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Double-blind placebo-controlled randomized clinical trial on the efficacy of Aerosal in the treatment of sub-obstructive adenotonsillar hypertrophy and related diseases.

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ABSTRACT

BACKGROUND:
Adenotonsillar hypertrophy (ATH) is a frequent cause of upper airways obstructive syndromes associated to middle ear and paranasal sinuses disorders, swallowing and voice disorders, sleep quality disorders, and occasionally facial dysmorphisms. ATH treatment is essentially based on a number of medical-surgical aids including nasal irrigation with topical antibiotics and corticosteroids and/or treatment with systemic corticosteroids, immunoregulators, thermal treatments, adenotonsillectomy, etc.

OBJECTIVES:
The aim of the present study is to assess the efficacy of Aerosal halotherapy in the treatment of sub-obstructive adenotonsillar disease and correlated conditions compared to placebo treatment.

METHODS:
A total of 45 patients with sub-obstructive adenotonsillar hypertrophy were randomized to receive either Aerosal halotherapy or placebo for 10 treatment sessions. The main outcome was a reduction greater than or equal to 25% from the baseline of the degree of adenoid and/or tonsillar hypertrophy.

RESULTS:
In the intention-to-treat analysis, a reduction of the degree of adenoid and/or tonsillar hypertrophy ≥25% from baseline after 10 therapy sessions was found in 44.4% of the patients in the halotherapy arm and in 22.2% of the patients in the placebo arm (P=0.204). Among the secondary outcomes, the reduction of hearing loss after 10 treatment sessions in the halotherapy arm was higher than the placebo arm (P=0.018) as well as the time-dependent analysis showed significantly improved peak pressure in the Aerosal group (P=0.038). No side effects were reported during the trial. In addition, the therapy was well accepted by the young patients who considered it as a time for play rather than a therapy.

CONCLUSIONS:
Aerosal halotherapy can be considered a viable adjunct, albeit not a replacement, to conventional medical treatment of sub-obstructive adenotonsillar syndrome and related conditions. Further research is however needed to improve ATH treatment.

TRIAL REGISTRATION:
ClinicalTrials.gov NCT01574885.