Zagazig University Medical Journal
www.zumj.journals.ekb.eg
https://doi.org/10.21608/zumj.2024.272590.3194 Volume 30, Issue 1.4, June 2024, Supplement Issue
Manuscript ID ZUMJ-2402-3194 (R3)
DOI 10.21608/ZUMJ.2024.272590.3194
ORIGINAL ARTICLE

Impact of Use of Local Phenytoin on Postoperative Outcomes of Paediatric Tonsillectomy Patients

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Submit Date 28-02-2024
Revise Date 05-05-2024
Accept Date 2024-03-23

ABSTRACT

Background: In otolaryngology practice, pediatric tonsillectomy is one of the most often done surgeries. We aimed to assess the short-term results of tonsillectomy alone versus tonsillectomy with local phenytoin with regard to postoperative pain, analgesia, bleeding and appetite. **Methods:** The study included in all 107 paediatric tonsillectomy patients; seven patients were excluded due to incomplete follow up only 100 patients completed follow up (60% female, 40% male, with age of (4–11 years) randomly chosen for tonsillectomy alone (group1 or TA; n = 50) and tonsillectomy with local phenytoin use (TPHT group, n = 50). Patient characteristics were recorded such as age, sex, and postoperative visual analogue scale (VAS), pain scores (2 hours postoperatively and first 10 days), appetite scores (first 7 days), also analgesia requirement (first 10 days) with documentation of bleeding complications.

Results: From the third postoperative day, there was a noticeable decline in pain scores, which reached 0.0 ± 0.0.and on day 10 was 0.49± 0.79 in the TPHT and TA groups, respectively ($p < 0.001$ for each). comparing the TPHT group to the TA group, there were significant differences in pain and appetite scores from day 1 to day 10, as well as a decreased need for analgesia from day 1 to day 10. Additionally, there were few bleeding complications. **Conclusion:** The study of paediatric tonsillectomy patients proved effectiveness of local phenytoin use with tonsillectomy other than tonsillectomy without local phenytoin use**. Keywords:** Postoperative Pain, Tonsillectomy, Phenytoin, Bleeding, Paediatrics.

INTRODUCTION

In otolaryngology practice, paediatric tonsillectomy is one of the most often done surgeries. It is recommended for obstructive sleep apnea, ,recurrent tonsillitis, and sleep breathing disorders [1], [2],[3],[4]. Significant postoperative pain following a paediatric tonsillectomy has been reported for up to 14–21 days, along with a 2-4 percent chance of bleeding [5], [6], [7], [8], [9].

Since insufficient pain management has been linked to reduced oral intake, a higher risk of infection, and postoperative bleeding [10], [11], [12], having appropriate analgesic control is thought to be essential for a seamless recovery after a pediatric tonsillectomy [4], [11], [13].

Consequently, there is growing interest in otolaryngology for ways to manage bleeding and pain following tonsillectomy [11], [12], [14], [15]. Nevertheless, a range of approaches have been tried thus far to enhance management of post-tonsillectomy pain that includes surgical approaches (such as plasma field dissection, bipolar diathermy, and partial tonsillectomy) [16], injections of tonsillar bed with (ropivacaine, ketamine ,lidocaine, others) [18,19], usage of honey [20, 21], steroids [19], topical solutions like fibrin sealing [22] or fibrin glue can be used. There is still disagreement over the best course of action for managing pain after tonsillectomy patients, and no regimen has been found to be ideal [5], [12], [15], [21].

The anticonvulsant phenytoin is believed to facilitate healing of the wounds via a number of pathways, such as fibroblast proliferation, the creation of granulation tissue, antimicrobial action, and pain relief [23]. Shapiro conducted study in 1958 on the impact of oral phenytoin pre-treatment on periodontal disease patients' ability to repair surgically produced gingival lesions [23].

Its use in wound healing is motivated by its apparent stimulatory impact on connective tissue.

Various studies have now been carried out to evaluate effectiveness of topical phenytoin in treating different wounds, including decubitus ulcers , diabetic ulcers [24], and venous stasis ulcers, traumatic wounds and leprosy atrophic ulcers [27,28]. It is believed to facilitate wound healing via a number of methods [31], [32], [33], [34]. Its effectiveness has also been demonstrated to include pain relief through membrane stabilisation and antibacterial activity through both direct and indirect methods [24], [30].

Our study was aimed to assess the short-term results of tonsillectomy alone versus tonsillectomy with local phenytoin therapy with regard to postoperative pain, analgesia requirement, bleeding complications and appetite status.

METHODS

Technical design: This is a prospective comparative study including all patients underwent tonsillectomy with or without adenoidectomy, Zagazig university hospitals. The study included 107 paediatric tonsillectomy patients, seven patients were excluded due to incomplete follow up only 100 patients completed follow up (60% female, 40% male, with age of (4–11 years) have been randomly chosen for tonsillectomy alone (group1 or TA; n = 50) and tonsillectomy with local phenytoin therapy (TPHT group or GROUP 2, n = 50).

Patients complaining from haemorrhagic dyscrasias, or bleeding diathesis, any co-morbid diseases (like diabetes, epilepsy or heart disease), immunosuppressive treatment, acute respiratory tract infection, cleft palate, and poliomyelitis were excluded.

After a full declaration of the study's goals and procedures, each patient's legal guardian or parent provided written, informed consent and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University (Institutional Research Board IRB) (IRB No. 10217). The work has been carried out under The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Patient characteristics such as age, sex and postoperative visual analogue scale (VAS) pain scores (2 hours postoperatively and for first 10 days), appetite scores (first 7 days), and analgesia requirement (first 10 days) with documentation of bleeding complications in each group scoring for tonsil grade had been recorded.

Operative technique:

On the day of Tonsillectomy, all patients were admitted to the hospital, and those who did not experience any postoperative difficulties were released the following day following the operating surgeon's clinical review. Oral premedication was not administered to any patient. General anaesthesia was induced with (sevoflurane) and IV propofol. After that the tonsillectomy procedure was consistently completed by the same ENT surgeon and using the traditional cold dissection approach for every case.

Bipolar electrocautery was used for haemostasis. At the end of the surgery 0.5 ml of phenytoin (250 ml /5 mg ampoule) was taken and diluted in 500 ml saline .5 ml of this solution was injected (phenytoin 1%) was injected in both tonsillar beds in the TPHT group and the surgery was done without topical phenytoin in the other group. The resident who evaluated the patients' pain, appetite, also need for analgesia was not told about allocations of the group, nor were the patients. Topical phenytoin 1%was given in form of spray to the patients in TPHT group to be used once daily on the tonsillar bed by the parent himself for 5 days.

Post-operative management:

Following the surgery, all patients were given intravenous paracetamol (10 mg/kg every 6 hours as needed) with amoxicillin (30-40 mg/kg daily). all patients were given intravenous paracetamol (10 mg/kg) at the final moment of the procedure before being taken to the recovery area. Oral intake of food wasn't allowed for the first four hours following the procedure. First, at the two-hour postoperative mark, the pain levels were assessed; a second assessment was carried out at the twenty-four-hour mark. Prior to administering an analgesic, the pain scales were assessed. The pain assessment was then repeated every eight hours, with the average of the three assessments serving as the daily pain threshold. The Facial Pain Scale and The Visual Analogue Scale (VAS) were included to assess the pain levels for every patient. The questionnaires for pain assessment were passed along with the patients and/or their guardians. The Facial Pain Scale have been used for children under age of seven. The evaluation of the Facial Pain Scale was conducted in

accordance with guidelines that were provided in an article [34].

Over seven-year-old patients used a 0–10 point rating system to indicate their level of pain (0 = no pain, 10 = excruciating agony). Following surgery, appetite was divided into three status categories: good, moderate, and poor [35].

STATISTICAL ANALYSIS

Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 17.0 (IBM Corp., Armonk, NY). To compare categorical data, Chi-square ($\chi 2$) test was utilized. The Friedman test and the Wilcoxon Sign Rank test were both used to observe changes in the study parameters over the follow-up period, while the student's t test and the Mann-Whitney U test were utilised for the parametric variables. Data were presented as mean ± standard deviation (SD), minimum, maximum values and number (*n*) and percentage (%) if applicable. $P < 0.05$ was the acceptable value for statistical significance.

RESULTS

The TA group and TPHT group were homogenous in regards to gender (males: females 30% and 70%, consequently) and the age (mean ± SD: 6.8 ± 2.8 vs. 6.5 ± 2.7 years, consequently) as shown in (Table 1).

Each group's tonsil grading scores were comparable. (3.23 ± 0.60 vs. 3.12 ± 0.68). Significant reduction in pain scores 2 hours after surgery till day1 (5.43 ± 1.63 to 4.17 ± 1.07 in TPHT groups, $p < 0.001$ for each), but pain scores from 2nd hour to day 1 increased significantly (from 5.98± 1.89 to 7.79 ± 1.98 in TA group ,a gradual significant decline was noticed in the pain scores to both groups in the period from the 3rd day, to be 0.1 ± 0.02 and 0.61 ± 0.77 on the 10th day in the(TPHT)group and (TA group), respectively ($p < 0.001$ for each) as shown in (Table 2). The (TPHT) group had significantly lowered pain scores on every postoperative day from 2nd hour to day 10 than the (TA) group ($p < 0.001$) as shown in (Table 2).

The appetite status in the TPHT group was higher than in the other group starting from postoperative day 1 till day 6, ($p < 0.001$). Both groups' appetite status on day 7 was similar as shown in (Table 3). The percentage of patients who had a good appetite increased significantly over the course of the third postoperative day, rising from 57% on the third day to 90 % on the 7th day in the TPHT group, and from 8% on the third day to 70% on the 7th day in the Tonsillectomy alone group ($p < 0.001$) (Table 3).

The TPHT group required significantly fewer analgesics from day 1 to day 10 than the other group (p value < 0.001) as in (Table 4). There was a gradual significant decline in the frequency of analgesics from the third day with a decline from 2.39 ± 1.72 to be (0.00 ± 0.00) on the 10th day in the TPHT group and from 4.45 ± 1.89 to 0.56 ± 0.77 in the TA group for the same period ($p < 0.001$).

No early or late bleeding was happened in the TPHT group. Minimal bleeding happened in three patients on the 8th and 10th days. control of bleeding was done with bipolar cautery in those patients.

Table (1): Demographics of the two Groups.

Study group	Age (years), mean ± SD)	Gender Male %	Female %
Group1 TA(n.50)	6.8 ± 2.8	15 (30%)	35(70%)
Group2 TPHT(n 50)	6.5 ± 2.7	25(50%)	25(50%)
P value	0.344	0.389	

Table (2): Post operative pain score.

	The Facial Pain score (≤ 7 years) The VAS score (> 7years) Total							Total		
Time	**Group**	**Number**	**Means**	**P value**	**Number**	**Means**	**Value**	**Number**	**Means**	**Value**
2nd hour	**TPHT**	50	5.43 ± 1.63	0.001	50	27 3.77 ± 1.15	0.301	50	27 3.77 ±1.15	0.054
	TA	50	5.98± 1.89			3.77±1.15			3.77±1.15	
Day1	**TPHT**	50	4.17 ± 1.07 7.79 ± 1.98	0.001	50	3.77±1.15		50	3.77±1.15	
	TA	50				3.77±1.15			3.77±1.15	
Day2	**TPHT**	50	4.37±1.57		50	4.37±1.57	0.001	50	4.37±1.57	0.001
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day3	**TPHT**	50	4.51±1.52	0.001	50	4.51±1.52		50	4.51±1.52	
	TA	50	3.87±1.15			3.77±1.15			3.77±1.15	
Day4	**TPHT**	50	7.62±0.79		50	7.62±0.79	0.001	50	7.62±0.79	0.001
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day5	**TPHT**	50	3.92±1.41	0.001	50	3.92±1.41		50	3.92±1.41	
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day6	**TPHT**	50	7.62±0.79		50	7.62±0.79	0.001	50	7.62±0.79	0.001
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day7	**TPHT**	50	2.66±1.24	0.001	50	2.66±1.24		50	2.66±1.24	
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day 8	**TPHT**	50	6.51±1.42		50	6.51±1.42	0.001	50	6.51±1.42	0.001
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day 9	**TPHT**	50	2.37±1.24	0.001	50	2.37±1.24		50	2.37±1.24	
	TA	50	3.77±1.15			3.77±1.15			3.77±1.15	
Day 10	**TPHT**	50	00.0		50	5.55±1.50	0.001	50	5.55±1.50	0.054
	TA	50	0.61 ± 0.77			3.77±1.15			3.77±1.15	

Table (3): Post-operative appetite status.

Days	**Group TPHT**			**Group TA**			**P value**
	Fair appetite	**Moderate appetite**	**Poor appetite**	**Fair appetite**	**Moderate appetite**	**Poor appetite**	
Day1	6 (12.0)	24 (48.0)	10 (20.0)	2(2.0)	18 (36.0)	30 (60.0)	0.001
Day2	17(17.5)	23 (57.5)	10 (25.0)	10 (0.0)	14 (35.0)	26 (65.0)	0.001
Day3	25 (50.0)	20 (45.0)	5 (5.0)	3 (7.5)	13 (52.5)	16 (40.0)	0.001
Day4	27 (67.5)	23 (32.5)	0 (0.0)	30 (12.5)	12 (67.5)	8 (20.0)	0.001

Days	Group TPHT			Group TA			P value
	Fair appetite	Moderate appetite	Poor appetite	Fair appetite	Moderate appetite	Poor appetite	
Day5	30 (60.0)	20 (40.0)	0 (0.0)	33 (30.0)	10 (52.5)	7 (17.5)	0.001
Day6	35 (12.5)	15(57.5)	0 (0.0)	36 (2.5)	9 (22.5)	5 (75.0)	0.001
Day7	40 (80)	13 (57.5)	0(0.0)	28 (0.0)	17(35.0)	5 (65.0)	0.001

Table (4): Need for analgesics in the two groups with follow-up.

	Group 1	Group 2	P value
Day1	2.73±0.75	3.83±0.38	0.001
Day2	2.43±0.71	3.85±0.36	0.001
Day3	1.78±0.83	3.53±0.60	0.001
Day4	1.18±0.68	3.25±0.63	0.001
Day5	0.88±0.69	2.88±0.61	0.001
Day6	0.68±0.69	2.58±0.87	0.001
Day7	1.78±0.83	3.83±0.38	0.001
Day 8	.18±01.68	3.53±0.60	0.001
Day9	0.88±0.69	3.25±0.63	0.001
Day10	0.68±0.69	2.88±0.61	0.001

DISCUSSION

This study is considered to be the first one to evaluate the effect of local phenytoin use on tonsillectomy patients. The findings of this clinical controlled trial study of paediatric tonsillectomy showed that both the TA and TPHT groups had considerable improvements in pain scales and appetite status in addition to a progressive reduction in the need for analgesics in the first 10 postoperative days. The TPHT group showed better outcomes with regards to of appetite, postoperative pain, need for analgesia, and risk of bleeding over the course of the whole postoperative period. The data from the TA group are in keeping with the typical course of pain following tonsillectomy, which decreases gradually in the first postoperative week and then more quickly thereafter [12].

Prolonged and severe pain following a tonsillectomy surgery has been linked to increased risk of complications, including inadequate oral intake and dehydration, morbidity, and delayed recuperation [21]. The TPHT group had better control over post-tonsillectomy pain for the whole 10-day follow-up period, indicating the potential for the use of topical phenytoin as an adjuvant therapy to promote rapid recovery after surgery.

In a previous study for behaviour changes and pain in children after elective surgery, it was found that on the second day following hospital discharge, 73% of the children (ages 2 to 12) exhibited their highest frequency of pain and problematic behaviour [36]. This study indicates that TPHT is superior to TA in regards to pain control and appetite starting on the first postoperative day. This suggests that TPHT could promote long-term functional outcomes and increase satisfaction among patients and their families. Additionally, each group in the study experienced a significant decrease in postoperative pain and an improvement in appetite scores by the third postoperative day.

Previous studies comparing the effect of Phenytoin Mouthwash and Mucoadhesive Tablet on Chemotherapy-Induced Oral Mucositis concluded severity of mucositis and VAS in the two groups was significantly lesser than onset of the treatment without any significant differences was noted between both groups. As a result, both forms worked well to cure mucositis [37]. Some researchers have examined using phenytoin topically to treat a variety of disorders because its systemic absorption is negligible and its topical consequences are uncommon [37].

The effectiveness of mouthwash containing 0.5 and 1% phenytoin was examined by ***Hamian*** and ***Baharvand.*** Within one week, the majority of patients (70% in group A and 80% in group B) in both groups were pain-free [38]. ***Sameh*** and

Amany conducted randomized controlled study on children with adenotonsillectomy to assess the effect glossopharyngeal nerve block bilaterally, they found that there was improvement in the period and intensity of analgesia following surgery, a reduction in swallowing challenges, and an increase in parent satisfaction [38].

This study gave us the idea of using phenytoin in tonsillectomy as spray with 1% concentration. The results of our study demonstrated more effectiveness of pain control with a less requirement for analgesics in the TPHT group than in the other group during the 10-day follow-up period. In addition to better appetite status in the TPHT group during the first five postoperative days. No Postoperative haemorrhage was observed in TPHT group. However, only the TA group showed late-term bleeding, this explains accelerated wound healing as a result of the local phenytoin therapy in the TPHT group. Consequently, our results highlight the possible contribution of Phenytoin to the decrease of bleeding risk, postoperative analgesic need, and post tonsillectomy pain in paediatric tonsillectomy patients, as well as to the enhancement of appetite status. This seemed noteworthy considering applying local phenytoin immediately to the wound to speed up healing is quite safe. [37].

CONCLUSION

Tonsillectomy with local phenytoin use is superior to tonsillectomy alone for lowering post tonsillectomy pain and enhancing appetite status in paediatric tonsillectomy patients, in addition to a decreased need for analgesics and a lower risk of bleeding after tonsillectomy within the first ten days following surgery. Larger scale studies are required to address the use of topical phenytoin in tonsillectomy patients across age groups and with varying surgical procedures to validate the possible value of PHT as local therapy in wound healing and post tonsillectomy pain control.

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To Cite:

Abdelhamid, H., ashraf, A. Impact of Use Of Local Phenytoin On postoperative outcomes of pediatric tonsillectomy. *Zagazig University Medical Journal*, 2024; (111-117): -. doi: 10.21608/zumj.2024.272590.3194