

## **Efficacy of Lukewarm Saline Water and Exercise as Colonoscopy Preparation – A Randomized, Endoscopist Blinded Study**

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**Purpose:** Normal Saline (7 litres) has been used in the past for colonoscopy preparation but did not become common because of marked weight gain and salt retention. In our pilot study, 0.9N lukewarm saline water (LWSW)(3 litres) and exercise (EXE) were used as preparation for colonoscopy. Results were very encouraging, and we were inspired to conduct this randomized, endoscopist blinded study.

**Methods:** After IRB approval, 53 patients were randomized into two groups. Patients with salt-sensitivity, hypertension, congestive heart failure and renal dysfunction were excluded. Group A (n=26) drank 0.9N LWSW and performed a defined set of yoga exercises (known as "Shankh prakshalana") as described on a provided DVD. Group B (n=27) 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. All patients reported the amount of solution drank and evaluated their preps regarding palatability, ease of prep, willingness to repeat prep, side effects and time required to complete the prep. Total scores were compared via the Mann-Whitney (MW) test.

**Results:** Group A and B total scores did not differ significantly (Mann-Whitney test  $p < 0.13$ , Mean (SD) 15.8 (6.5) and 18.9 (3.7), respectively). In Group A, 21 of 26 patients (81%) had excellent or optimum preparation, compared to 25 of 27 patients (93%) in Group B ( $p < 0.25$ , Fisher exact test). None of the patients had any electrolyte imbalance. 72% of patients in group A and 62% of patients in group B reported minor side effects, predominantly nausea and abdominal cramps. There were no differences in palatability rating and willingness to repeat prep.

**Conclusion:** In this preliminary study, LWSW and exercise was no different from Halflytely® + Dulcolax® in the quality of bowel preparation, whether judged by total colon prep score or by the rate of excellent/optimum preps. More precise estimates of efficacy and adverse event rates will be obtained in a larger scale randomized clinical trial of 200 patients.

**Disclosure:** Dr. Vijaypal Arya - President Vikalp Inc. Dr. Kalpana Arya Gupta - no financial relationship Swarn Arya - no financial relationship.