

# Prospective, Randomized Comparison of Castor Oil and Sodium Phosphate Preparation for Barium Enema

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**Objective:** To compare castor oil and sodium phosphate preparation (Swiff) in patients' satisfaction, efficacy for colon cleanness, side effects, and prices.

**Material and Method:** One hundred patients referred for barium enema were randomized to receive castor oil ( $n = 50$ ) and sodium phosphate preparation ( $n = 50$ ). They graded their satisfaction using a 5-point scale (easy, acceptable, slightly difficult, extremely difficult, and unacceptable). The efficacy for colon cleanness was graded by two radiologists using a 5-point scale (excellent, easy for evaluation, acceptable, difficult for evaluation, and unacceptable). Side effects were evaluated by patients' vital signs, total number of bowel frequency, and 10 associated symptoms.

**Results:** Both preparations revealed no difference in patients' satisfaction ( $p = 0.882$ ) and efficacy of colon cleanness ( $p = 0.130$ ). Sodium phosphate preparation was more expensive (79 vs. 10 Baht) and caused higher number of bowel frequency ( $p < 0.001$ ).

**Conclusion:** With a cheaper price, castor oil was comparable with sodium phosphate preparation in patients' satisfaction and efficacy of colon cleanness.

**Keywords:** Barium sulfate, Castor oil, Cathartics, Colon, Enema, Phosphates, Sodium phosphate

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Colonic preparation is essential and inevitable to maximize colonic visualization in any colonic procedures (direct colonoscopy, virtual colonoscopy, barium enema, etc.). There are many recommended regimens for colonic preparations, in either oral or enema form. Prior studies<sup>(1-3)</sup> preferred oral colonic preparation than enema form due to its higher efficacy for colon cleanness, better tolerability, and more cost-effectiveness.

Even though there are many widely used oral preparations, there is no agreement on the best and the most cost-effective preparation for barium enema. Castor oil, an oral colonic preparation routinely used in the authors' department, is highly efficacious for colon cleanness, safety, and cheap. The only disadvantages

are unpleasant taste and smell which may decrease the patients' compliance and cause inadequate bowel preparation. The present study aimed to compare castor oil with monobasic and dibasic sodium phosphate preparation (Swiff), another oral preparation that claimed to be more palatable and very effective for colon cleanness. Because it was expected that there would be no difference in colon cleanness between these two preparations, the present study was focused primarily on comparison of patients' satisfaction and secondarily on the efficacy for colon cleanness, side effects, and prices.

## Material and Method

### Sample size estimation

Sample size was calculated based on a primary study endpoint *i.e.*, patients' satisfaction, using a

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5-point ordinal scale (1 = easy, 2 = acceptable, 3 = slightly difficult, 4 = extremely difficult, and 5 = unacceptable), which was adapted from Bini et al<sup>(3)</sup>. The satisfaction scores were grouped as “satisfied group” if score  $\leq 2$  and “unsatisfied group” if score  $> 2$ . Due to no prior reports on patients’ satisfaction of these two preparations, it was anticipated that subjects in the sodium phosphate group would be more satisfied than those in the castor oil group (95% vs. 75%). On the assumption of these satisfaction levels, a sample size of 50 participants would be required in each group (a total of 100) to demonstrate the superiority of sodium phosphate at the two-sided significant level of 5% with a power of 80%.

### **Patients**

The present study was approved by Siriraj Hospital institutional review board. Between March and August 2006, 100 cooperated adult patients, referred to Siriraj Department of Radiology (a tertiary-cared, 3000-bedded university hospital) for barium enema, were recruited in the present study. Patients with ascites, heart failure, or renal insufficiency were excluded to prevent possible adverse effect of electrolyte imbalance, which was a reported complication from sodium phosphate preparation<sup>(4-8)</sup>. Patients with prior colonic surgery were also excluded from the present study to avoid the difficulty in colon cleanliness evaluation. After signing consent forms, patients were equally randomized into two groups according to a computer-generated list from a statistician using a block of four randomizations. Fifty patients received castor oil (castor oil group) and the other fifty patients received monobasic and dibasic sodium phosphate (sodium phosphate group) for colonic preparation.

### **Colonic preparations**

Subjects in the castor oil group received a 30-ml bottle of castor oil (B.L.Hua&Co.,Ltd., Bangkok, Thailand) at 8.00 pm the night before barium enema. Subjects in sodium phosphate group received a total of 90 ml of monobasic and dibasic sodium phosphate (Swift, Berlin Pharmaceutical Industry Co., Ltd., Bangkok, Thailand), with the first 45 ml at 4.00 pm and second 45 ml at 8.00 pm the night before the barium enema. Both groups had liquid or clear diet with low residues for two days before barium enema. All patients drank a large amount of water in the night before the barium enema (at least ten 240-ml glasses of water with additional one glass every time they had bowel frequency). In addition, all patients had warm

water enema twice in the morning before barium enema to promote the efficacy of colon cleanliness.

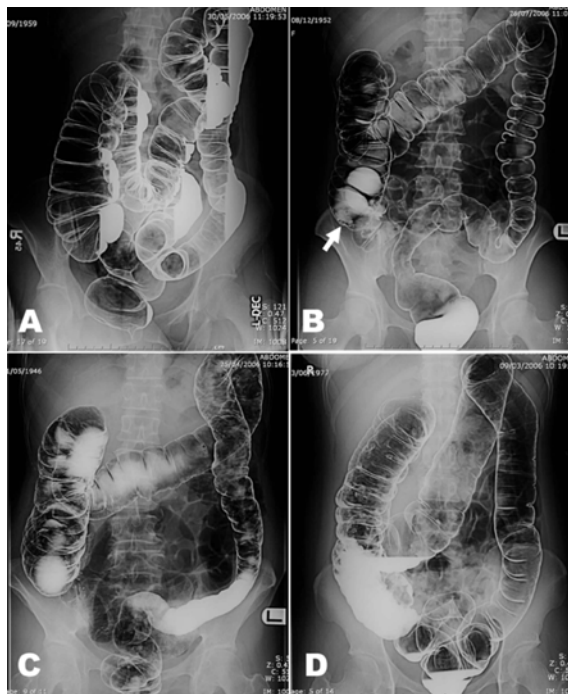
### **Data record**

Just before the warm water enema, all patients were interviewed by one of our investigators (BR) who was blinded to the type of received preparation. The recorded data were age, sex, vital signs (systolic and diastolic blood pressure and pulse rate), total number of bowel frequency after receiving the oral preparation, and 10 associated symptoms (dizziness, nausea, vomiting, abdominal cramping, rectal pain, incontinence, thirsty, palpitation, fatigue, and fainting). Each symptom was graded by patients as score 0-2 (0 = none, 1 = mild, and 2 = severe), resulting in a total score of 0-20. Patients were then asked to grade their attitude / satisfaction of the received preparations, using a 5-point ordinal scale (1 = easy, 2 = acceptable, 3 = slightly difficult, 4 = extremely difficult, and 5 = unacceptable). The satisfaction scores were grouped as “satisfied group” if score  $\leq 2$  and “unsatisfied group” if score  $> 2$ .

All patients had barium enema studies, which were subsequently interpreted by radiologists who were on duty that day. All barium enema pictures were sent to Picture Archiving and Communicating System (PACS) and retrospectively reviewed by two gastrointestinal radiologists (PA and AC, with 10 and 8 years of experience with barium enema). Both radiologists were blinded to either type of received preparation or the data in a case record form. They graded the adequacy of colon cleanliness according to the ease of barium enema interpretation using ordinal grade 1-5 [1 = excellent (colon is totally clean), 2 = easy for evaluation (few remaining stools, interpretation is easy), 3 = acceptable (some remaining stools, interpretation could be done reasonably), 4 = difficult for evaluation (lots of stool, barium enema could be evaluated with difficulty), and 5 = unacceptable (full of stools, study could not be evaluated)] (Fig. 1). The colon cleanliness scores were grouped as “adequate group” if score  $\leq 3$  and “inadequate group” if score  $> 3$ .

### **Statistical analysis**

The agreement in grading of colon cleanliness between two readers was assessed by weighted kappa using a quadratic weight along with its 95% confidence interval (CI). To compare the difference between castor oil and sodium phosphate groups in terms of patients’ satisfaction score (1-5,  $\leq 2$  vs.  $> 2$ ),



**Fig. 1** Barium enema pictures show the difference in grading of colon cleanliness. (A) Grade 1: excellent. (B) Grade 2: easy for evaluation. Notice few remaining stools at cecum (arrow). (C) Grade 3: acceptable. Notice more amount of remaining stools in colon compared to (B), however the visualization of whole colon could be done by changing patient's positions. (D) Grade 4: difficult for evaluation. Notice more amount of remaining stools in colon compared to (C). The visualization of whole colon needs close observation during fluoroscopy and changing patient's positions

colon cleanliness score (1-5,  $\leq 3$  vs.  $> 3$ ), and each of 10 associated symptoms, a Fisher's exact test was applied. A Mann-Whitney U test was employed to compare the total number of bowel frequency and total score of associated symptoms between two preparations.

All statistical data analyses were performed using SAS 8.1 (Cary, NC) and StatXact 6. A 2-sided p-value of less than 0.05 was considered a statistical significance.

## Results

One hundred patients included in the present study were 39 males, 61 females with age range between 22-82 years (mean = 53.0, SD = 13.5). Subjects in the castor oil and sodium phosphate groups were

comparable with regard to gender (female: 64% vs. 58%) and age (mean  $\pm$  SD: 53.0  $\pm$  13.8 vs. 53.0  $\pm$  13.4).

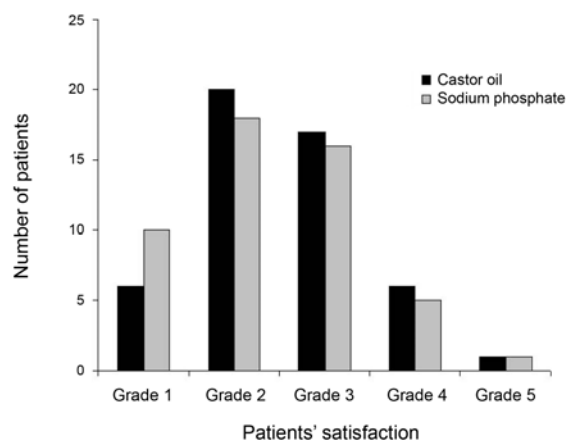
Among 100 recruited patients, four (two in each group) were excluded from the evaluation of colon cleanliness due to incomplete barium enema [three patients (two in the sodium phosphate group and one in the castor oil group) had obstructed colonic CA and one patient (in castor oil group) had rectovaginal fistula]. However, all 100 patients were included for the evaluation of patients' satisfaction and side effects.

## Patients' satisfaction

Twenty-six patients in the castor oil group (26/50 = 52%) graded their satisfaction as easy (grade 1) or acceptable (grade 2) and were grouped in the "satisfied group" compared to 28 patients in the sodium phosphate group (28/50 = 56%) (Fig. 2) [Fisher's exact test:  $p = 0.841$ , 95% CI of difference (sodium phosphate-castor oil) = -15.4%, 23.1%]. One patient in each group (2%) graded the colonic preparation as unacceptable (grade 5). Comparison of satisfaction score (1-5) between the two preparations also showed no statistical difference (Fisher's exact test:  $p = 0.882$ ).

## The efficacy of colon cleanliness

The efficacy of colonic preparation in 96 patients was evaluated by two readers. Reader 1 assigned the grade of colon cleanliness as 1-4 compared to grade 2-4 by reader 2 (Table 1). None was graded as grade 5 (unacceptable). The observed agreement



**Fig. 2** Comparison of patients' satisfaction between castor oil and sodium phosphate groups. Overall, there is no significant difference between these 2 groups ( $p = 0.882$ )

**Table 1.** The grading of colon cleanness evaluated by 2 readers. The agreement in grading of 2 readers (as displayed as underlined numbers) was 78.1% (75/96)

	Reader 2's grading*					Total
	1	2	3	4	5	
Reader 1's grading*	1	<u>0</u>	4	0	0	4
	2	0	<u>17</u>	7	0	24
	3	0	3	<u>56</u>	2	61
	4	0	0	5	<u>2</u>	7
	5	0	0	0	0	0
Total		0	24	68	4	96

\* Grade: 1 = excellent, 2 = easy for evaluation, 3 = acceptable, 4 = difficult for evaluation, and 5 = unacceptable.

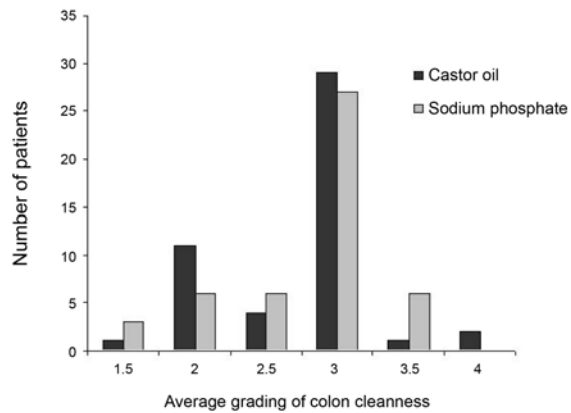
between the two readers was 78.1% (75/96) with the weighted kappa of 0.67 (95% CI = 0.57, 0.78). In all 21 cases (21.9%) with disagreement between the two readers, the disagreement was not more than one grade. Thus, the average of two readers' grading of colon cleanness (range 1.5-4) was used to represent the degree of colon cleanness in each patient (Fig. 3). The average cleanness scores were very similar for the sodium phosphate and castor oil groups (mean  $\pm$  SD: 2.78  $\pm$  0.54 vs. 2.75  $\pm$  0.54, median: 3.0 vs. 3.0) with no significant statistical difference (Fisher's exact test:  $p = 0.130$ ). If the average cleanness score of less than or equal to 3 were considered as adequate, sodium phosphate resulted in adequate colon cleanness for 87.5% (42/48) compared to 93.8% (45/48) in castor oil (Fisher's exact test:  $p = 0.486$ , 95% CI of difference (sodium phosphate-castor oil) = -19.5%, 6.2%).

#### Side effects

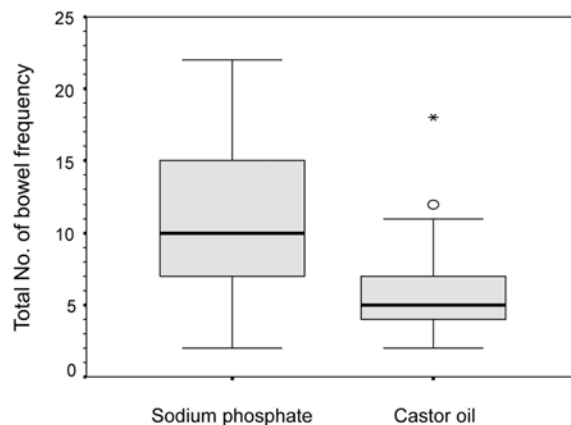
Mean systolic blood pressure in the castor oil group and sodium phosphate group were 127.0 (range from 100-170) and 122.8 (range from 90-160) mmHg, respectively. Mean diastolic blood pressure in the castor oil group and sodium phosphate group were 81.0 (range from 60-110) mmHg and 79.4 (range from 60-100) mmHg, respectively. None in both groups had systolic blood pressure less than 90 mmHg and diastolic blood pressure less than 60 mmHg. For pulse rate, mean pulse rate in castor oil group and sodium phosphate group were 79.9 (range from 56-104) and 75.3 (range from 56-112) beats per minute, respectively. None had pulse rate more than 120 beats per minute. Only one patient (2%) in each group had a pulse rate

more than 100 beats per minute (104 and 112 beats per minute in the castor oil group and sodium phosphate group, respectively). A patient with a pulse rate of 104 beats per minute in the castor oil group was also had a mild degree of palpitation symptom.

The total number of bowel frequency was higher in the sodium phosphate group than castor oil group (Fig. 4). The means ( $\pm$  SD) of total number of bowel frequency in each group were 11.1  $\pm$  5.1 and 5.8  $\pm$  3.0, respectively ( $p < 0.001$ ).



**Fig. 3** The average grading of colon cleanness in castor oil and sodium phosphate groups. Overall, there is no significant difference between these 2 groups ( $p = 0.130$ )



**Fig. 4** The total number of bowel frequency in castor oil and sodium phosphate group. Notice the significant higher in number of bowel frequency in sodium phosphate group than castor oil group (mean = 11.1  $\pm$  5.1 and 5.8  $\pm$  3.0,  $p < 0.001$ )

Regarding each of 10 associated symptoms (dizziness, nausea, vomiting, abdominal cramping, rectal pain, incontinence, thirsty, palpitation, fatigue, and fainting), only the nausea symptom score tended to be higher in the sodium phosphate group ( $p = 0.067$ ) (Table 2). In terms of the total score of 10 associated symptoms (ranging from 0 to 8), it tended to be higher in the sodium phosphate than the castor oil group (mean  $\pm$  SD:  $3.26 \pm 2.07$  vs.  $2.66 \pm 1.78$ ), however this did not reach the significant level ( $p = 0.142$ ).

### Prices

The price of a 90 ml-bottle of monobasic and dibasic sodium phosphate (Swift) was 79 Baht, which was significantly higher than a 30-ml bottle of castor oil (10 Baht).

### Discussion

The present study showed no significant difference in the efficacy of colon cleanness between both groups. Although these two preparations differed in volume and method of intake, both are recommended, labeled technique. Thus, these differences could not be considered as a limitation of the present study. Since nausea may cause inadequate sodium phosphate preparation intake and result in a decrease in its efficacy for colon cleanness, one may think of the addition of antiemetic drug to increase the efficacy of sodium phosphate preparation. Nevertheless, with the fact that there was no significant difference in vomiting between these two groups ( $p = 0.487$ ), the adequacy of drug intake of these two preparations should not be different. Addition of antiemetic drug

**Table 2.** Comparison of ten associated symptoms between the castor oil and sodium phosphate groups

Symptoms	Colonic Preparations	Symptom score			Exact p-value
		None (0)	Mild (1)	Severe (2)	
Dizziness	Castor oil	42 (84%)	8 (16%)	0	1.000
	Sodium phosphate	41 (82%)	9 (18%)	0	
Nausea	Castor oil	28 (56%)	20 (40%)	2 (4%)	0.067
	Sodium phosphate	17 (34%)	28 (56%)	5 (10%)	
Vomiting	Castor oil	47 (94%)	3 (6%)	0	0.487
	Sodium phosphate	44 (88%)	5 (10%)	1 (2%)	
Abdominal cramping	Castor oil	31 (62%)	17 (34%)	2 (4%)	0.750
	Sodium phosphate	34 (68%)	15 (30%)	1 (2%)	
Rectal pain	Castor oil	34 (68%)	14 (28%)	2 (4%)	0.548
	Sodium phosphate	34 (68%)	16 (32%)	0	
Incontinence	Castor oil	35 (70%)	12 (24%)	3 (6%)	0.777
	Sodium phosphate	33 (66%)	15 (30%)	2 (4%)	
Thirsty	Castor oil	31 (62%)	19 (38%)	0	1.000
	Sodium phosphate	30 (60%)	20 (40%)	0	
Palpitation	Castor oil	47 (94%)	3 (6%)	0	0.487
	Sodium phosphate	44 (88%)	6 (12%)	0	
Fatigue	Castor oil	34 (68%)	16 (32%)	0	0.303
	Sodium phosphate	28 (56%)	21 (42%)	1 (2%)	
Fainting	Castor oil	47 (94%)	3 (6%)	0	0.200
	Sodium phosphate	42 (84%)	8 (16%)	0	

will complicate the preparation process and increase the total preparation cost.

Although many patients, who experienced these two preparations, claimed that sodium phosphate preparation was more palatable than castor oil, the present study showed no statistical difference in overall patients' satisfaction between these two groups. This could be explained by the facts that sodium phosphate preparation tended to cause more nausea symptom and increased number of bowel frequency than castor oil.

The present study had some limitations. First, the authors' department routinely adds two warm water enema before barium studies to maximize the adequacy of colonic cleanness. Although both groups received the same enema technique, one may suspect that the result of colon cleanness was influenced by the enema process. Prior studies<sup>(2,3)</sup> showing superior quality of oral preparation over enema technique make us think that the result of colon cleanness in each group was mainly from oral preparation. However, a new study comparing two oral preparations without enema technique should be carried out.

Second, there was no laboratory evaluation included in the present study. Sodium phosphate preparations were prior reported to cause electrolyte imbalance (e.g. hyperphosphatemia, hypocalcemia) and renal problems<sup>(4-8)</sup>. Therefore, patients with potential problems with electrolyte imbalance (renal insufficiency, heart failure or ascites) were excluded from the present study. Although, the presented patients showed no clinical signs of such complications, laboratory evaluation should be obtained to identify subclinical abnormalities.

Third, there was no record of baseline blood pressure and pulse rate of patients before receiving bowel preparations. Therefore, this could make it difficult to appreciate that there was no change in the patients' vital signs after receiving bowel preparations.

In summary, using castor oil should decrease the cost of bowel preparation process but maintain the same quality and patients' satisfaction compared to sodium phosphate preparation.

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## การศึกษาเปรียบเทียบน้ำมันละหุ่งและยาระบายกลุ่มไซเดียมฟอสเฟต ในการเตรียมลำไส้ใหญ่ ก่อนการตรวจโดยการสวนแบ่ง

ปิยาภรณ์ อภิสารธนรักษ์, เบญจพร โรจนอารีย์, จุฬาลักษณ์ โกมลตรี, อภิญญา เจริญศักดิ์, อนุชา อภิสารธนรักษ์, นฤมล ศรีสุธาพรรณ ฮาร์โกรฟ

**วัตถุประสงค์:** เพื่อเปรียบเทียบน้ำมันละหุ่งและยาระบายกลุ่มไซเดียมฟอสเฟต (สวิฟท์) ทั้งในด้านความพึงพอใจของผู้ป่วย ประสิทธิภาพในการทำความสะอาดลำไส้ใหญ่ ผลข้างเคียง และราคา

**วัสดุและวิธีการ:** สุ่มผู้ป่วยที่มารับการตรวจลำไส้ใหญ่โดยการสวนแบ่ง 100 คน โดย 50 คน ได้น้ำมันละหุ่ง อีก 50 คน ได้ยากกลุ่มไซเดียมฟอสเฟต ผู้ป่วยให้คะแนนความพึงพอใจโดยแบ่งเป็น 5 ระดับ ประสิทธิภาพของยาระบายถูกประเมินโดยรังสีแพทย์ 2 คน โดยแบ่งความสะอาดของลำไส้ใหญ่เป็น 5 ระดับ ผลข้างเคียงถูกประเมินโดยดูจากสัญญาณชีพของผู้ป่วย จำนวนครั้งที่ถ่าย และอาการข้างเคียง

**ผลการศึกษา:** ยาระบายทั้ง 2 ชนิดไม่มีความแตกต่างกันทั้งในด้านความพึงพอใจของผู้ป่วย ( $p = 0.882$ ) และประสิทธิภาพ ( $p = 0.130$ ) แต่ยากกลุ่มไซเดียมฟอสเฟตมีราคาแพงกว่า (79 vs. 10 บาท) และมีจำนวนครั้งที่ถ่ายมากกว่า ( $p < 0.001$ )

**สรุป:** น้ำมันละหุ่งช่วยประหยัดเงินมากกว่ายากกลุ่มไซเดียมฟอสเฟต โดยไม่มีผลต่อความพึงพอใจของผู้ป่วย และประสิทธิภาพในการทำความสะอาดลำไส้ใหญ่

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