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Clinical efficacy of local infiltration of lidocaine and tranexamic acid application in tonsillar region on postoperative pain and bleeding during tonsillectomy: prospective, randomized, double-blind controlled study

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Abstract

Background Anesthetic techniques are designed to minimize intraoperative surgical bed bleeding which is a major problem that may interfere with precision, surgery duration, or postoperative wound healing. The main reason for reoperation and/or mortality in children who have had tonsillectomies is post-tonsillectomy hemorrhage. We evaluate the local application effect of tranexamic acid and lidocaine local infiltration in the tonsillar bed during tonsillectomy surgery on postoperative analgesia and bleeding.

Results FLACC scores showed a statistically significant reduction in the first 24 h in group T ($P < 0.05$). Post-tonsillectomy hemorrhage was significantly minimized in group T. No complications were recorded following the local application of tranexamic acid and local lidocaine infiltration inside the tonsil bed.

Conclusions Local infiltration of lidocaine provides adequate postoperative analgesia, and tranexamic acid application during tonsillectomy surgery minimizes postoperative bleeding and shortens surgery duration.

Trial registration This study was preregistered with the Clinical Trials Registry (NCT05817474).

Keywords Tranexamic acid, Lidocaine infiltration, Tonsillectomy

Background

It is crucial to receive adequate perioperative analgesia during tonsillectomy operations since throat discomfort may limit swallowing, leading to an increased hazard of dehydration, infection, and subsequent bleeding, and can hinder a quick recovery and painless convalescence. This pain is at its utmost immediately following surgery and during the first 24 h (Ahmed and Omara 2019).

The most serious problems following a tonsillectomy operation include hemorrhage and respiratory obstruction from edema, whereas the most frequent complication in the initial postoperative phase is pain (Yücel and Özdoğan 2020).

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Preemptive analgesia, which reduces surgical pain, includes nonsteroidal anti-inflammatory drugs (NSAIDs), steroids, and opioids which have all been tested as preemptive analgesics (Debasish et al. 2018). A local anesthetic applied to the tonsillar region either by spray or local infiltration can efficiently diminish pain with minimal side effects in tonsillectomy operation (Ozmen and Ozmen 2011).

The main reason for reoperation and/or mortality in children who have had tonsillectomy is post-tonsillectomy hemorrhage (PTH). Two categories of PTH are well recognized: primary bleeding type within the first 24 h and secondary bleeding type (after 24 h). The secondary type represents most PTH cases, with an incidence reaching its peak between days 5 and 7 after surgery when a clot of fibrin breaks in the tonsillar region. PTH, in need of surgical intervention, remains an urgency that most anesthesiologists often encounter in clinical practice (Wall and Tay 2018).

In numerous surgical procedures, bleeding has been observed to be reduced by antifibrinolytic tranexamic acid (Relke et al. 2021). It has been demonstrated that tranexamic acid could decrease the loss of blood during tonsillectomy operations but had no impact on the prevention of PTH in tonsillectomy patients, although tranexamic acid was found to reduce secondary PTH when administered in an emergency situation by nebulization to a 3-year-old patient (Schwarz et al. 2019) and used successfully in some studies. Further studies are needed to reach the easiest method and best dose of tranexamic acid combined with local lidocaine infiltration.

Aim of the work

We evaluate the effect of lidocaine local infiltration and application of tranexamic acid in the tonsillar bed during tonsillectomy surgery on postoperative analgesia and PTH.

Methods

After approval from the local ethics council (approval no. 00309/2022) and clinical trial registration (NCT05817474), eighty-two children between 4 and 12 years old of both sexes were scheduled for a tonsillectomy between March 2022 and December 2022. Informed written consent approval was obtained from the parents or the legal guardian of the child who participated in this research and randomly split into two groups:

1. *Group T*: Received local infiltration of lidocaine (2%) 2 ml after induction of general anesthesia and before starting the surgery, and soaked two cotton balls with tranexamic acid 10 mg/kg (2 ml), one in each tonsillar bed at the end of surgery for 3 min and removed before extubation.
2. *Group N (control group)*: Two milliliters of normal saline 0.9% was locally infiltrated after general anesthesia and before starting the surgery, and soaked 2 cotton balls of normal saline (2 ml), one in each tonsillar bed at the end of the surgery for 3 min and removed before extubation.

The primary outcome was post-tonsillectomy analgesia, while *secondary outcomes* included post-tonsillectomy bleeding, anesthesia, operative time, paracetamol use, pain scores, and occurrence of adverse effects.

The study involved 82 children between the ages of 4 to 12 years who were randomly assigned to either the intervention group or the control group. The intervention group received lidocaine local infiltration and tranexamic acid application, while the control group received normal saline infiltration. The abstract mentions that post-tonsillectomy hemorrhage was minimized in the intervention group, and no complications were recorded following the local application of tranexamic acid and lidocaine.

Inclusion criteria

Male or female children between 4 and 12 years old, and their American Society of Anesthesiology (ASA) (I or II), were planned for an elective tonsillectomy.

Exclusion criteria

These are patients with severe obstructive sleep apnea (OSA), patient has coagulation disorders such as hemophilia, those suspected of having an allergy to the drug being administered, and those undergoing concurrent surgery such as an adenoidectomy.

Anesthetic technique

Preoperative assessment in the form of history taking, clinical examinations, and blood tests is performed preoperatively for all patients. When the patients reach the operating theater, standard monitoring is applied by a pulse oximeter, noninvasive arterial blood pressure, and electrocardiogram (ECG). Inhalational anesthesia induction with titrated sevoflurane through a face mask. After insertion of venous access, fentanyl 1 µg/kg and atracurium (0.5 mg/kg) were injected IV. The oral endotracheal tube was inserted and fixed centrally down, and then anesthesia was maintained by sevoflurane (Mac 2.5%) with mechanical ventilation and paracetamol 15 mg/kg infusion.

Forty-one children lidocaine (2%) 2 ml Infiltration in each Tonsillar bed, by (23 Gauge X 1. 1/4 inches), (Fig. 1) and 2 soaked cotton balls with tranexamic acid in each tonsillar bed at the end of the surgery (Fig. 2).

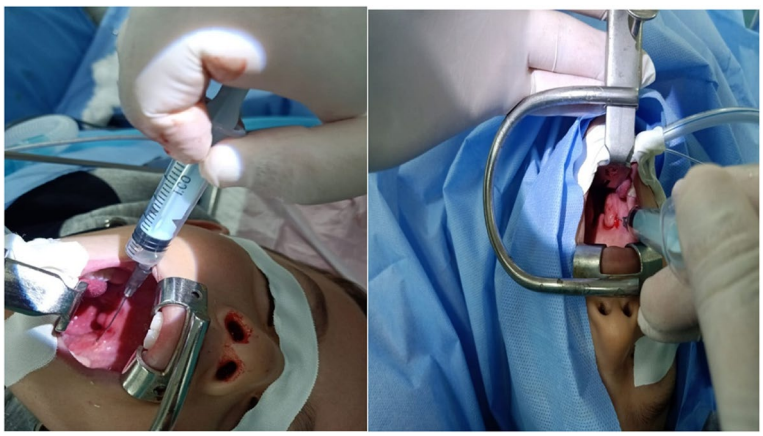

Fig. 1 During lidocaine 2% injection in tonsillar beds

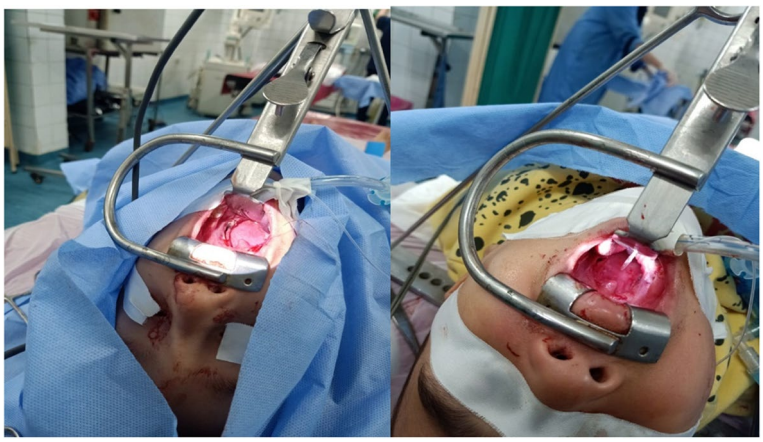

Fig. 2 Examination of tonsillar bed after tonsillectomy

The other 41 children received 2 ml of normal saline infiltration in each tonsillar bed by 23 Gauge × 1.1/4 inch, and sevoflurane was discontinued and reversed muscle relaxation. Before awake extubation and transferred to the recovery room.

The Face, Legs, Activity, Cry, and Consolability (FLACC) pain score has been found reasonable interrater reliability and validity and recommended for pain assessment in children. Each of the five categories (F), (L), (A), (C), and (C) is scored from 0 to 2, which results in a total score between 0 and 10. Pain scores were categorized as mild (scores 0–3), moderate (4–6), and severe (7–10) (von Baeyer et al., 2007).

Time to the first requirement for supplemental painkillers was recorded. Paracetamol (IV) 15 mg/kg was given if the pain scores ≥ 4, and paracetamol dose (g /24 h) was recorded. Amount of tonsillectomy bleeding postoperative assessed by visual method.

Sample size calculation methods

Using a clinical sample size calculator for an intervention study; with 0.05 alpha error and power of the study 0.0.80, CI of 95%, enrolment ratio of 2. According to the literature, there was a significant difference in the need for cauterization in the operating theater between those treated with tranexamic acid and those who were not (22.2% in the group, 53.6% in the non-tranexamic group) (Spencer et al. 2022). The sample size was calculated to compare the clinical efficacy of lidocaine local infiltration and topical application of tranexamic acid in the tonsillar region during tonsillectomy operation on postoperative pain and bleeding. The least required number of patients is 74 patients including a 10% increase to cover the follow-up period (37 in each subgroup).

Method of randomization

Sampling technique

A convenient sample of patients with the inclusion and exclusion criteria was sampled and enrolled in

the research. Cases are to be randomly allocated into arms of the study using the concealed random allocation method until reaching total sample size calculated. Anesthetists, otorhinolaryngology surgeons, nurses, and all other researchers were unaware of each subject's randomization.

The attendant anesthetists encoded randomly the lidocaine and tranexamic acid with the patient number and kept the clue until it matched with the results; the surgeon injected the syringe and put the cotton balls given to him by the attendant anesthetist. Post-operative, another anesthetist follows up with the patients, collects the data, and then sends it back to the attendant anesthetist. Neither the surgeon nor the follow-up anesthetist knows the clue codes or the type of medications given. The medications were labeled as number one to lidocaine and tranexamic acid and number two to saline and randomly allocated to closed envelopes with patients' numbers.

Statistical analysis

The statistical analysis was carried out using Statistical Package for Social Sciences (SPSS) version 17 Inc. (Chicago, IL, USA). To express the data, means with standard deviations (mean ± SD) and frequencies were used. To compare both groups, a neutral *T*-test was applied. To check the differences for groups, the Fisher exact examination and chi-square calculation were employed. The result was deemed significant if the *P* was < 0.05.

Results

According to the data flow diagram for CONSORT, 94 cases were assessed for eligibility, a distributed 82 patients equally among the two groups were kept secret inside sealed envelopes, and 12 patients were removed by exclusion criteria as shown in Fig. 3.

Demographic features of patient groups' age, weight, sex, and ASA levels were comparable to the control group ($P > 0.05$) as shown in Table 1.

On comparing hemodynamics parameters between both groups, there was no significant difference ($P > 0.05$) as illustrated in Table 2.

Operative time, anesthesia time, and paracetamol (g/24 h) were lower in group T, the time to request analgesia was longer, and the number of children receiving

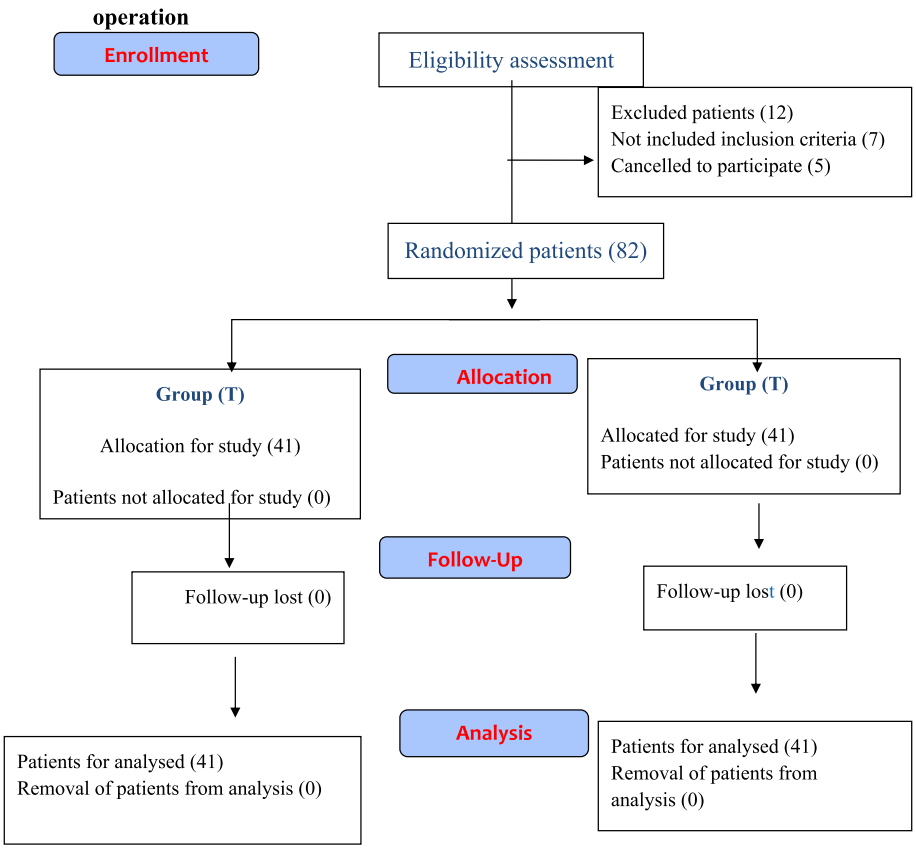

Fig. 3 CONSORT chart of research

Table 1 Basic data from research groups

Groups Parameters	Group (T) ($n=41$)	Group (N) ($n=41$)	*p*-value
Sex (male (*n*) (%): female (*n*) (%)	23 (56.1%): 18 (43.9%)	25(61%): 16(39%)	0.82
Age (year) (mean ± SD)	7.71 ± 2.59	7.33 ± 2.13	0.77
Weight (kg) (mean ± SD)	18.31 ± 1.59	15.71 ± 2.62	0.68
ASA I (*n*) (%): II (*n*) (%)	36 (87.8%): 5 (12.5%)	34 (85%): 6 (15%)	0.79

Group T, received lidocaine (2%) 2 ml and tranexamic acid 1.5 ml. Group N, received 3.5 ml of normal saline

Table 2 Comparisons of hemodynamic parameters in research groups

Groups Parameters	Group (T) ($n=41$)	Group (N) ($n=41$)	*p*-value
Heart rate base line	95.7 ± 1.6	90.6 ± 2.8	0.67
Heart rate after 10 min	99.5 ± 3.4	98.2 ± 2.7	0.78
Heart rate after 20 min	102.6 ± 2.9	99.3 ± 5.5	0.66
Heart rate after 30 min	97.7 ± 5.2	105.6 ± 2.8	0.67
Heart rate after 40 min	99.5 ± 3.4	98.2 ± 3.7	0.78
Heart rate at the end	107.6 ± 1.9	109.3 ± 2.5	0.66

Group T, received lidocaine (2%) 2 ml and tranexamic acid 1.5 ml. Group N, received 3.5 ml of normal saline

analgesics in 24 h was reduced in group T ($P<0.05$) as presented in Table 3.

The amount of tonsillectomy bleeding postoperative (assessed by the number of soaked cotton balls) in both groups was lower ($P<0.05$), as displayed in Table 4.

Regarding the postoperative comparison of pain scores in each group using (the FLACC) pain scale, there was a statistically significant reduction in group T (Table 5).

No complications were recorded in either group as obstruction of the upper airway, nerve palsy, and vocal cord paralysis.

Discussion

Many approaches were attempted trying to manage the postoperative pain after tonsillectomy but inconsistent results. Tonsillectomy postoperative throat discomfort can be reduced by the glossopharyngeal nerve block, which also reduces painkiller use. Successful analgesia can improve outcomes through reducing morbidity with subsequent better parent satisfaction (Wang and coworkers 2016).

A randomized double-blinded trial found that preincisional local anesthetic injection considerably reduced post-tonsillectomy throat discomfort and aided in a quicker return to normal activities in children who were scheduled for tonsillectomy. Lidocaine 2% infiltration showed a longer duration of action in reducing postoperative pain, compared to lidocaine 10% spray (Zhang et al. 2014). This coincides with our study, as on assessing postoperative pain there was a statistically significant drop in FLACC scores in group T.

In this current study, no case needed reoperation in group T, whereas as regards postoperative bleeding in the control group (N), two cases among 41 patients suffered from severe bleeding on the first day and needed

Table 3 Operative time (min), anesthesia time (min), postoperative paracetamol consumption (g/24 h), time to request of analgesic (h), and no. of children received analgesics in 24 h of the studied groups

Groups Parameters	Group (T) ($n=41$)	Group (N) ($n=41$)	*p*-value
Operative time (min.) (mean ± SD)	42.65 ± 4.25	47.50 ± 5.87	0.046*
Anesthesia time (min) (mean ± SD)	48.65 ± 4.85	50.65 ± 7.85	0.025*
Paracetamol (g/24 h) (mean ± SD)	0.55 ± 0.16	1.05 ± 0.24	0.032*
Time to needed analgesic (h) (mean ± SD)	3.67 ± 0.78	1.5 ± 0.65	0.027*
Number of children received analgesics in 24 h	15 (36.5%)	29 (70.1%)	0.034*

Group T, received lidocaine (2%) 2 ml and tranexamic acid 1.5 ml. Group N, received 3.5 ml of normal saline

* Statistically significant at *p*-value ≤ 0.05

Table 4 Amount of postoperative tonsillectomy bleeding in both groups

Groups Parameters	Group (T) ($n=41$)	Group (N) ($n=41$)	*p*-value
Mild postoperative bleeding (no need for reoperation)	3 (7.3%)	8 (19.5%)	0.037*
Severe postoperative bleeding (need for reoperation)	0 (0%)	3 (7.3%)	0.023*

Group T, received lidocaine (2%) 2 ml and tranexamic acid 1.5 ml. Group N, received 3.5 ml of normal saline

* Statistically significant at *p*-value ≤ 0.05

Table 5 Comparison of pain scores postoperatively in each group using FLACC score

Groups Parameters	Group (T) ($n=41$)	Group (N) ($n=41$)	*p*-value
2nd h	0 (0-1)	1 (0-1)	< 0.05*
4th h	1 (1-2)	2 (2-3)	< 0.05*
8th h	2 (1-2)	3 (2-3)	< 0.05*
12th h	3 (1-2)	4 (3-4)	< 0.05*
16th h	4 (2-4)	5 (4-5)	< 0.05*
18th h	4 (4-5)	5 (4-5)	< 0.05*
20th h	5 (4-5)	6 (5-6)	< 0.05*
24th h	5 (4-6)	6 (5-7)	0.75

Group T, received lidocaine (2%) 2 ml and tranexamic acid 1.5 ml. Group N, received 3.5 ml of normal saline. Data represented by IQR

* Statistically significant at *p*-value ≤ 0.05

reoperation, and 1 case on the 7th day suffered from severe bleeding and needed for reoperation ($P<0.05$).

Likewise, in a retrospective study, Erwin et al. (2021) found a statistically significant decline in the requisite for operation room cauterization for PTH in the patients who got nebulized tranexamic acid (29%) compared to those who did not take tranexamic acid (73%) ($P=0.005$). Moreover, George and colleagues (2011) revealed a statistically significant decrease in intraoperative blood loss when tranexamic acid was given as a single dose with induction of anesthesia. Nevertheless, the risk of bleeding was not abolished.

Similarly, Spencer and coworkers (2022) reported that PTH was significantly low in the study group who received tranexamic acid ($p=0.03$). In addition, Robb and Thorning (2014) suggested that a potentially beneficial outcome could be obtained when tranexamic acid was used prophylactically for tonsillectomy surgery, helping to reduce PTH and enhance the discharge rate from the hospital as day-case surgery.

Furthermore, Santosh and associates (2016) performed a randomized controlled trial on 50 participants, which documented a statistically significant lessening in mean blood loss ($P<0.05$) once tranexamic acid was injected as one IV dose at induction.

In contrast, other studies did not provide benefit from tranexamic acid as regards intraoperative bleeding, as Brum et al. (2012) used a single 10 mg/kg intravenous (IV) tranexamic acid with induction of anesthesia ($P=0.18$).

The conflicting results could be attributed to different sample sizes, timing of drug administration, and methodology used between studies.

In support of the role of lidocaine local infiltration in analgesia and tranexamic acid in hemostasis in various fields other than tonsillectomy, topically applying tranexamic acid aids can be a useful supportive way to stop mild bleeding as the bloody ooze from oral wound (Zirk and colleagues 2018). Moreover, Couto et al. (2020) study found that tranexamic acid local infiltration with a local anesthetic before the facelift appears to reduce bleeding, surgical duration, and output from surgical drains.

In the current study, no complications were found from an infiltration of local anesthetics in each tonsillar area as upper airway obstruction, nerve palsy, or paralysis of the vocal cord. Meanwhile, Shlizerman and Ashkenazi (2005) reported a case of a 4-year patient who developed facial nerve paralysis after perioperative bupivacaine infiltration. That event was noted shortly after extubation and disappeared after 8 h; this was explained by the direct action of local anesthetic on the facial nerve. Thromboembolic events have not been reported in any study conducted on tranexamic acid application (Fuzi and coworkers 2021) and in our study.

Limitations

Limitations of the current study include the lack of comparison between local and intravenous injections of tranexamic acid and the short time of postoperative follow-up. Further longitudinal studies comparing different methods of administration are recommended.

Conclusions

Lidocaine local infiltration and tranexamic acid local application during tonsillectomy surgery shorten surgery duration, minimize postoperative bleeding, and provide adequate postoperative analgesia.

Abbreviations

ASA American Society of Anesthesiology
CBC Complete blood count
FLACC Face, Legs, Activity, Cry, and Consolability

PTH	Post-tonsillectomy hemorrhage
ECG	Electrocardiogram
OSA	Obstructive sleep apnea
SPO2	Oxygen saturation
SPSS	Statistical Package for Social Sciences

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Authors' contributions
MAAA conceived the study and share in its design. AMA and IMA coordinate data analysis. SHS drafted the manuscript. AMH undertook data collection, data capturing, and handling. All authors approved the final article.

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Availability of data and materials
The data of this article is available from the corresponding author.

Declarations

Ethics approval and consent to participate
This study was conducted after obtaining approval from Al-Azhar University of Scientific Research Ethical Committee with approval number 00309 March 2022. Informed written consent approval was obtained from the parents or the legal guardian of the child who participated in this research. This study was registered with *ClinicalTrials.gov identifier*: NCT05817474.

Consent for publication
We have taken informed consent for publication and the collection of patient information from the parents or the legal guardian of the child who participated in this research.

Competing interests
The authors declare that they have no competing interests.

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