method of allocation concealment in which group assignments are placed in opaque, sealed envelopes that are opened only after a participant is enrolled in the study. A research assistant who was not involved in the administration of the anaesthesia, pain assessment, or data analysis prepared 64 sealed opaque envelopes. These envelopes were labelled serially from 1 to 64. Each envelope contained either the letter "A" or "B, and all patients had an equal chance of being placed in either the intervention or control group. A second research assistant prepared the drug solutions corresponding to the letter assigned to the envelope in a sterile manner. The drug preparation was done in the theatre to ensure asepsis. The envelope was sealed again and attached to the patient's folder. The process was repeated for each enrolled patient until the end of the study. The researcher and the patient were blinded to the type of solution it contained. Hence, no person involved in the preoperative, intraoperative, or postoperative care of the patient had any knowledge of the drug given to the patient. This ensures that each participant has an equal opportunity and avoids bias. Group A (control) received bupivacaine 15 mg (3 ml) plus 3 ml of normal saline, for a total of 6 ml. Group B (study) received bupivacaine 15 mg (3 ml), 4 mg (1 ml) dexamethasone, and 2 ml of normal saline, for a total of 6 ml.

All patients were visited and evaluated a day before the surgery; the study protocol and objectives were explained to parents and guardians. Written informed consent was obtained. Patients were instructed to fast according to fasting guidelines and were educated on the use of the Visual Analogue Scale (VAS).

Routine laboratory investigations, including full blood count, clotting profile, serum electrolytes, electrocardiogram (ECG), and chest x-ray, were reviewed.

The following were used during the procedure: Bupivacaine 0.5% (Duracaine, plain injection, 20 ml), Sterile 5 ml syringes and 10 ml syringes, Injection dexamethasone (Philodexa) 4 mg/ml, Normal saline: 0.9%, Sterile gloves and Multi-parameter patient monitor, Dash 4000 (SAKOMED, Laguna Nguel, USA), non-invasive blood pressure, pulse oximetry (CAS M. California, USA), ECG, and end-tidal carbon dioxide concentration.

The anaesthetic machine was checked, anaesthetics and resuscitative drugs were drawn and labelled, intravenous access with an appropriate size cannula for the patient (18–22 G) was established, monitoring devices were attached, and basic vital signs were taken. The baseline blood pressure, pulse rate, oxygen saturation, respiratory rate, temperature, and pain were recorded. All patients received glycopyrrolate 0.005 mg/kg and dexamethasone 0.15 mg/kg intravenously 30 minutes before induction of anaesthesia. General anaesthesia induced with intravenous propofol 2.5 mg/kg, fentanyl 1 µg/kg, and intravenous suxamethonium 1.5 mg/kg was used to facilitate orotracheal intubation using an appropriate-size armoured endotracheal tube (ETT). The correct tube placement was confirmed by capnography and a chest auscultation. The ETT was firmly secured to the midline with adhesive tape. Anaesthesia was maintained with isoflurane at 1–1.5 volume per cent in 50%

oxygen. The patients were mechanically ventilated using volume-controlled ventilation with a ventilatory rate of 12–16 breaths per minute, an inspiratory–expiratory ratio of 1: 2, peak inspiratory pressure of 16–20 mmHg, and a tidal volume of 7–10 ml/kg adjusted to maintain end-tidal carbon dioxide (ETCO₂) between 35 and 45 mmHg with an oxygen flow rate of 3 l/min using a closed-circuit system. Muscle relaxation was maintained with pancuronium at 0.1 mg/kg, and 0.5 µg/kg of fentanyl was used for intraoperative analgesia. Intravenous fluid was given as per individual requirements, using 4 ml/kg for the first 10 kg, 2 ml/kg for the second 10 kg, and 1 ml/kg for the remaining 10 kg of body weight as hourly maintenance.

Before surgical incision, the peritonsillar region was superficially infiltrated with the drug solutions according to the research methodology by the researcher at two different points, at the superior and inferior poles, with a total volume of 3 ml. Ten (10) ml syringes with a 23G needle were used. After the infiltration of drugs, a duration of five minutes was allowed before the surgical incision. Oxygen saturation, pulse rate, blood pressure, ETCO₂, and airway pressure were continuously monitored with pulse oximetry, non-invasive automated blood pressure, and capnography, respectively.

At the end of the procedure, all patients were extubated fully awake with adequate respiratory function, and oxygen was administered via face mask for 3–5 minutes and then turned off. The patients were transported to the post-anaesthesia care unit (PACU) for continued care and monitoring of their vital signs, including oxygen saturation, blood pressure, and the Glasgow Coma Scale (GCS), for 1 hour prior to the VAS assessment.

At the end of 1 hour in the PACU, the VAS was assessed at 0 hours and subsequently repeated at 2, 4, 8, 12, and 24 hours in the ward. The duration of analgesia—the time between the infiltration and the time at which the VAS \geq 4 or the patient requests analgesia—was recorded. A rescue systemic analgesia, intravenous acetaminophen at a dose of 20 mg/kg, was given to those patients (both groups) with a VAS of \geq 4. The postoperative visual analogue pain score (VAS) after recovery from anaesthesia, at 0, and subsequently at 2, 4, 8, 12, and 24 hours was recorded. The duration of analgesia: This is defined as the time between the infiltration of the study drugs and the time to request the first analgesic or a recorded VAS of \geq 4, which was assessed by the researcher after recovery (0 hours), 2, 4, 8, 12, and 24 hours in the postoperative period.

The data were analysed using SPSS version 25.0 (IBM) and presented in relevant tables and figures. Statistical tests of association were performed at a 95% confidence level. Parametric data were summarised as mean (SD) and proportional data as frequency. Comparison of the VAS and analgesia duration between the two groups was performed using the unpaired Student's t-test, while quantitative variables were compared using the chi-square test. The null hypothesis was tested by calculating the p-value. A p-value of less than 0.05 was taken as significant.

Results

Sixty-four patients scheduled for tonsillectomy who met the eligibility criteria were recruited into the study and were randomly allocated into groups A and B. The missing data were excluded from the study. There was no statistically significant difference in age, sex, ASA physical status, or weight among these patients, as shown in Table I.

Table I. Comparison of demographic profile

| Variables | GROUP A | GROUP B | p-value |
|-----------------------|------------|------------|------------------------|
| Age (years) | | | |
| Mean (\pm SD) | 8.8 (1.6) | 8.6 (1.5) | 0.499 |
| Sex (%) | | | |
| Male | 20 (62.5) | 22 (68.8) | 0.168 (Fisher's exact) |
| Female | 12 (37.5) | 10 (31.3) | |
| ASA status (%) | | | |
| I | 25 (78.1) | 24 (75.0) | 0.805 (Fisher's exact) |
| II | 7 (21.9) | 8 (25.0) | |
| Weight (kg) | | | |
| Mean (\pm SD) | 25.7 (4.9) | 26.4 (3.5) | 0.269 |

$P > 0.05$, the difference is not statistically significant.

Table II compares the mean VAS for the two groups at 0, 2, 4, 8, 12, and 24 hours postoperatively. At 0 hours, the VAS for group A was 2.3 (\pm 0.2), while for group B it was 1.6 (\pm 0.4), $p < 0.001$. The difference was statistically significant. At the 2nd hour, group A has a VAS of 2.5 (\pm 0.2), while group B has 1.6 (\pm 0.4), $p < 0.001$. At the 4th hour, group A has 3.2 (\pm 0.6), while group B has 2.1 (\pm 0.5), $p < 0.001$. At the 8th hour, group A has 3.9 (\pm 0.6), while group B has 2.7 (\pm 0.6), $p < 0.001$. At the 12th hour, group A had a VAS score of 4.4 (\pm 0.4), as compared to group B's score of 3.5 (\pm 0.9), $p < 0.001$, and at the 24th hour, the VAS score was higher for group A, 4.9 (\pm 0.3), compared to the VAS score of 4.4 (\pm 0.8) for group B, $p < 0.001$. All these differences were statistically significant.

Table II. Postoperative 24-hour pain score (visual analogue score)

| Variables | GROUP A | GROUP B | p-value |
|-----------|------------------|------------------|---------------------------|
| | Mean(\pm SD) | Mean(\pm SD) | unpaired Student's t-test |
| VAS 0hr | 2.3 (\pm 0.2) | 1.6 (\pm 0.4) | <0.001 |
| VAS 2hr | 2.5 (\pm 0.2) | 1.6 (\pm 0.4) | <0.001 |
| VAS 4hr | 3.2 (\pm 0.6) | 2.1 (\pm 0.5) | <0.001 |
| VAS 8hr | 3.9 (\pm 0.6) | 2.7 (\pm 0.6) | <0.001 |
| VAS 12hr | 4.4 (\pm 0.4) | 3.5 (\pm 0.9) | <0.001 |
| VAS 24hr | 4.9 (\pm 0.3) | 4.4 (\pm 0.8) | <0.001 |

$P < 0.05$ indicates a statistically significant difference.

Table III compares the duration of analgesia between the two groups; group A has 502.5 \pm 348.1 minutes (8.38 \pm 5.80 hours), while group B has 855 \pm 83.4 minutes (14.25 \pm 1.39 hours). The difference was statistically significant ($p < 0.001$). The time to first analgesic request was compared; group A had 592 \pm 200.1 minutes (9.87 \pm 3.34 hours), while group B had 880 \pm 359.0 minutes (14.67 \pm 5.98 hours). The difference was statistically significant ($p = 0.002$). The total analgesic consumption was also compared between the two groups; group A had 780 (\pm 380.2) mg, while group B had 455 (\pm 513.9) mg. The difference was statistically significant ($p = 0.027$).

Table III. Duration of analgesia, time to first analgesic request, cumulative dose of acetaminophen and time to first oral intake

| Variables | GROUP A | GROUP B | p-value |
|------------|-----------------|-----------------|---------------------------|
| | Mean(\pm SD) | Mean(\pm SD) | unpaired Student's t-test |
| DOA (mins) | 502.5 (348.1) | 855 (83.4) | <0.001 |
| TFA (mins) | 592 (200.1) | 880 (359.0) | 0.002 |
| CDA (mg) | 780 (380.2) | 455 (513.9) | 0.027 |
| TFO (mins) | 256.9 (34.9) | 215 (45.4) | <0.001 |

Key: DOA = Duration of analgesia in minutes, TFA = Time to first dose of acetaminophen administration, CDA = Cumulative dose of acetaminophen, TFO = Time to first oral intake

$P < 0.05$ indicates a statistically significant difference.



Discussion

The study demonstrated a significant reduction in pain scores (VAS) in patients who received 0.25% bupivacaine plus 4 mg dexamethasone infiltration at the peritonsillar bed before tonsillectomy, compared with the control group who received 0.25% bupivacaine alone.

The result of this study, the first of its kind in African patients, revealed that postoperative pain intensity was significantly lower in the bupivacaine plus dexamethasone group than in the bupivacaine alone group at all time points studied (0 to 24 hours). These findings were consistent with the results of the Ju et al.¹³ study of ropivacaine with dexamethasone in 200 children undergoing tonsillectomy. They found that combining 0.2% ropivacaine with dexamethasone for infiltration resulted in superior analgesia in children after tonsillectomy and adenoidectomy. Despite the superior pain control in the dexamethasone group in the study by Ju et al.¹³, they did not account for pain assessment and treatment during the first 3 hours postoperatively, unlike our study. Another study by Moghadam et al.¹⁴ found no significant difference at 6 and 12 hours after surgery between the dexamethasone and bupivacaine-only groups. However, at 24 hours after surgery, the difference was significant. It can be seen that there was a 6-hour gap between the surgery and the commencement of the pain assessment in their study. Similarly, Honarmand et al.¹⁵ demonstrated longer (24 hours) effective pain control in patients who received peritonsillar infiltration with tramadol 2 mg/kg and bupivacaine 1 mg/kg with adrenaline, compared with tramadol or bupivacaine alone. Despite favourable outcomes, in their study, the choice of rectal acetaminophen for rescue analgesia may interfere with the pain assessment because a grown-up child may not easily accept that method of intervention and thus underreport their pain. Abrão et al.¹⁶ said, "It is a good practice nowadays to infiltrate local anaesthetics along the incision to prevent postoperative pain."

Duration of analgesia: Our study demonstrated a significant difference in analgesia duration between the study and control groups. Kilinc et al.¹² findings which is supported by Mansour et

al.¹⁷ concurred in their trial where they found significant prolongation of analgesia time in the dexamethasone group with our finding of longer duration of analgesia in their study and they attributed the pain relief at an early period to the local anaesthetic infiltration into the surgical region, while the results for the late-term pain relief mechanism could be the anti-inflammatory effect of the corticosteroid in the surgical region leading to late-term pain relief. Similarly, Ahmed et al.¹¹ conducted a comparative study of bupivacaine infiltration, topical lidocaine, and intravenous paracetamol for post-tonsillectomy pain. They found a statistically significant difference in pain scores between the three groups after 12, 18, and 24 hours, with the bupivacaine infiltration group having the lowest pain scores.

Conclusion

This study has shown that preincisional infiltration of bupivacaine and dexamethasone is safe and effective for prolonged post-tonsillectomy pain control in children.

Limitations

1. The patients were not followed beyond 24 hours after discharge to observe the longer duration of analgesia.
2. There is potential for suboptimal allocation concealment, which may lead to centre-specific bias.
3. There is no prior sample size calculation, and this may result in potential under- or over-powering.
4. The fixed dosing across a heterogeneous age and weight range may affect the efficacy and safety.

Conflict of Interest: There is no conflict of interest

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