

Randomized, double-blind trial on the efficacy of homeopathic treatment in children with recurrent tonsillitis

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Abstract

Objective: The efficacy and safety of homeopathic treatment was investigated on children with recurrent tonsillitis justifying surgery. **Methods:** Prospective, randomized, double-blind clinical trial that included 40 children between ages of 3 to 7 years old; 20 children were treated with homeopathic medication and 20 children with placebo. Follow up was 4 months per child. Assessment of results was clinical by means of a standard questionnaire and clinical examination on the first and last day of treatment. Recurrent tonsillitis was defined as 5 to 7 episodes of bacterial acute tonsillitis per year. **Results:** From the group of 18 children who completed homeopathic treatment, 14 did not present any episode of acute bacterial tonsillitis; from the group of 15 children who received placebo 5 patients did not present tonsillitis; this difference was statistically significant ($p= 0,015$). None of the patient exhibited side effects. **Conclusions:** Homeopathic treatment was effective in children with recurrent tonsillitis compared to placebo, 14 children (78%) were no longer indicated surgery. Homeopathic treatment was not associated with adverse events.

Keywords

Homeopathy; Recurrent tonsillitis; Children; Randomized controlled trial

· Revised version of article published in Revista de Homeopatia. 2007;70:21-26.

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Introduction

Acute tonsillitis is an acute infectious inflammation of the palatine tonsils; antibiotic treatment is commonly indicated. In the first half of the 20th century, tonsillectomy and adenoidectomy came to be indicated in the presence of minimal symptoms as routine surgery for almost all childhood diseases. Starting in the 1960s, several studies demonstrated the inefficacy of surgery in many cases, and doubts on its indication arose. By that time, research began to be conducted on the immune role of Waldeyer's lymphatic ring, resulting in more conservative and judicious indication of surgery [1].

Homeopathy, formulated by the German doctor Samuel Hahnemann in 1796, is successfully used for prevention and treatment of palatine and pharyngeal tonsil disease, with reduction of the number of patients indicated surgery [2]. However, the literature on the efficacy of homeopathy is scarce.

The present randomized double-blind study sought to assess the efficacy and safety of homeopathic treatment for children indicated tonsillectomy for recurrent tonsillitis.

Materials and methods

Patients

Forty patients cared at the pediatric otorhinolaryngology outpatient clinic of São Paulo School of Medicine, Federal University of São Paulo (EPM/UNIFESP) and São Paulo Hospital were selected from March 2000 to September 2001. Eligible participants were children 3 to 7 years old indicated tonsillectomy for recurrent tonsillitis while they waited for surgery. Patients with systemic diseases or immunodeficiency were excluded.

Bacterial acute tonsillitis was defined as presence of sore throat, fever (> 37.8 °C), prostration, pain on deglutition, lack of appetite and enlarged neck lymph nodes; hyperemia, swelling and purulent exudate on physical examination [3]. Recurrent acute tonsillitis was defined as 5-7 episodes/year [4].

Participants were randomly and blindly allocated to 2 groups: I- n= 20, subjected to homeopathic treatment for 4 months; II – n= 20, subjected to placebo for 4 months.

Parents/guardians were informed as to the study goals and signed an informed consent form. The study was approved by the research ethics committee of EPM/UNIFESP (ruling no. 012/00).

Treatment

Treatment consisted in administration of 3 homeopathic medicines for all patients in group I, selected according to Costa's [5] and Linhares' [2] experience: 1) individualized constitutional medicine, i.e. chosen based on the similarity of the

patient's physical and mental signs and symptoms as collected during interview and physical examination; remedies were administered in potency 30cH, one single dose; patients were assessed every 4 weeks along 4 months; medicines were selected using Digital Homeopathic Repertory II [6]; 2) *Baryta carbonica* 6cH, daily, along 4 months; the proving of this remedy matches the local characteristics of the palatine tonsils; and 3) isopathic medicine composed of β -hemolytic *Streptococcus*, *Staphylococcus aureus*, *Haemophilus influenzae* and Tonsil, 12cH, daily, for 4 months.

Group II received placebo instead of the constitutional remedy, one single dose; placebo instead of *Baryta carbonica* 6cH; and placebo instead of the isopathic combination; the latter 2 daily for 4 months.

Both investigators and patients were blinded to intervention. Randomization was performed by the homeopathic pharmacist who prepared the medicine. The code was broken only after the end of the treatment of all patients. Placebo was 30% ethanol, namely, the solvent used for preparation of homeopathic medicines; ethanol is used as preservative. All the medicines were prepared according to the Brazilian Homeopathic Pharmacopoeia [7].

Clinical assessment included application of a questionnaire once per month for 4 months to investigate the frequency and intensity of tonsillitis episodes. In addition, all the participants were subjected to otorhinolaryngological assessment (oral inspection, anterior rhinoscopy and otoscopy) on the first and last day of treatment, performed by an otolaryngologist from the pediatric otorhinolaryngology staff, EPM/UNIFESP.

Patients who developed acute bacterial tonsillitis during the study period were treated with antimicrobial agents. At the end of the study, all the cases with surgical indication were referred to surgery.

Statistical analysis

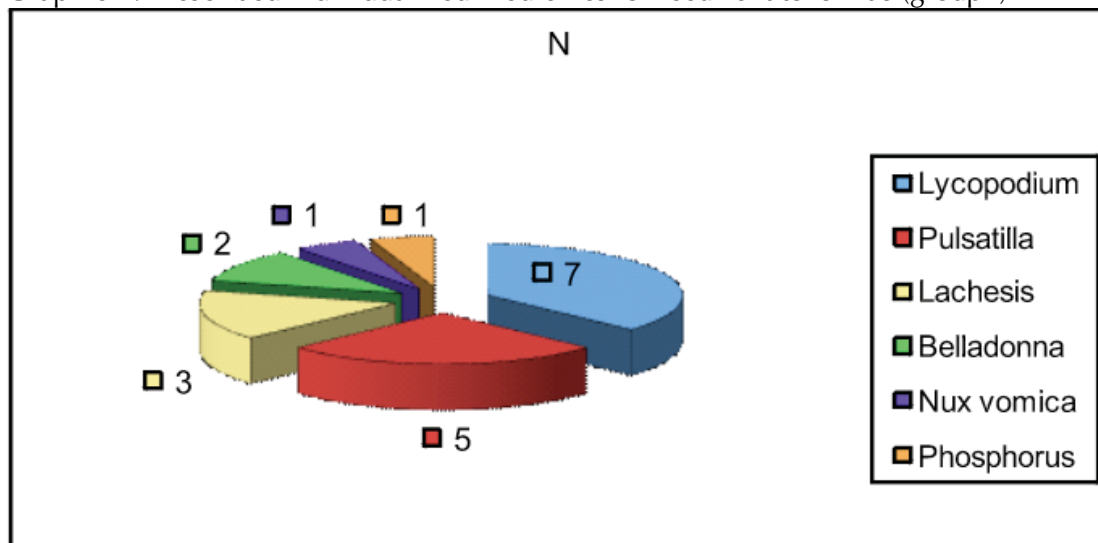
Statistical analysis was performed by means of Fisher's exact test or an extension for tables larger than 2 x 2. The statistical level was set to $p=0.05$ (5).

Results

Forty children aged 3 to 7 years old diagnosed with recurrent tonsillitis and surgical indication were initially recruited. However, only 33 patients completed the study. 20 (61%) were female and 13 (39%) male. Seven participants dropped out, being 2 from group I (homeopathy) and 5 from group II (placebo). The 2 children in group I dropped out because they lived too far from the hospital (cases 24 and 37). In group placebo, 1 child moved to another town (case 4), 1 had tonsillitis and febrile seizure (case 22) and 3 dropped out for unknown reasons (cases 14, 27 and 37).

The constitutional medicines selected for children in group I were: *Lycopodium clavatum*, *Pulsatilla nigricans*, *Lachesis muta*, *Belladonna*, *Nux vomica* e *Phosphorus* (Graphic 1).

Graphic 1. Prescribed individualized medicines for recurrent tonsillitis (group I)



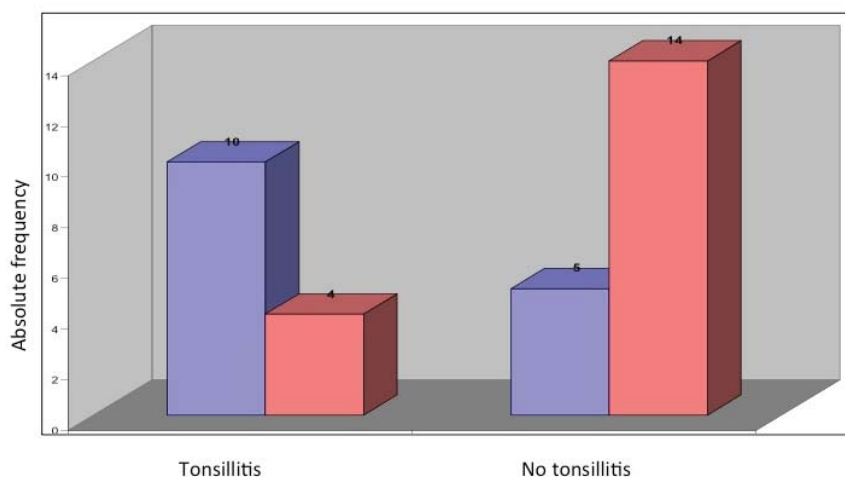
Four (22%) participants in group I (homeopathy) had acute tonsillitis and were treated with antibiotics; 14 patients (78%) did not develop tonsillitis (Table 1; Graphic 2). Ten (67%) patients in group II (placebo) had tonsillitis and were treated with antibiotics (Table 1; Graphic 2); 5 patients (33%) did not have tonsillitis. The 4 and 10 children, respectively, who had tonsillitis were referred to surgery.

Statistical analysis revealed significant difference ($p= 0.015$) showing greater efficacy of homeopathic treatment compared to placebo. Neither group exhibited adverse events.

Table 1. Clinical progression of participants; Fisher’s exact test ($p= 0.015$)

Group	No tonsillitis	Tonsillitis	Total
Placebo	5	10	15
Intervention	14	4	18
Total	19	14	33

Graphic 2. Clinical progression of participants; Fisher’s exact test ($p= 0.015$) (blue: placebo; red: intervention)



Discussion

Homeopathy is used as option for treatment of recurrent tonsillitis to avoid abuse of antibiotics and reduce surgical indication. In 1941, Lustoza [8] published an article entitled "Throat diseases and their homeopathic treatment", which is valid to this day, thus demonstrating the permanence of homeopathic notions and treatments over time.

The well-known difficulty for randomized double-blind trials of homeopathy is due to need to individualize each treatment, a *sine qua non* for application of the therapeutic similitude principle. Homeopathy approaches the patient as a whole, rather than his/her symptoms or diseases. Application of the therapeutic similitude principle led to select 6 different, individualized medicines for one and the same condition, namely, recurrent tonsillitis. The average duration of the first consultation was 60 minutes. All the participants were seen by one and the same doctor, which limited the sample size.

The placebo effect of a good doctor-patient relationship is a subject of discussion opposing conventional and homeopathic doctors. The former adduce that the efficacy of homeopathic treatment derives from suggestion (placebo effect). The latter cite the use of homeopathy in animals and children, who are not likely to be influenced by their relationship with doctors. Gonçalves, in his study with rats, advocated the experimental model, to avoid the effect of the "doctor-patient" relationship [9].

Although Hahnemann [10] recommended the use of one single remedy for treatment of chronic diseases, in the present study we preferred a combination, including the constitutional remedy, an organ-centered remedy and isopathic agents, as a function of the personal experience of the investigators, Costa [6] and Linhares [2]. It is worth to observe that *Baryta carbonica* is considered a classical remedy for recurrent tonsillitis, according to Cairo [11], Costa [5], Tejada [12], Hom [13] and Linhares [2]. The isopathic combination included remedies prepared from the etiologic agents of disease as starting material, to wit, β -hemolytic *Streptococcus*, *Staphylococcus aureus* and *Haemophilus influenzae*, which are the most often related to acute bacterial tonsillitis [15,16].

A total of 7 patients (17.5%) dropped out from the study, being 2 (5%) from group I (homeopathy) and 5 (12.5%) from group II (placebo). The latter's higher frequency of dropouts might be attributed to lack of motivation to continue treatment, perhaps due to therapeutic failure.

Most patients who seek homeopathy do so for believing it is more natural and safe than conventional treatment. In the present study, no adverse effects of homeopathic medicines were reported.

Conclusions

The results obtained from the clinical assessment of 33 children aged 3 to 7 years old with recurrent tonsillitis randomly allocated to receive homeopathy or placebo and followed up along for 4 months allows concluding: 1) homeopathic treatment was efficient; 14 patients (78%) from group I was spared from surgery; 2) homeopathic treatment was not associated with side effects.

Acknowledgments

To Dr. Carlos Roberto Dias Brunini for his support and to homeopathic pharmacist Andréa Cristina de Oliveira for providing the medicines. To graduate students at the pediatric otorhinolaryngology discipline, EPM/UNIFESP, for the assessment of patients.

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