Whether Post-Tonsillectomy Medication Should be Liquid Based or Can be Solid? A Randomised, Single-Blinded, Controlled Trial

Pattaramon Wijakkanalan MD, FRCOT*, Patchareeporn Saesaew MD, FRCOT*, Malinee Wongsawatdiwat MD, FRCPT**, Patorn Piromchai MD, MSc, FRCOT, FICS*

** Department of Otorhinolaryngology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand*
*** Department of Anaesthesiology, Faculty of Medicine, Khon Kaen University, Khon Kaen, Thailand*

Background: *Tonsillectomy is a common operation for the otolaryngologist. There has been a discrepancy in recommending prescribing a liquid based or solid medication for post-tonsillectomy patients.*
Objective: *To compare the pain scores, adverse effects and complications between the post-tonsillectomy patients who were given liquid medication in comparison with patients who were given non-restricted medication.*
Material and Method: *Patients with chronic hypertrophic tonsillitis who underwent tonsillectomy were recruited. In the control group, patients were given liquid medication. The experimental group was given a non-restricted form of medication. Pain scores, adverse effects and complications and patient satisfaction data were collected.*
Results: *Twenty-six patients were enrolled. The pain score difference between the 2 groups at 4 hours was -0.23 (95% CI -1.57 to 1.11, p = 0.73) and 0.15 (95% CI -0.77 to 1.08, p = 0.73) at 72 hours. There was no statistically significant difference between the early and late complications between the control group and the experimental group (p>0.05).*
Conclusion: *There was no statistical difference in the pain scores, adverse effects and complications between groups. There is no necessity to restrict patients to liquid medication.*

Keywords: *Tonsillectomy, Therapy, Therapeutic use, Adverse effects*

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Tonsillectomy is a common operation for the otolaryngologist. Our institution conducts 100-200 of such operations each year. This procedure is simple, but there is a potential of post-operative life threatening complications from massive hemorrhaging[1-4]. Patients who undergo tonsillectomy usually experience adverse effects such as wound pain and swallowing disorders[4].

We routinely prescribe liquid medications to these patients in our institution based on the fact that liquid materials are easier for the patients to swallow. However, this practice comes with trade-offs such as a higher cost of the medication and difficulties in handling large heavy containers of medication. A review of this protocol indicates that this protocol is not based on the evidence. Many studies suggested that after tonsillectomy pain diminishes in the first few days in most cases[5,6]. It is, therefore, necessary to prove that the liquid medication is superior to solid medication in terms of reducing pain associated with swallowing.

There was a discrepancy in the recommendations of care for post-tonsillectomy patients. Drake et al[7] and Poole[8] suggested that syrup solutions were easier to swallow, whereas solid food and medication can cause pain with swallowing. However, Zagolski[9] found that patients who were prescribed with diet and activity restrictions required repeat surgery under general anesthesia more than patients without any restrictions, and the parental satisfaction level was also higher in the non-restricted group. The current American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) and the Scottish Intercollegiate Guidelines Network (SIGN) clinical practice guidelines for tonsillectomy in children did not address this problem in their guidelines[10,11]. To our knowledge, there was no randomised controlled trial comparing the effectiveness of liquid versus solid medication to reduce the swallowing pain.

The major complication of tonsillectomy is post-operative hemorrhage. The important factors that

Correspondence to:
Piromchai P, Department of Otorhinolaryngology, Faculty of Medicine, Khon Kaen University, Khon Kaen 40002, Thailand.
Phone: +66-81-5444463
E-mail: patorn@gmail.com

have impacts on hemorrhage in the literature include age, gender, operative techniques, wound infection, and pathological conditions of tonsillitis. The diet and the form of prescribed medication were not regarded as significant factors[3,12-14]. The pain mechanism related to swallowing is triggered by pressure, temperature, and chemicals[15]. Normal swallowing requires a coordination of muscles in the mouth, pharynx, and esophogus. Food is mixed into the bolus in the mouth by the tongue, the teeth, and the cheek bulges. The tongue is raised to push the food upward towards the back of the mouth through the pharynx into the esophagus in the midline position[16]. The bolus typically does not come into contact with the tonsillectomy bed. These reasons indicate that liquid medication may not be a reasonable option for post-tonsillectomy patients.

We compared the pain scores, adverse effects and complications between the post-tonsillectomy patients given liquid versus non-restricted forms of medications. The outcome could be useful for developing care strategies for such patients and improving their quality of life and satisfaction.

Material and Method

Patients who were aged 12 and over who underwent tonsillectomy at Department of Otolaryngology, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University from February 1, 2011 to January 31, 2012 were investigated in this study. The exclusion criteria for this study were patients with bleeding tendencies, peritonsillar abscess, heart or pulmonary disease, psychiatric disorders, and allergies to the medication used in this study. The protocol was approved by the Khon Kaen University Ethics Committee in Human Research before the study was initiated.

The patients who were eligible for investigation were approached by the research assistant. The patients and relatives were given detailed explanations about the research procedures and possible impacts of this study. Patients who agreed to participate in this study gave their written consent on the accepted form. The patients were randomly allocated to the liquid or non-restricted medication groups. The randomisation list was computer generated based on the block randomisation method and confidentially sealed in opaque, sequentially numbered envelopes.

All medical personnels in the operating room were blinded to the patient group allocations. The patients were assessed for their pain with swallowing prior to operation as the baseline data. They received standard anesthetic drug treatments according to the anesthesia protocol. Tonsillectomy was done bilaterally by the same consultant otolaryngologists or residents under supervision. The cold dissection and snare technique was used. Bleeding was stopped by bipolar electro cauterization.

After the operation, the post-treatment care nurse opened the allocation envelope. The control group received liquid medication, whereas the experimental group was received solid medication. The Amoxicillin (40-50 mg/kg/day) in either form (syrup or capsule) was prescribed according to the patient allocation. The first dose was given 4 hours after the operation. Paracetamol (15 mg/kg/dose) was also prescribed for pain control as needed at 6-hour intervals.

The pain score was assessed using a numerical pain intensity scale from 0-10. The early phase of pain was assessed at four hours after the operation by the ward nurses who were not aware of the patient's group allocation, while the late phase of pain was assessed three days after the operation using a questionnaire. The patients were followed-up for one week after the operation. Their adverse reactions and complications were recorded. The satisfaction score was collected using the questionnaire.

The sample size was calculated based on a confidence level of 95 percent and a power of 90%. The estimation of the population pain score and the standard deviation was based on previous studies[17-19]. There were 13 patients in each group. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 20.0. Data were described by either mean for continuous variables or frequencies and percentages for categorical variables. Significant differences between groups were determined using a Student t-test for continuous variables. The Chi-square test was used to determine whether there was a significant difference between the expected frequencies and the observed frequencies. For all tests, $p<0.05$ was considered statistically significant.

Results

One hundred and thirty-five cases that underwent tonsillectomy during the recruitment period. One hundred and nine were aged under 12 and excluded from the study. Twenty-six cases were eligible for the study. All of these 26 patients agreed to participate in our trial. The informed consent forms were obtained from all participants before they were recruited.

There were 15 females (57.7%) and 11 males (42.3%) with an age range from 14 to 56 years (average 29.2 years). The indications for surgery were recurrent tonsillitis (53.6%) followed by snoring (25%) and obstructive sleep apnea (6%). One patient in the experiment group had diabetes mellitus while one patient in the control group had allergic rhinitis. The patients in the control and experiment groups were not significantly different in terms of demographic data (p>0.05). Tonsil sizes were scored as grade 4, 2, and 1, respectively. No intra-operation complications were found. The average operation time was 60.9 minutes (25-105 minutes). The average blood loss during the operation was 77.3 ml (Table 1).

Baseline pain scores pre-operatively were 0 in both groups. Post-operatively, average pain scores before and while swallowing of the two groups at the early stage did not differ (p = 0.79 and 0.70, respectively). At 72 hours, the average scores of both groups before and while swallowing decreased and were also no statistically significant difference (p = 0.56 and 0.77, respectively) (Table 2).

The changes in the pain scores from before to while swallowing had no statistically significant difference both at the early stage and at 72 hours after the operation (p = 0.73 and 0.73, respectively) (Table 3).

During hospital admissions, the most common complications that were found were post-operative fever (7.7%) and nausea and vomiting (7.7%). During the first week, 11.5% of the patients were found to experience hemorrhages in the operated area. All of these patients were in the liquid group (p = 0.07). There was no statistically significant difference between the early and late complications when comparing the control group and the experimental group (p>0.05). The average patient satisfaction scores were higher in the non-restricted group than the liquid group. There was no significant difference between the two groups (p>0.05).

Discussion

Pain after tonsillectomy is an important factor that impacts the quality of life of the patients. There were many proposed methods to reduce the pain after tonsillectomy, including topical or oral analgesic drugs[20-24] and corticosteroids[25-28]. We found that the practice of using liquid medication was not based on the best evidence. This study is trying to prove if it

Table 1. Demographic data

Factors	Liquid group (n = 13)	Non-restricted group (n = 13)
Sex (%)		
Male	6 (46.2)	5 (38.5)
Female	7 (53.8)	8 (61.5)
Age (SD)	31.9 (14.5)	26.5 (9.6)
Grading of tonsils (%)		
Right side		
I	0 (0.0)	0 (0.0)
II	4 (30.8)	3 (23.1)
III	6 (46.2)	4 (30.8)
IV	3 (23.1)	6 (46.2)
Left side		
I	0 (0.0)	1 (7.7)
II	3 (23.1)	2 (15.4)
III	7 (53.8)	4 (30.8)
IV	3 (23.1)	6 (46.2)
Underlying diseases (%)	1 (7.7)	1 (7.7)
Indication for surgery (%)		
Recurrent, acute tonsillitis	8 (57.0)	7 (50.0)
Excessive snoring	3 (21.5)	4 (28.5)
OSA	2 (21.5)	2 (21.5)
Surgical time (min) (SD)	59.23 (18.1)	62.7 (22.3)
Intra-operative blood loss (ml) (SD)	81.5 (83.8)	73.1 (88.5)

Table 2. Pain with swallowing scores

	Liquid group (n = 13)	Non-restricted group (n = 13)	*p*-value
4 hour post-operation			
Before swallowing medication ($\bar{x}$±SD)	5.54±2.26	5.77±2.09	0.789
While swallowing medication ($\bar{x}$±SD)	6.08±3.12	6.54±2.73	0.692
72 hour post-operation			
Before swallowing medication ($\bar{x}$±SD)	4.23±1.79	4.62±1.50	0.558
While swallowing medication ($\bar{x}$±SD)	4.46±2.22	4.69±1.75	0.771

Table 3. Pain score changes from before to during swallowing between groups

Groups	Mean change	SD	Mean diff.	*p*-value	95% CI
4 hour post-operation					
Liquid	0.54	1.61	-0.23	0.725	(-1.57 to 1.11)
Non-restricted	0.77	1.69			
72 hour post-operation					
Liquid	0.23	1.36	0.15	0.734	(-0.77 to 1.08)
Non-restricted	0.08	0.86			

was necessary to prescribe these preparations.

We found that there was no statistical difference in post-operative pain between groups (p>0.05). Surprisingly, we found that the patients in the liquid medications group had higher pain scores than the non-restricted group, which could be explained from the characteristic of the syrup itself. The syrup is hypertonic and might be difficult to swallow. It also has the potential to irritate the tonsillectomy wound and increase the pain score.

The complications within the first 24 hours were minor and treated accordingly. Three patients from the liquid medication group were found with hemorrhages during 7 days after the operation. When the wound was examined, no specific causes were found. These patients were re-admitted for close observation and stayed in the hospital for 2 more days under observation to ensure that there was no additional bleeding. One patient was sent to the operating room for hemostasis. No complications or recurrence of bleeding was found.

From the results above, a prescription for post-tonsillectomy medications could be given in either form. However, the syrup would be twice as expensive as the solid medications, and patients have to carry 10-12 bottles of syrup back home.

There was an issue that each individual could have a different pain perception and threshold. Therefore, a comparison of the pain scores between individuals may not be a good way to represent the effectiveness of the procedure. As the result, we also recorded the change of the pain score for each individual to obtain more reliable results.

This study was limited to a prescribed medication not including the type of diet. The medication passes from the pharynx to the esophagus without any chewing involved. Therefore, no effects should be observed in the tonsillectomy area. For further studies, comparisons should include various types of diet to obtain appropriate treatment and care approaches for patients.

Conclusion

There was no statistical difference in the pain scores, adverse effects and complications between groups. There is no necessity to restrict the patients to liquid medication.

What is already known on this topic ?

Tonsillectomy is a common operation.

Pain after tonsillectomy is a primary concern.

No guideline for a preferred form of the medication.

What this study adds ?

There is no necessity to restrict the patients

to liquid medication.

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Potential conflicts of interest

None.

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ผู้ป่วยควรได้รับยาน้ำหรือยาเม็ดหลังผ่าตัดต่อมทอนซิล? การวิจัยแบบสุ่ม มีการปกปิดข้างเดียวที่มีกลุ่มควบคุม

ภัทรมน วิจักขณาลัญจฉ์, พัชรีพร แซ่เซียว, มาลินี วงศ์สวัสดิวัฒน์, ภาธร ภิรมย์ไชย

ภูมิหลัง: *การผ่าตัดต่อมทอนซิลเป็นการผ่าตัดที่พบบ่อยสำหรับแพทย์โสต ศอ นาสิก ผู้นิพนธ์พบว่าการให้ยาหลังการผ่าตัดยังมีข้อแตกต่างกัน คือมีความเห็นเป็นสองทางว่าจะให้เป็นยาน้ำหรือยาเม็ด*

วัตถุประสงค์: *เพื่อเปรียบเทียบคะแนนความเจ็บปวด ผลข้างเคียงและอาการแทรกซ้อนที่เกิดขึ้นระหว่างกลุ่มผู้ป่วยที่ได้รับยาน้ำและยาเม็ด*

วัสดุและวิธีการ: *ผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นต่อมทอนซิลอักเสบเรื้อรังและมีแผนการผ่าตัดจะได้รับเชิญเข้าการศึกษานี้ ในกลุ่มทดลองผู้ป่วยจะได้รับยาเม็ด ในขณะที่กลุ่มควบคุมได้รับยาน้ำ ผู้นิพนธ์ได้บันทึกคะแนนความเจ็บปวด ผลข้างเคียงและอาการแทรกซ้อนที่เกิดขึ้นระหว่างกลุ่มผู้ป่วยที่ได้รับยาน้ำและยาเม็ด*

ผลการศึกษา: *ผู้ป่วย 26 รายเข้าร่วมการศึกษานี้ คะแนนความเจ็บปวดของทั้งสองกลุ่มที่เวลา 4 ชั่วโมงมีความแตกต่างกันเท่ากับ -0.23 (95% CI -1.57 to 1.11, p = 0.73) และ 0.15 (95% CI -0.77 to 1.08, p = 0.73) ที่ 72 ชั่วโมง มีความแตกต่างอย่างไม่มีนัยสำคัญทางสถิติของอาการแทรกซ้อนระหว่างทั้ง 2 กลุ่ม (p>0.05)*

สรุป: *คะแนนความเจ็บปวด ผลข้างเคียงและอาการแทรกซ้อนมีความแตกต่างอย่างไม่มีนัยสำคัญทางสถิติ ดังนั้นจึงไม่มีความจำเป็นที่จะต้องจำกัดผู้ป่วยให้ได้รับเฉพาะยาน้ำ*