ORIGINAL ARTICLE

Antibiotic Prophylaxis in Tonsillectomy and its Relationship With Postoperative Morbidity⁎

Manuel Gil-Ascencio,a,* Carlos Jorge Castillo-Gómez,b Gerardo del Carmen Palacios-Saucedo,c Adrián Valle-de la O,d

a Otorrinolaringología, Instituto Mexicano del Seguro Social, Monterrey, Mexico
b Otorrinolaringología, Unidad Médica Atención Ambulatoria Nº 65, Instituto Mexicano del Seguro Social, Monterrey, Mexico
c División de Investigación en Salud, Hospital de Especialidades Nº 25, Instituto Mexicano del Seguro Social, Monterrey, Mexico
d Departamento de Ciencias Básicas, División Ciencias de la Salud, Escuela de Biotecnología y Salud del Tecnológico de Monterrey, Monterrey, Mexico

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KEYWORDS
Tonsillectomy; Antibiotics; Pain; Morbidity

Abstract

Introduction and objectives: Postoperative pain is the main symptom and the most incapacitating one in tonsillectomy, and prescribing oral antibiotics to reduce postoperative pain is common. The objective of this study was to evaluate the efficacy of 2 different prophylactic antibiotic schemes to reduce postoperative morbidity in paediatric patients undergoing tonsillectomy. One scheme consisted of a single-dose preoperative cephalothin, while the second was an oral antibiotic.

Methods: This was an open randomised trial on patients aged 4–15 years undergoing tonsillectomy. The experimental group received single-dose intravenous cephalothin, while the control group received single-dose intravenous cephalothin+oral suspension of amoxicillin/clavulanate for 7 days. We compared the presence and intensity of pain, limitations to normal diet, habitual activities, halitosis, otalgia and nausea within 7 days after surgery using the Wong-Baker FACES Pain Scale and a questionnaire for the parents.

Results: For the 102 patients that underwent tonsillectomy (51 per group), there was no difference in the presence and severity of postoperative pain between the 2 groups (P > .05). Neither was there any difference in the days needed to return to normal activities, normal diet, and duration of days with halitosis, otalgia or nausea. Just 1 patient from the control group had postoperative bleeding. There were no infectious complications.

Conclusions: The use of single-dose preoperative intravenous cephalothin has the same efficacy as the use of oral amoxicillin/clavulanate for 7 days in reducing morbidity in paediatric patients undergoing tonsillectomy and offers safe antimicrobial prophylaxis. Consequently, the routine use of oral antibiotics should be avoided.

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* Corresponding author.
E-mail address: orl.manuelgil@gmail.com (M. Gil-Ascencio).

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PALABRAS CLAVE
Amigdalectomía; Antibióticos; Dolor; Morbilidad

Profilaxis antibiotica en amigdalectomías y su relación con la morbilidad postoperatoria

Resumen
Introducción y objetivos: El dolor postoperatorio en amigdalectomía es el síntoma principal y el más incapacitante, la prescripción de antibióticos es una práctica común para disminuir el dolor postoperatorio. El objetivo del estudio fue comparar la eficacia del control de la morbilidad postoperatoria de un esquema de profilaxis antibiotica intravenosa dosis única preoperatorio contra un antibiótico vía oral postoperatorio en pacientes pediátricos sometidos a amigdalectomía.
Métodos: Ensayo clínico controlado aleatorizado abierto, pacientes de 4-15 años sometidos a amigdalectomía. Grupo experimental: cefalotina IV dosis única; grupo control: cefalotina IV dosis única + amoxicilina/clavulanato durante 7 días. Se comparó la presencia e intensidad del dolor, tolerancia a vía oral, limitación de actividades, halitosis, otalgia y náuseas en los primeros 7 días de postoperatorio mediante la Escala Visual Análoga del Dolor de Wong-Baker y un cuestionario contestado por los padres.
Resultados: 102 pacientes sometidos a amigdalectomía, 51 por grupo. No hubo diferencia en la presencia ni intensidad del dolor postoperatorio entre ambos grupos (p > 0,05). No se encontró diferencia en los días para la reincorporación a las actividades habituales, dieta normal, días con halitosis, otalgia o náuseas. Se presentó solo un caso de sangrado postoperatorio en el grupo control. No ocurrieron complicaciones infecciosas.
Conclusiones: El uso de cefalotina IV dosis única en el preoperatorio tiene la misma eficacia que el uso de amoxicilina/clavulanato vía oral durante 7 días para el control de la morbilidad en pacientes pediátricos operados de amigdalectomía y ofrece una profilaxis antimicrobiana segura, por lo que el uso rutinario de antibióticos vía oral debe ser evitado.
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Introduction

Tonsillectomy is the treatment of choice for obstructive tonsillar hypertrophy and chronic tonsillitis,1,2 and is one of the most frequently performed surgical procedures by otolaryngologists in the paediatric population. The improvement of new surgical techniques has reduced the mortality and complications of this procedure, however, postoperative morbidity is usually significant and postoperative pain continues to be the main symptom in these patients.3 One study mentions that over 90% of patients report pain in the first day after surgery and between 60% and 70% report pain at 2 or 3 days after surgery despite medical treatment.4 Thus, postoperative pain continues to be one of the most controversial points and there is, as yet, no clear consensus regarding its ideal treatment.

Regardless of the surgical technique employed, following tonsillectomy the tonsil beds remain exposed to bacteria from the oral cavity and, since the healing process is by secondary intention, there is an inflammatory response which contributes to postoperative morbidity. Some authors argue that this contributes to postoperative morbidity, especially in terms of pain, and have proposed that the use of antibiotics in the postoperative period could reduce local inflammation, stimulate healing and enhance recovery by reducing the amount of bacteria in the surgical wound.5,6

Recent studies have assessed the impact of oral antibiotics on morbidity of patients undergoing tonsillectomy and concluded that antibiotics do not have a significant effect on pain reduction, need for analgesics, return to oral feeding or presence of postoperative bleeding.5,6 However, despite the lack of evidence showing a reduction in morbidity, the use of oral antibiotics in these patients as a form of "prophylaxis" and adjuvant treatment for reducing morbidity remains a routine practice by most otolaryngologists. There are even some otolaryngology books which suggest the prophylactic use of antibiotics routinely for 7 or 10 days, without justifying the benefits of their use. Moreover, current guidelines suggest that the indiscriminate and unjustified use of antibiotics promotes an increase of bacterial resistance. The most common aetiological agent has been Streptococcus pyogenes (S. pyogenes) sensitive to penicillin and amoxicillin. However, an increase in the incidence of tonsillitis by species such as β-lactamase-producing Staphylococcus aureus, S. pyogenes and Haemophilus influenzae has been observed in the last decade.3 Therefore, current treatment guidelines suggest avoiding the use of oral antibiotics postoperatively and limit their use to cases in which they are truly indicated (patients with cardiac valvulopathies or prosthetic valves).3

The objective of this study was to compare the postoperative morbidity of patients undergoing tonsillectomy using an antibiotic prophylaxis scheme with a single dose of intravenous (IV) antibiotics against an oral antibiotic for 7 days.

Methods

This was an open, randomised clinical trial conducted at a medical unit of the Mexican Social Security Institute of Monterrey, in the northeast of Mexico, among patients aged between 4 and 15 years and presenting clinical criteria of
chronic tonsillitis or obstructive tonsillar hypertrophy, exclusively treated with tonsillectomy or adenotonsillectomy, between August 2010 and September 2011. Any patients who were allergic to penicillin, cephalosporins or paracetamol were excluded from the study. Exclusion criteria corresponded to patients who presented postoperative bleeding or who did not attend any of the 3 control visits. We obtained informed consent from the parents or guardians of each patient. The study protocol was approved by the Ethics Committee of Specialty Hospital No. 25.

Patients were randomly assigned to one of 2 groups using a computer program. The experimental group was administered IV cephalothin 25 mg/kg in a single preoperative dose (during anaesthetic induction), whilst the control group received IV cephalothin 25 mg/kg in a single dose plus amoxicillin/clavulanate 50 mg/kg/day (dosage depending on amoxicillin) divided into 3 doses for 7 days. All surgical interventions were performed by the same otolaryngologist (CGCJ) using a 13 W monopolar electrocautery technique. The surgical procedure was performed on an outpatient basis. Both groups were prescribed oral paracetamol at a dosage of 15 mg/kg every 6 h.

After the surgery, parents were given a questionnaire which had to be completed daily for 7 days. This questionnaire used the Wong-Baker visual analogue pain scale in order to help children to describe the intensity of their pain. The scale consists of 6 faces which are assigned a numerical value, where 0 represents no pain and 10 represents the worst possible pain. In addition, they were also asked to record the degree of limitation of normal activities, the level of damage to oral tolerance, the presence of nausea, halitosis and otalgia during the first 7 days. Patients were scheduled for days 4 and 7 after surgery, in order to conduct an evaluation and confirm the progress of the questionnaire, and at 14 days for reassessment.

For the statistical analysis we used descriptive tests such as absolute frequencies, percentages, means and standard derivations. For the differential analysis we used the χ²-test and the Student’s t-test for independent samples. We considered a value of P<.05 as statistically significant. We used the statistical software package SPSS® version 17.0.

Results

The study included 103 patients undergoing tonsillectomy or adenotonsillectomy (Table 1), who were randomly assigned to either of the 2 treatment groups: experimental group, preoperative IV antibiotic alone (n=51), or control group, preoperative IV antibiotic + oral antibiotic for 7 days (n=52). One patient in the control group had to be eliminated due to suffering postoperative bleeding which required surgical revision. Therefore, each group was composed of 51 patients (102 in total). A total of 78 patients underwent adenotonsillectomy (76.5%), whilst 24 only underwent tonsillectomy (23.5%).

We evaluated the presence and intensity of pain during the first 7 days after surgery (Fig. 1 and Table 2). We also evaluated the presence and intensity of postoperative pain at 3 and 7 days after surgery, with no significant differences being found between both groups (Table 3). The intensity of pain at 3 days was 2.12±1.46 in the experimental group and 2.16±1.32 in the control group (P=.89). In the experimental group, 42 patients (82%) suffered some degree of pain after 3 days, compared with 43 patients in the control group (84%) (P=.70). The intensity of pain on the seventh postoperative day in the experimental group was 0.08±0.39, whilst in the control group it was 0.04±0.28 (P=.56). During this period, 2 patients in the experimental group (3%) suffered some level of pain, compared to only 1 patient in the control group (2%) (P=.31).

The return to normal activities in patients in the experimental group took place after 3.08±1.34 days, and in those in the control group after 3.24±1.42 days (P=.71). A total of 17 patients in the experimental group (33.33%) and 19 patients in the control group (37.25%) reported some degree of otalgia (P=.56). The days of duration of otalgia in these patients were 1.71±1.53 days for the experimental group and 1.84±1.42 days for the control group (P=.72). In total, 25 patients in the experimental group reported some degree of nausea (49%), compared to 24 patients in the control group (47%) (P=.78). The days of duration of nausea in the experimental group were 1.17±0.38, whilst in the control group they were 1.32±0.75 days (P=.80). In the experimental group, 25 patients reported some degree of halitosis (49%), compared to 28 patients in the control group (54.9%) (P=.40). The mean number of days with halitosis of these patients was 1.60±0.96 in the experimental group and 1.75±0.84 in the control group (P=.93). The return to normal diet took place after 4.88±1.14 days in the experimental group and after 4.98±1.16 days in the control group (P=.67) (Table 4). There was only 1 case of postoperative bleeding, in the control group, which occurred in the first 24 h postoperatively and required surgical revision and treatment. There were no cases of postoperative bleeding in the experimental group (P=.31). The incidence was 0.9% out of the

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Demographic Data of Patients.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total (n=102) (%)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>53 (52)</td>
</tr>
<tr>
<td>Girls</td>
<td>49 (48)</td>
</tr>
<tr>
<td>Age</td>
<td>7.39±2.73</td>
</tr>
<tr>
<td>P</td>
<td>.35</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
</tr>
<tr>
<td>Tonsillectomy</td>
<td>78 (76.5)</td>
</tr>
<tr>
<td>Adenotonsillectomy</td>
<td>24 (23.5)</td>
</tr>
</tbody>
</table>
Figure 1  The value corresponds to the mean±standard deviation. Intensity of postoperative pain measured with a visual analogue scale in 102 children undergoing tonsillectomy between both antibiotic prophylaxis groups, who received preoperative prophylaxis with a single dose of IV Cephalothin (experimental group) or IV cephalothin+oral amoxicillin/clavulanic acid during 7 days (control group).

Table 2 Presence and Intensity of Postoperative Pain in 102 Children Undergoing Tonsillectomy or Adenotonsillectomy, Who Received Preoperative Prophylaxis With a Single Dose of IV Cephalothin (Experimental Group) or IV Cephalothin+Oral Amoxicillin/Clavulanic Acid During 7 Days (Control Group).

<table>
<thead>
<tr>
<th>Day</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental group (n=51)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of pain</td>
<td>51</td>
<td>51</td>
<td>42</td>
<td>28</td>
<td>16</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Intensity of pain</td>
<td>5.14±1.88</td>
<td>3.37±1.57</td>
<td>2.12±1.46</td>
<td>1.29±1.37</td>
<td>0.71±1.12</td>
<td>0.08±0.39</td>
<td>0.08±0.39</td>
</tr>
<tr>
<td>Control group (n=51)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Presence of pain</td>
<td>51</td>
<td>50</td>
<td>43</td>
<td>30</td>
<td>14</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Intensity of pain</td>
<td>5.25±1.74</td>
<td>3.29±1.54</td>
<td>2.16±1.32</td>
<td>1.37±1.30</td>
<td>0.59±1.00</td>
<td>0.12±0.48</td>
<td>0.04±0.28</td>
</tr>
</tbody>
</table>

Values correspond to the frequency and mean±standard deviation.

Table 3 Presence and Intensity of Postoperative Pain at 3 and 7 Days.

<table>
<thead>
<tr>
<th>Postoperative pain at 3 days</th>
<th>Experimental group (n=51)</th>
<th>Control group (n=51)</th>
<th>P=</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensity of pain</td>
<td>2.12±1.46</td>
<td>2.16±1.32</td>
<td>.89</td>
</tr>
<tr>
<td>Presence of pain</td>
<td>42</td>
<td>43</td>
<td>.70</td>
</tr>
<tr>
<td>Postoperative pain at 7 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intensity of pain</td>
<td>0.08±0.39</td>
<td>0.04±0.28</td>
<td>.56</td>
</tr>
<tr>
<td>Presence of pain</td>
<td>2</td>
<td>1</td>
<td>.31</td>
</tr>
</tbody>
</table>

Table 4 Comparison of Other Symptoms of Postoperative Morbidity in Both Groups.

<table>
<thead>
<tr>
<th>Return to normal diet, days</th>
<th>Experimental group (n=51)</th>
<th>Control group (n=51)</th>
<th>P=</th>
</tr>
</thead>
<tbody>
<tr>
<td>Return to normal activities</td>
<td>4.88±1.14</td>
<td>4.98±1.16</td>
<td>.67</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.08±1.34</td>
<td>3.24±1.42</td>
<td>.71</td>
</tr>
<tr>
<td>Otalgia</td>
<td>1.17±0.38</td>
<td>1.32±0.75</td>
<td>.80</td>
</tr>
<tr>
<td>Halitosis</td>
<td>1.60±0.96</td>
<td>1.75±0.84</td>
<td>.93</td>
</tr>
</tbody>
</table>
total number of patients. There were no cases of infectious complications in any of the patients during the follow-up period (14 days).

**Discussion**

Tonsillectomy is one of the most commonly performed procedures by otolaryngologists and is the treatment of choice for tonsillar hypertrophy and chronic tonsillitis.\(^1\)\(^4\) Advances in new surgical techniques make this surgery a safe procedure, however, postoperative morbidity and in particular the treatment of postoperative pain continues to be a controversial point, with no clear consensus on its ideal treatment.\(^3\) The search for various treatments to decrease postoperative morbidity in tonsillectomy is justifiable, as analgesics do not control pain adequately and this is reflected as postoperative pain. Some authors accept the theory that, due to the fact that the tonsil beds remain exposed to bacteria in the oral cavity and that the healing process is through secondary intention, there is an inflammatory response which contributes to postoperative morbidity. Therefore, they have chosen the postoperative use of oral antibiotics, aiming to reduce pain during this period, and this has now become a common practice by most otolaryngologists. However, very few studies have evaluated the effect of antibiotics in the reduction of postoperative morbidity.\(^2\)

The present study compared 2 different antibiotic prophylaxis schemes: IV cephalothin in a single preoperative dose and IV cephalothin in a single preoperative dose plus oral amoxicillin/clavulanate for 7 days, in order to evaluate their efficacy in reducing postoperative morbidity in paediatric patients undergoing tonsillectomy.

The results showed that pain in patients undergoing tonsillectomy reached its maximum intensity in the first postoperative day and decreased thereafter, tending to remit on the sixth day in the majority of patients (95%). Furthermore, no difference in the presence and intensity of pain between the 2 groups of prophylactic antibiotics was observed during the first 7 postoperative days, so both schemes appear to be equally effective for postoperative pain control. We compared the presence and intensity of pain reported between the third and seventh postoperative days and found no difference between them. This was consistent with other studies, such as that by Dhiwakar et al.\(^1\) and that by Burkart and Steward,\(^2\) which concluded that the postoperative use of oral antibiotics does not reduce pain significantly in patients undergoing tonsillectomy. Based on these findings, it is not possible to justify the use of postoperative antibiotics with the objective of reducing postoperative pain.

Regarding the number days until return to normal activities, the results of the study showed that there were no differences between both groups. Regarding the time period until return to normal diet, the results showed that the use of oral antibiotics did not reduce the number of days. We evaluated the presence and duration of other symptoms, such as nausea, vomiting and halitosis, and found no differences between the 2 groups. The meta-analysis conducted by Dhiwakar et al.\(^1\) and the revision conducted by Burkart and Steward\(^2\) concluded that the use of oral antibiotics had a marginal influence on some symptoms such as fever, halitosis and return to normal diet. Therefore, the present study showed that there is no justification for the use of antibiotics in the postoperative period to decrease the morbidity of paediatric patients undergoing tonsillectomy.

Postoperative bleeding is one of the most feared complications of tonsillectomy. The reported incidence varies widely, ranging from 0% to 11.5% of cases, depending on the series and on the surgical technique employed.\(^9\) In this study, only 1 case of postoperative bleeding took place in the first 24 h after the procedure, which corresponded to a patient in the control group who required surgical revision and treatment. There were no cases of postoperative bleeding in the experimental group. In the present study, the incidence of postoperative bleeding was 0.9%. Since this event appeared in the first 24 h and the patient corresponded to the control group, this complication could be attributed to the surgical technique, without any benefit from the use of oral antibiotics to reduce the incidence of postoperative bleeding being observed. No infectious complications appeared in any patient during the follow-up period (14 days), showing that the administration of a single dose of IV cephalothin is sufficient as a method of prophylaxis to prevent infectious complications.

The unjustified use of antibiotics in the postoperative period may entail consequences for the patient and the community, as an increase in bacterial resistance to antibiotics is a factor to be taken into account to prevent such indiscriminate use.\(^10\) From the economic standpoint, the use of a single dose of an intravenous antibiotic, such as cefalothin, is much more economical than the postoperative oral use of amoxicillin/clavulanic acid. The cost of 1 vial of Keftin\(^6\) (IV cephalothin) is $152.67 MXP (Mexican pesos), whilst that of 3 bottles of Amoxiclav\(^8\) suspension (amoxicillin/clavulanate 125 mg/31.25 mg/5 ml, a dose equivalent to the presentation volume in the Mexican healthcare sector) is $144.89 MXP each bottle. Calculating for a normal, 7-year-old child weighing 25 kg (3 bottles), the cost would be $434.67 MXP. This shows that the use of a single IV antibiotic dose helps to reduce costs in healthcare institutions or the financial burden for patients who have to acquire the drug by themselves.

Although the present study did not assess the potential adverse effects of the use of antibiotics in the postoperative period, this factor should also be taken into account. However, we did not observe adverse effects which led to suspension of treatment or any severe adverse effects. Some studies have reported a 0.18% incidence of adverse effects in patients who were treated with penicillin.\(^11\) Moreover, some case reports have described patients suffering ana- phylaxis and death secondary to the use of antibiotics.\(^10\)\(^,\)\(^11\) Due to the frequency and volume of patients undergoing tonsillectomy, the risk of adverse effects may translate into a significant risk for patients if we consider the limited efficacy of postoperative antibiotics to control morbidity in patients undergoing tonsillectomy.

**Conclusions**

The use of preoperative intravenous cephalothin has the same efficacy as oral antibiotics in the postoperative period for the control of morbidity among patients undergoing
tonsillectomy and offers a safe option for antimicrobial prophylaxis. There is no evidence to support the routine prescription of oral amoxicillin/clavulanic acid in paediatric patients undergoing tonsillectomy, as it has not been shown to offer a significant benefit in reducing postoperative pain, the number of days until usual activities and normal diet are resumed, the presence and duration of nausea, otalgia and halitosis, and the incidence of postoperative bleeding and infectious complications. Routine use of oral antibiotics for antibiotic prophylaxis in paediatric patients undergoing tonsillectomy should be avoided, as they offer no benefit for the control of postoperative morbidity.

Conflict of Interests

The authors have no conflict of interests to declare.

References