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**MAIN ARTICLE**

# Efficacy of clindamycin in reducing pain following tonsillectomy in adults: a double-blind, randomised trial

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## Abstract

*Objective*: Tonsillectomy is a common operation performed in children and young adults. Pain and post-operation haemorrhage are its most common complications. This study was designed to evaluate the efficacy of topical antibiotics in reducing throat pain after tonsillectomy in adult patients.

*Methods*: A double-blind, placebo-controlled, randomised clinical trial was conducted, enrolling 30 patients older than 18 years who were scheduled to undergo tonsillectomy. Patients were randomly assigned to receive either clindamycin or normal saline (as placebo). Throat pain severity was evaluated using a visual analogue scale.

*Results*: All patients in both groups had experienced a reduction in pain by the seventh day after surgery. There was no statistically significant difference in the extent of visual analogue scale pain score reduction, comparing the placebo and clindamycin groups throughout the study course ($p = 0.424$).

*Conclusion*: Topical clindamycin was not demonstrated to be more effective than normal saline in the reduction of throat pain following tonsillectomy in adults.

**Key words:** Tonsillectomy; Pain; Antibiotics; Clindamycin; Administration, Topical

## Introduction

Tonsillectomy is a common operation performed in children and young adults.[1] It is associated with various kinds of post-operation morbidity, including nausea, vomiting, haemorrhage, sore throat and otalgia.[2,3] Pain and post-operation haemorrhage are the complications which most commonly result in a follow-up visit to the emergency department or outpatient clinic after discharge.[4] Children undergoing tonsillectomy experience considerable post-operative pain, for which optimal management has yet to be established.[5–7]

Throat pain associated with tonsillectomy impairs swallowing and delays the patient's return to a normal diet, causing dehydration.[8] Nerve irritation, inflammation and pharyngeal muscle spasm have been proposed as the underlying mechanisms responsible for this complication of tonsillectomy.[9]

Various analgesic methods and drugs have been used to reduce morbidity following tonsillectomy, including peritonsillar infiltration of analgesia,[10] cryoanalgesia,[8] paracetamol,[11] steroids[12–14] and antibiotics.[15] However, trial results have been inconsistent.

The rationale for the use of antibiotics as a possible method of analgesia in this setting is based upon the hypothesis that reducing oral bacterial load at the site of surgery will diminish inflammation, resulting in better pain control.[16] The efficacy of pre- or post-operative antibiotic administration in reducing post-operation morbidity has been assessed in various trials, but results have been controversial. Some authors have reported a significant decline in post-operative morbidity in patients receiving antibiotics,[16–18] while others have observed little benefit.[19] Moreover, a systematic review by Dhiwakar *et al.*[15] concluded that systemic antibiotics are beneficial in reducing some but not all post-operative symptoms.

To our knowledge, most studies on this topic have evaluated the efficacy of local antibiotic administration in paediatric populations.[20–22] In the available studies of adult patients, the quality of results has been hindered by design flaws (e.g. lack of adequate blinding).[18,23]

Given the current knowledge gap in this setting, we undertook the present study with the aim of evaluating the efficacy of topical antibiotic administration in pain

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reduction following tonsillectomy in Iranian adult patients.

## Materials and methods

### *Patients*

A double-blind, placebo-controlled, randomised clinical trial was conducted to assess the effect of clindamycin on pain reduction following tonsillectomy undertaken at Shahid Sadoughi General Hospital, Yazd, Iran.

Patients older than 18 years who were scheduled to undergo tonsillectomy because of recurrent tonsillitis, peritonsillar abscess or chronic tonsillitis were enrolled in the study. We excluded patients with (1) a known allergy to clindamycin, or (2) a history of antibiotic use in the week prior to surgery, or a history of any medical condition requiring antibiotic therapy.

Cold-dissection tonsillectomy was performed by the same surgeon (MHB) for all patients. Anaesthetic technique was similar in all operations. Haemostasis was achieved by packing wet gauze over the operative site, rather than using electrocautery.

A total of 30 patients were recruited. Written, informed consent was obtained from all patients. The local ethics committee of the Shahid Sadoughi University approved the study protocol. All procedures were conducted in accordance with the guidelines of the Declaration of Helsinki regarding human subjects.

### *Study design*

Patients were randomly assigned to two groups using a computer-generated randomisation code, and received either clindamycin (cases) or isotonic saline as placebo (controls).

Clindamycin (1 g) was dissolved in 100 ml normal saline. The placebo solution was prepared in an identical manner to the active medication, and the two preparations had the same colour, odour and taste. Patients received either 100 ml normal saline alone or 100 ml normal saline with clindamycin, in bottles with the same appearance. The solutions were prepared by a nurse who was blinded to the study protocol. Clindamycin or normal saline alone was applied at the surgical site prior to incision and again at the end of the operation, after the achievement of complete haemostasis.

Post-operatively, patients were asked to gargle with 10 ml of the relevant prepared solution, once daily for six days.

As adjunctive analgesia, patients were also prescribed paracetamol tablets (325 mg, four times daily).

### *Assessment*

The severity of patients' throat pain was evaluated 1, 4 and 7 days after surgery using a 100 mm visual analogue scale (VAS). The two extremes of the scale were designated as indicating no pain (giving a score of 0) and severely debilitating pain (giving a score of 10). Scores of 1 to 4 were taken to indicate mild pain, 5 to 6 moderate pain and 7 to 9 significant pain.

At each follow-up visit, patients were also asked whether they had used extra doses of paracetamol, and whether they had developed any treatment complications such as bleeding, otalgia, skin rash, diarrhoea, nausea or vomiting.

### *Statistical analysis*

Statistical analyses were performed using the SPSS version 17.0 software program (SPSS Inc, Chicago, Illinois, USA). Continuous variables are presented as means ± standard deviations, and categorical variables as percentages. Repeated measures analysis of variance (ANOVA) was conducted to compare treatment efficacy between groups. Additionally, posthoc analysis was conducted using Bonferroni correction to evaluate the difference between each time point. The effect size was computed using partial $\eta^2$. Based on Cohen's recommendations, $\eta^2$ values of 1, 6 and 13.8 per cent were taken to demonstrate small, medium and large effect sizes, respectively.[24] The median VAS scores for each day were compared between trial arms using the Mann–Whitney U test.

## Results and analysis

Thirty patients were enrolled in the study and were divided into two groups: clindamycin and placebo. Each group consisted of 15 patients. The mean patient age was 25.76 ± 6.32 years (range, 18 to 42 years) (Table I). The study group consisted of 15 (50 per cent) women and 15 (50 per cent) men.

The most common reasons for tonsillectomy were chronic tonsillitis (22 patients, 73.3 per cent) and recurrent tonsillitis (7 patients, 23.3 per cent). One patient (3.3 per cent) had a peritonsillar abscess and therefore underwent delayed surgery after resolution of the abscess.

### *Placebo group*

The mean age of the placebo group patients was 25.4 ± 6.06 years (range, 18 to 34 years).

TABLE I
PATIENTS' BASELINE CHARACTERISTICS

| Characteristic | Value |
|---|---|
| Age (mean ± SD; yr) | |
| – Total group | 25.76 ± 6.32 |
| – Clindamycin group | 26.13 ± 6.75 |
| – Placebo group | 25.4 ± 6.06 |
| Gender (*n* (%)) | |
| – Male | 15 (50) |
| – Female | 15 (50) |
| Cause of surgery (*n* (%)) | |
| – Chronic tonsillitis | 22 (73.3) |
| – Recurrent tonsillitis | 7 (23.3) |
| – Peritonsillar abscess | 1 (3.3) |

SD = standard deviation; yr = years

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TABLE II
SUBJECTIVE PAIN SEVERITY: VAS SCORES

| Parameter | Score (mean ± SD) | | $p^*$ |
|---|---|---|---|
| | Placebo grp† | Clind grp | |
| Day | | | |
| – 1 | 6.73 ± 1.38 | 7 ± 1.13 | 0.625 |
| – 4 | 4.26 ± 0.96 | 4.26 ± 1.38 | 0.844 |
| – 7 | 2.06 ± 0.70 | 1.73 ± 1.03 | 0.172 |
| $p^\dagger$ | | | |
| – Within grp | <0.001 | <0.001 | |
| – Between grps | 0.424 | | |

*Mann–Whitney U test, placebo *vs* clindamycin group. †Repeated measures analysis of variance. VAS = visual analogue scale; SD = standard deviation; grp = group; Clind = clindamycin

The mean VAS pain score on the first day after surgery was 6.73 ± 1.88, decreasing to 4.26 ± 0.96 on the fourth day and 2.06 ± 0.7 on the seventh day (at the final follow-up visit). One-way repeated measures ANOVA was conducted to compare VAS scores at different time points. There was a significant effect for time (Wilks' $\lambda = 0.057$; F (2, 13) = 106.676; $p < 0.001$). Post hoc analysis using Bonferroni correction revealed that the difference between all three time points was statistically significant ($p < 0.001$ for all time to time comparisons).

*Clindamycin group*

The mean age of patients in this group was 26.13 ± 6.75 years.

The mean VAS score on the first day after surgery was 7.00 ± 1.13, decreasing to 4.26 ± 1.38 on the fourth day and 1.73 ± 1.03 on the seventh day. One-way repeated measures ANOVA revealed that there was a significant effect for time (Wilks' $\lambda = 0.052$; F (2, 13) = 118.533; $p < 0.001$; multivariate partial $\eta^2 = 0.948$). Post hoc analysis using Bonferroni correction showed that the VAS score reduction was statistically significant when comparing all pairs of time points ($p < 0.001$ for all time to time comparisons).

*Treatment efficacy*

On the first day after surgery, the mean VAS scores in the placebo and clindamycin groups were comparable ($p = 0.625$) (Table II). Similar results were observed when comparing the two groups' VAS scores on the fourth day ($p = 0.844$) and on the seventh day ($p = 0.172$). Repeated measures ANOVA revealed no statistically significant difference between the reduction in VAS scores in the placebo versus clindamycin groups, during the study course (Wilks' $\lambda = 0.938$; F (2, 27) = 0.886; $p = 0.424$; multivariate partial $\eta^2 = 0.062$ for between-group comparison).

## Discussion

This study evaluated the effectiveness of local antibiotic therapy in reducing pain after adult tonsillectomy. Patients were randomly assigned to receive either isotonic saline or clindamycin. Clindamycin has been shown to be an effective prophylactic medication for head and neck surgical procedures.[25] There are no current data concerning the sensitivity of oropharyngeal flora to clindamycin in an Iranian population. However, previous reports from several countries have shown promising findings in this regard, and have even proposed that antibiotic treatment be considered as an alternative to tonsillectomy in patients with recurrent tonsillitis.[26,27] It has been suggested that clindamycin is an effective agent against β-lactamase producing bacteria which show resistance to penicillin.[28]

Previous studies have compared various analgesic techniques and medications, but have often presented inconsistent and contrasting results.

A number of studies have used peri-operative injection of analgesic medication to reduce pain; bupivacaine,[29] lignocaine[30] and ropivacaine[31] have all been used in this regard. Jebeles *et al.*[32] used pre-incisional infiltration of bupivacaine to reduce post-tonsillectomy pain in children. Their results indicated that patients receiving bupivacaine had significantly less pain on the fourth to fifth day after surgery, compared with the placebo group. Similar results regarding the efficacy of bupivacaine have been reported by other research groups.[33] In contrast, Ørntoft *et al.*[34] found that pre-operative infiltration of bupivacaine produced no significant reduction in post-tonsillectomy pain in adults. Other studies have concluded that local infiltration of anaesthetics has little or no benefit.[35]

The use of systemic steroids for pain reduction after tonsillectomy has provoked heated debate in several studies. The most common corticosteroid used in this setting is dexamethasone.[36] Some investigators have reported no significant difference in pain reduction in patients receiving steroids versus placebo,[37–40] while others have concluded that steroids are a good choice for reduction of post-tonsillectomy pain.[41]

Antibiotics have been used as alternative analgesic medication prior to or following tonsillectomy. However, similarly to other classes of analgesics and steroids, substantial controversy exists regarding their efficacy.

Telian *et al.*[42] evaluated the efficacy of antibiotic therapy by administering intravenous ampicillin at the time of surgery and for 12 to 24 hours afterwards; patients also received oral ampicillin for 7 days post-operatively. The authors assessed pain severity by comparing the mean number of continuous days with reported pain (assessed subjectively), in the ampicillin versus placebo groups. They concluded that administration of antibiotics leads to a significant reduction in throat pain.

Colreavy *et al.*[20] administered amoxicillin and clavulanic acid for one week after tonsillectomy, and reported a significant reduction in analgesia requirement and pain analogue score.

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Contrarily, other authors have reported that antibiotic administration after tonsillectomy has no significant effect on pain severity, in agreement with our own observations. O'Reilly *et al.*[19] examined the efficacy of pre-operative amoxicillin administration and concluded that pain severity was not affected by antibiotic therapy.

Dhiwakar *et al.*[15] conducted a systematic review including five double-blind, placebo-controlled clinical trials that assessed the efficacy of systemic antibiotic administration in reducing post-operation morbidity. They concluded that patients who received antibiotics returned to their normal activity sooner, were less likely to experience fever and had a shorter duration of halitosis, compared with placebo patients. However, antibiotics had no effect on the degree of pain or the need for rescue analgesia. We observed similar results with respect to the ineffectiveness of antibiotics in reducing post-operative pain.

A few authors have reported that local antibiotics can reduce post-tonsillectomy morbidity in paediatric populations.[20–22] However, our study did not replicate these results in adult patients.

Previous studies have indicated that both Gram-positive and Gram-negative bacteria can induce a host inflammatory response. The pro-inflammatory activity of Gram-negative bacteria is caused by the lipopolysaccharide component of the cell wall outer membrane. Lipopolysaccharide can activate the release of various inflammatory cytokines from host cells, such as interleukin (IL) 1, IL-6 and tumour necrosis factor α.[43,44] The cell walls of Gram-positive bacteria have different chemical components, such as lipoteichoic acid and peptidoglycan, but these trigger a pro-inflammatory response in a similar manner to lipopolysaccharide.[45,46] The inflammation induced by these various chemicals results in nerve irritation, leading to significant pain and discomfort.[47,48] In theory, reducing oropharyngeal bacterial growth hinders the inflammatory cascade, thus reducing the severity of post-tonsillectomy pain.

- **Pain and post-operative haemorrhage are the commonest complications of tonsillectomy**
- **The effect of pre- or post-operative antibiotics on post-operative morbidity is controversial**
- **In this adult study, local antibiotics did not reduce post-tonsillectomy throat pain more than placebo**

One limitation of our study was the relatively small number of patients enrolled. This limited number of patients reduced the chance of detecting a difference between the two groups, hence increasing the risk of type II error. In future studies, the probability of this error could be minimised by using larger sample sizes.

## Conclusion

Our results indicate that local antibiotic administration has no greater efficacy in reducing throat pain after tonsillectomy in adults, compared with placebo. Further investigation is warranted.

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