547

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TRANSCUTANEOUS PARASACRAL ELECTRICAL STIMULATION VERSUS OXYBUTYNIN IN THE TREATMENT OF OVERRACTIVE BLADDER IN CHILDREN: A RANDOMIZED CLINICAL TRIAL.

Hypothesis / aims of study
To compare the effectiveness of two treatment methods for overactive bladder (OAB) in children by comparing intra and inter groups in a randomized clinical trial.

Study design, materials and methods
We evaluated 9 boys and 19 girls aged 6.4 ± 2.18, who were divided into Group A (Transcutaneous Parasacral Electrical Stimulation, TPES with placebo) and Group B (oxybutynin and sham – scapular electrotherapy). A total of 20 sessions, 20 minutes each, three times a week associated with syrup, a daily dose of 0.3 mg/kg/day every 12 hours were administered. The criteria used to assess the success rate were as follows: a) Rate of complete resolution of symptoms; b) Visual Analogue Scale (VAS) (0-10); c) DVSS; d) voiding diary records; e) ROME III; and f) description of the frequency of side effects in both groups.

Results

A total of 13 patients in Group A and 15 in Group B. In Group A, 06 (46%) achieved complete response to treatment; and in Group B, 03 (20%) (p = 0.204. A statistically significant improvement was found in both groups according to the DVSS and voiding diary records, but no statistically significant difference was found between the groups, respectively (p = 0.295, p = 0.152, p = 0.098, p = 0.538, p = 0.650). In Group A, constipation improved 100% (p = 0.031) and only 55% in Group B (p = 0.073). Group A showed no side effects and 58% of patients in Group B presented/reported dry mouth (p = 0.002), 25% hyperthermia (p = 0.096), 50% hyperemia (p = 0.005), and 13.3% of patients discontinued treatment in Group B. All patients in Group A 13 (100%) and 13 (87%) of patients in Group B would recommend and repeat treatment.

Interpretation of results
A total of 13 patients in Group A and 15 in Group B. In Group A, 06 (46%) achieved complete response to treatment; and in Group B, 03 (20%) (p = 0.204. A statistically significant improvement was found in both groups according to the DVSS and voiding diary records, but no statistically significant difference was found between the groups, respectively (p = 0.295, p = 0.152, p = 0.098, p = 0.538, p = 0.650). In Group A, constipation improved 100% (p = 0.031) and only 55% in Group B (p = 0.073). Group A showed no side effects and 58% of patients in Group B presented/reported dry mouth (p = 0.002), 25% hyperthermia (p = 0.096), 50% hyperemia (p = 0.005), and 13.3% of patients discontinued treatment in Group B. All patients in Group A 13 (100%) and 13 (87%) of patients in Group B would recommend and repeat treatment.

Concluding message

TPES was effective was oxybutynin in the treatment of overactive bladder in children, but more effective against constipation, and no detectable side effects were found. Already oxybutynin was more effective in reducing voiding frequency. Satisfaction and adhesion to the two treatment methods were similar

Disclosures
Funding: Fundação de Amparo à Pesquisa da Bahia (FAPESB) **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** COmitê de Ética em Pesquisa da Escola Bahiana de Medicina **Helsinki:** Yes **Informed Consent:** Yes