

TITLE: Efficacy of Bolus Lukewarm Saline and Yoga (Shankh Prakhshalana) as Colonoscopy Preparation – Interim Analysis of Randomized, Endoscopist Blinded Study

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ABSTRACT BODY:

Purpose: Bolus lukewarm saline and Yoga (Shankh Prakhshalana) was as efficacious as Halflytely® + Dulcolax® for colonoscopy preparation. We report the interim analysis of this study with an emphasis on efficacy and adverse events.

Methods: The protocol was approved by the IRB at WHMC. Patients with salt-sensitivity, arthritis limiting Yoga postures, hypertension, congestive heart failure and renal dysfunction were excluded. Group A (n=55) drank 0.9N lukewarm saline in bolus form (16 oz. in 1- 2minutes or 8 oz. in less than a minute) and performed a defined set of yoga exercises (known as "Shankh prakhshalana") as described on a provided DVD. Group B (n=53) followed Halflytely® with Dulcolax® prep as suggested by the manufacturer. All patients were directed to take only clear liquids after 12 pm the day before colonoscopy. All colonoscopies were performed by a single, blinded endoscopist at a JCAHO certified outpatient GI clinic. Colon prep was assessed on a 4 point grading scale; a score of 1 was given to a poor preparation, 2 to suboptimum preparation, 3 to optimum prep, and 4 to excellent prep. Colon cleansing was scored in six regions - rectum, sigmoid, left colon, transverse colon, right colon, and cecum-for a minimum score of 6 and a maximum of 24. Scores of 1-6 corresponded with poor cleaning, 7-12 with suboptimum, 13-18 with optimum, and 19-24 with excellent. Photographs were taken to substantiate the grading system. Blood was drawn before and after prep to check for electrolyte imbalance. Weight and vitals were also documented. All patients reported the amount of solution drank and evaluated their preps regarding palatability, ease of prep, willingness to repeat prep, side effects.

Results: Group A and B total scores did not differ significantly ($p < 0.13$), Mean (SD) 17.73 (5.92) and 19.53 (3.52), respectively). In Group A, 48 of 55 patients (87.27%) had excellent or optimum preparation, compared to 50 of 53 patients (94.34%) in Group B ($p < 0.25$). None of the patients in both groups had any clinically significant electrolyte imbalance. Minor side effects, predominantly nausea and abdominal cramps were reported in 69.1% of patients in group A and 56.6% of patients in group B. A trend towards weight loss (0.57lbs on average) was observed in group A.

Conclusion: In this interim analysis, Bolus lukewarm saline and Yoga (Shankh Prakhshalana/Shudh) was no different from Halflytely® + Dulcolax® in the quality of bowel preparation, judged by total colon prep score. In contrary to the previous studies of normal saline colon preps, Bolus lukewarm saline and Yoga colon prep is associated with weight loss rather than weight gain. More precise estimates of efficacy and adverse event rates will be obtained at the final analysis.

Gastric Emptying Pattern

