

Official Title of Study: -

**MASSAGE WITH SENNA-BASED LAXATIVES VERSUS
SENNA-BASED LAXATIVES IN MANAGING OVERFLOW
RETENTIVE STOOL INCONTINENCE IN PEDIATRICS: A
Randomized Controlled Trial**

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MASSAGE WITH SENNA-BASED LAXATIVES VERSUS SENNA-BASED LAXATIVES IN MANAGING OVERFLOW RETENTIVE STOOL INCONTINENCE IN PEDIATRICS: A Randomized Controlled Trial

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Abstract

Background: Overflow retentive stool incontinence is a common disorder affecting children that affect the quality of life in the form of shame, humiliation, depression, and decrease reduced self-esteem of children. **Aim:** To compare the effect of massage with senna-based laxatives versus senna-based laxatives in managing overflow retentive stool incontinence in pediatrics. **Methods:** Eighty-six children with overflow retentive stool incontinence enrolled in this study and were assessed for eligibility. Children's age ranged from four and fourteen. They were assigned randomly into two groups. Group (A) received abdominal massage with senna-based laxatives and group (B) received senna-based laxatives only. The application of massage was applied for 15 minutes, three times/day for six successive months. **Results:** Post-treatment there was a significant improvement in both groups in favor of massage group, $P < 0.05$. **Conclusion:** Abdominal massage with senna-based laxatives has a great effect on children with overflow retentive stool incontinence than senna-based laxatives only. **Keywords:** Overflow retentive stool incontinence, senna-based laxatives, and abdominal massage.

Introduction

Constipation is the most common colonic motility disorder in children affecting between 0.7% to 29.6 % of the pediatric population (**Rasquin 2006, Mugie 2011**) and is frequently associated with fecal incontinence secondary to overflow (**Voskuijl 2004**)

Laxatives are the main line of maintenance therapy of overflow retentive stool incontinence (ORSI) with satisfying results (**Yik 2012**) stimulant laxatives like senna based laxatives (SBL) are our standard choice in Egypt due to its availability (**Bassiuony 2015**).

Massage is the manipulation of muscles and connective tissues (CT) (superficial and deeper layers) by using different techniques. It has been practiced in many ancient civilizations for thousands of years. (**Weerapong 2005**)

Abdominal massage is a noninvasive, effective, and safe form of constipation management in the general population. (**Lamas et al. 2009, Lamas et al., 2012 and Turan&Asti 2016**) .It provides a low burden of risk, reduces symptoms of chronic constipation, improves the quality of life, decreases the use of laxatives and increases the frequency and consistency of bowel movements (**Smith and Moss, 2008; Moss et al., 2007; Richards 1998; Lamas et al., 2010**).

Subjects and methods:

This randomized controlled study was conducted in the out-patient clinic in the Faculty of Medicine, South Valley University from March 2016 to March 2019. The parents of each child submitted Informed consent. The procedures that followed had No: P.T. REC/012/002277 that approved by the Institutional Ethical Committee Clearance of the Faculty of Physical Therapy at Cairo University. The study had registration number NCT registered on Clinicaltrial.gov.

A total of one hundred and seventy children with overflow retentive stool incontinence were evaluated for eligibility. Twenty-seven children did not complete the treatment course, fifty-eight child excluded due to unresponsiveness or non-compliance to our protocol, and eighty-six child was divided randomly into two groups.

The children were selected according to these criteria: (i) Children's aged ranged from four to fourteen years, (ii) children were from both sexes, (iii) children had a history of overflow retentive stool incontinence. Other children were excluded from our study as they met one of the following criteria: (i) children had suspicion of Hirschsprung's disease, (ii) children had anorectal malformation, (iii) children had organic obstruction, (iv) children failed to complete treatment (if cramping abdominal pain or vomiting occurred), (v) children required bowel surgery.

Group A: Senna based laxative

Initial cleanout protocol for dis-impaction of the colon with the administration of one or two enemas per day with 20 ccs/Kg warm tap water with a salt enema (0.9 % saline can be made by adding 1.5 teaspoons of salt to 960 ml of water) (**Levitt 2010**) till been clean by radiologically. If initial dis-impaction was failed or not tolerated, shift to dis-impaction under general anesthesia.

Single 10 mg dose senna was given with the start of impaction. After dis-impaction; senna dose was increased if needed by 10 mg/clinic visit/week till achieving no soiling; Documentation of both initial effective starting dose and the time slipped till no soiling. Follow-up visits every month unless soiling recurs if soiling happens; additional dose (by 10 mg) was done. Treatment was continued for 6 months.

At the end of 6 months, the effective ending dose (maintenance dose) was documented.

Group B: Senna based laxative with massage

Laxative treatment as group A in addition to massage technique.

The massage technique was based upon the Tactile Stimulation Method of Birkestad that primarily consists of palm-to-skin stroking, gentle pressure and static touch (**Birkestad 1999**).

The patients lying in a comfortable relaxed supine position and physiotherapist performed slow circular clockwise movements on the abdomen, throw tangential pushing, with digital pulp, slow and gradual pressure, with fingers inclination 45

degrees (**Harrington & Haskvitz 2006**). The pressure applied to the abdomen on each point for 1 min, beginning with the ascending colon, transverse colon, descending colon and sigmoid; this sequence was repeated approximately 15 min. The therapist teaches the parents this technique and asked them to apply at home 3 times/day for 15 min.

Statistical analysis

The statistical analysis was conducted by using statistical SPSS Package program version 25 for Windows (SPSS, Inc., Chicago, IL). Data were normally distributed by using the Shapiro-Wilk test (parametric data). Additionally, testing for the homogeneity of variance revealed that there was no significant difference ($P>0.05$). Quantitative descriptive statistics included the mean and standard deviation for demographic data (age, weight, height, and BMI), constipation starting dose, constipation end dose, and time till not soiling variables. Qualitative descriptive statistics included number (percentage) for gender, area, breastfeeding, previous incomplete therapy for constipation, full urinary continence, fissure, psychosocial problems, developmental delay, and history of delayed passage of meconium variables. Using paired t-test to compare between rural area and the urban area within massage group and without massage group for constipation starting dose, constipation end dose, and time till not soiling variables. Using independent t-test to compare between massage group and without massage group for demographic data (age, weight, height, and BMI), constipation starting dose, constipation end dose, and time till not soiling variables. Also, to compare between two groups (massage group and without massage group) within the rural area and urban area for constipation starting dose, constipation end dose, and time till not soiling variables. Chi-square test used to compare between massage group and without the massage group for qualitative variables. All statistical analyses were significant at the level of probability ($P \leq 0.05$).

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