ORIGINAL INVESTIGATION

The Effect of Oral Sodium Phosphate Drug Products on Renal Function in Adults Undergoing Bowel Endoscopy

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Background: Oral sodium phosphate solution (OSPS) preparations are preferred cleansing agents for colonoscopy because of ease of use and excellent preparation quality. Besides causing acute renal failure in some patients, the high phosphorus content can potentially cause chronic kidney damage to patients undergoing colonoscopy.

Methods: We carried out a retrospective study on patients with creatinine levels in the normal range who had undergone colonoscopy or flexible sigmoidoscopy using OSPS preparation from January 1998 to February 2005 and followed them for 1 year to determine its effects on their renal function. A control group of patients with similar comorbidities during this period were chosen to assess age-related decline in renal function in this population.

Results: A total of 286 patients were selected in the study group, and 125 patients were selected in the control group. Both groups had similar baseline characteristics. The baseline glomerular filtration rate (GFR) in the study group was 79 mL/min/1.73 m^2, which declined to 73 mL/min/1.73 m^2 at 6 months after exposure to OSPS preparation. This finding was significantly different from the control group, in whom the baseline GFR was 76 mL/min/1.73 m^2 and remained stable at 6 months. Linear regression analysis showed that use of angiotensin-converting enzyme inhibitors and/or angiotensin receptor blockers and the presence of diabetes were significant determinants of the fall in GFR after use of OSPS preparation.

Conclusions: Oral sodium phosphate solution preparation is associated with decline in GFR in elderly patients with creatinine levels in the normal range. Its routine use for elective and screening procedures should be discouraged in the elderly population.

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Colonoscopy and flexible sigmoidoscopy are currently the most commonly used procedures for colon cancer screening and detection. Patients use a bowel cleansing agent the day prior to improve the diagnostic utility of the procedure. Oral sodium phosphate solution (OSPS), oral sodium phosphate tablets (OSPT), and polyethylene glycol solutions (PEG) are the commonly used preparations because of their ease of use and their safety profile.[1] Compared with PEG, OSPS has the advantage of requiring a lower volume of fluid to be ingested (2 bottles of 45 mL each).[2] The package insert instructs that at least 72 oz (2016 g) of clear liquids should be ingested with OSPS preparation.

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A 90-mL volume of OSPS contains 43.2 g of monobasic sodium phosphate and 16.2 g of dibasic sodium phosphate, which makes up a total of 11.52 g of elemental phosphate.[2] This recently has been recognized as causing acute kidney injury (AKI).[3-6] First recognized in 2005 by a retrospective analysis of biopsy findings at the Columbia College of Physicians and Surgeons in New York, New York, acute phosphate nephropathy (APN) has emerged as a diagnosis for many cases of unexplained acute and chronic kidney disease (CKD) at many centers.[3,5] Acute phosphate nephropathy has been proposed as a separate diagnosis to distinguish it from nephrocalcinosis, which is usually associated with hypercalcemia.

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Because an increasing number of patients are believed to have AKI from the use of OSPS and OSPT as bowel cleansing agents, the Food and Drug adminis-

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Table 1. Demographics of the Study and Control Groups

Characteristic	Study Group (n=286)	Control Group (n=125)	*P* Value
Age at baseline, mean ± SD, y	68 ± 10	69 ± 8	.18[a]
Sex, No (%)			
Male	103 (36)	33 (26)	.06[b]
Female	183 (64)	92 (74)	
Race, No (%)			
White	244 (85)	103 (82)	.35[c]
African American	25 (9)	9 (7)	
Hispanic	16 (6)	12 (10)	
Asian	1 (0)	1 (1)	

[a] The 2-sample *t* test was used.
[b] The χ^2 test was used.
[c] The Fisher exact test was used.

tration (FDA) issued a Black Box warning recommending that OSPS preparations should be used with caution in patients with impaired renal function. Case reports of acute renal failure in patients with presumably normal renal function are now being reported. We have previously reported a series of 15 patients with APN who had been diagnosed at our institution over the past year.[7] Our data suggested that elderly white women may be at increased risk. Whether this is true in the general population or is a selection bias based on the higher probability of this subset population undergoing screening colonoscopy procedures is unknown. There is a belief that in addition to causing AKI, OSPS and OSPT may also cause a chronic decline in renal function that might not be recognized and possibly not associated with OSPS or OSPT as causative agents. Because of a paucity of data on the effect of OSPS and OSPT on renal function, we report our findings on patients who used OSPS as a bowel cleansing agent for colonoscopy from 1998 to 2005.

METHODS

All clinical and administrative data on patients at the Scott & White Clinic, Temple, Texas, are archived in a text-searchable electronic format. This also includes all demographic and billing data. These were reviewed to identify patients who had undergone colonoscopy or flexible sigmoidoscopy procedure between 1998 and 2005. This was then confirmed with medical chart review. Our gastroenterology department preferentially used OSPS preparation in most patients during this period unless the baseline creatinine level was greater than 1.5 mg/dL (to convert to micromoles per liter, multiply by 88.4). Hence, this was used as a cutoff level for inclusion of patients in the study.

All patients received the standard precolonoscopy instructions. The day before the colonoscopy, they were advised to not consume any solid food; to drink only clear liquids for breakfast, lunch, and dinner; and to drink an 8– to 16–fl oz (240-480 mL) glass of liquid each hour throughout the day to prevent dehydration. The compliance of patients with these recommendations could not be assessed in this retrospective analysis.

Patients who had undergone endoscopy procedures during hospitalization for acute indications, specifically gastrointestinal bleeding or inflammatory bowel disease exacerbation, or those undergoing a diagnostic evaluation for colon cancer were excluded. Patients who had decompensated heart failure, systemic lupus erythematosus, human immunodeficiency viral infection, polycystic kidney disease, a known history of CKD, and diabetes mellitus with overt proteinuria were also excluded. Patients who had major cardiac, vascular, or abdominal surgery during this period or who underwent any contrast-enhanced computed tomography within 4 weeks of laboratory blood draws were also excluded. Because of the impact of various drugs on renal function, patients who were initiated on therapy with or had a dose change in angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), or diuretics after the procedure or who were given a prescription for nonsteroidal anti-inflammatory drugs or sulfamethoxazole-trimethoprim during the study period were also excluded from the analysis.

Age, race, sex, and clinical data sufficient to calculate an abbreviated Modification of Diet in Renal Disease Study Group (MDRD) glomerular filtration rate (GFR) were collected. The creatinine level within the last 6 months before exposure to OSPS was recorded as the patients' baseline renal function. The creatinine concentration at 6 months and 1 year after the procedure was recorded. For the purpose of this study, laboratory values were obtained from medical chart review at the following time intervals: baseline (within 6 months before colonoscopy) and at 6 months (6-9 months) and 1 year (12-18 months) after colonoscopy.

Glomerular filtration rate was calculated using the abbreviated MDRD formula[7]:

$$\text{GFR (mL/min/1.73 m}^2) = 186 \times (\text{Scr})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if Female}) \times (1.210 \text{ if African American}),$$

where Scr indicates serum creatinine.

Comorbid conditions of diabetes mellitus, hypertension and coronary artery disease and medications (ACEIs, ARBs, and diuretics) were noted. The clinical course of patients and laboratory data were followed until May 2006.

A control group of patients was obtained from more than 1000 patients from the database who were in a similar age range. This group comprised (1) patients who had not undergone colonoscopy at any time and (2) patients who had undergone colonoscopy prior to January 1996 and not after and their serum creatinine level following colonoscopy was the same as the precolonoscopy creatinine level. This control group was chosen so that the normal age-related decline in GFR could be determined. The creatinine measurement was recorded at time zero (baseline) level for these patients. The criteria for 6-month and 1-year laboratory values were similar to the study group. Exclusion criteria and comorbid conditions and medication data were identical to the study group.

Age, sex, and racial characteristics of the 2 groups were compared using the 2-sample *t* test, χ^2 test, and Fisher exact tests, respectively. The 2-sample *t* test was used to compare the creatinine level and GFR between the study and control groups. The χ^2 test was used to compare group characteristics of diabetes, hypertension, and use of angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), and diuretics. The data for the study and the control groups were then combined, and multivariate linear regression analysis was used to assess the relationship of drugs and comorbid conditions to the decline in renal function. A categorical "group effect" variable group was defined to specify whether the patient was in the study or the control group and was used in the multivariate regression model. $P < .05$ was considered significant.

RESULTS

More than 3000 patients underwent colonoscopy between January 1, 1998, and December 31, 2005. A total of 286 patients were eligible for the study group following application of the exclusion criteria. The baseline characteristics of the patients are outlined in **Table 1**. Their

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Table 2. Creatinine and GFR Trends in the Study and Control Groups

	Creatinine Level			GFR		
Evaluation Time	Study Group, Mean (SD), mg/dL (n=286)	Control Group, Mean (SD), mg/dL (n=125)	*P* Value	Study Group, Mean (SD), mL/min/1.73 m² BSA (n=286)	Control Group, Mean (SD), mL/min/1.73 m² BSA (n=125)	*P* Value
Baseline	0.92 (0.22)	0.92 (0.23)	.76[a]	79.33 (21.98)	76.25 (23.42)	.20[a]
6 mo	1.01 (0.32)	0.94 (0.25)	<.001[b]	73.31 (24.93)	76.83 (29.88)	.002[b]
1 y	1.04 (0.33)	0.96 (0.33)	<.001[c]	71.33 (24.66)	74.98 (24.88)	<.001[c]

Abbreviations: BSA, body surface area; GFR, glomerular filtration rate.
SI conversion factor: To convert creatinine to micromoles per liter, multiply by 88.4.
[a] Baseline measurements between the 2 groups were compared using the 2-sample *t* test.
[b] Changes from baseline to 6 months between the 2 groups were compared using the 2-sample *t* test.
[c] Changes from baseline to 1 year between the 2 groups were compared using the 2-sample *t* test.

mean age was 68 years, and there was a preponderance of white (85%) and female (64%) patients.

For the control group, 125 patients were selected, and their demographic data are given in Table 1. The mean age for this group was 69 years. There was again a preponderance of white (82%) and female (74%) patients.

Table 2 illustrates the trend of the renal function in both the colonoscopy and the control group. The values are reported as mean (SD). The baseline creatinine value for the study group varied from 0.5 to 1.5 mg/dL (0.92 [0.22] mg/dL), with a calculated MDRD GFR ranging from 35 to 143 mL/min/1.73 m² body surface area (BSA) (79 [22] mL/min/1.73 m² BSA). The creatinine value at the 6-month time interval ranged from 0.4 to 3.0 mg/dL (1.01 [0.32] mg/dL). The corresponding GFR was 22 to 175 mL/min/1.73 m² BSA (73 [25] mL/min/1.73 m² BSA). The creatinine deterioration that happened right after the procedure continued to stabilize at 1 year, with the creatinine level ranging from 0.5 to 2.4 (1.04 [0.33] mg/dL). The corresponding GFR for this period was 20 to 170 mL/min/1.73 m² BSA (71 [25] mL/min/1.73 m² BSA).

To assess the effects of time and similar comorbidities on the renal function, the control group of 125 patients was analyzed. The baseline creatinine value for this group varied from 0.5 to 1.5 mg/dL (0.92 [0.23] mg/dL), with a calculated GFR between 36 and 170 mL/min/1.73 m² BSA (76 [23] mL/min/1.73 m² BSA). The creatinine value at the 6-month time interval ranged between 0.5 and 1.5 mg/dL (0.94 [0.25] mg/dL). The corresponding GFR ranged from 36 to 170 mL/min/1.73 m² BSA (77 [30] mL/min/1.73 m² BSA). At the 1-year point, the creatinine value was 0.5 to 3.3 mg/dL (0.95 [0.32] mg/dL). The corresponding GFR for this period was between 14 and 170 mL/min/1.73 m² BSA 75 [25] mL/min/1.73 m² BSA).

There was no significant difference between the prevalence of diabetes mellitus and hypertension between the 2 groups. Likewise, there was no difference in the use of ACEIs, ARBs, or diuretics between the 2 groups. These data are given in **Table 3**.

Other risk factors believed to be significant have been the use of ACEIs, ARBs, and diuretics. To further identify the variables involved in the deterioration of renal function in patients who were exposed to the OSPS preparation, we fit a linear regression model with the dependent variable (change in creatinine level and MDRD GFR from baseline to 6 months) and the following independent variables: age, sex, race, ACEI and/or ARB use, diuretic use, diabetes mellitus, and hypertension for creatinine; and ACEI and/or ARB use, diuretic use, diabetes mellitus, and hypertension for MDRD GFR.

Table 3. Baseline Data on Diabetes Mellitus, Hypertension, and Use of ACEIs, ARBs, and Diuretics in the Study and Control Groups

Variable	Study Group, No. (%) (n=286)	Control Group, No. (%) (n=125)	*P* Value[a]
Hypertension	272 (95)	117 (94)	.53
Diabetes	130 (45)	63 (50)	.36
ACEIs and/or ARBs	174 (61)	70 (56)	.36
Diuretics	133 (47)	54 (43)	.54

Abbreviations: ACEIs, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers.
[a] The χ^2 test was used.

Results indicated that the change in 6-month creatinine value was significantly related to the baseline creatinine and group effect variable (colonoscopy group) (**Table 4**). Diabetes mellitus, use of ACEIs and/or ARBs, and the group effect variable had a significant effect on the MDRD GFR at 6 months besides the baseline GFR (**Table 5**).

COMMENT

Oral sodium phosphate solution is a common preparation that is available over the counter for general use. It has been a preferred agent for preparation for colonoscopy because it requires the patient to drink a smaller volume of solution for bowel cleansing compared with PEG preparations that use 4 L of PEG-electrolyte solution. We have previously reported a series of 15 patients with APN who were diagnosed at our institution over the past year.[8] These patients had an acute decline in renal function consistent with AKI related to OSPS use. Our findings suggest that the magnitude of the problem may be far greater than had been recognized.

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Table 4. Multivariate Linear Regression Model on Change in Creatinine Level From Baseline to 6 Months (R^2=0.065)[a]

Variable	Correlation Coefficient (95% CI)	P Value
Creatinine level at baseline	−0.156 (−0.263 to −0.048)[b]	.005[d]
Group effect	0.075 (0.028 to 0.123)[c]	.002[d]
Sex	0.038 (−0.009 to 0.086)	.11
Age at first creatinine measurement	0.000 (−0.002 to 0.003)	.82
Diuretics	0.019 (−0.029 to 0.067)	.44
Diabetes	−0.043 (−0.088 to 0.001)	.06
Hypertension	−0.044 (−0.144 to 0.055)	.38
ACEI/ARB use	0.038 (−0.009 to 0.086)	.11

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CI, confidence interval.

[a] The response variable is change in creatinine level from baseline to 6 months.

[b] For every 1-unit increase in creatinine level at baseline, all other explanatory variables remaining constant, the change in creatinine level decreases by 0.16 units.

[c] The change in creatinine level for the study group is 0.075 units higher than that for the control group when all other variables remain constant.

[d] Based on the multiple linear regression model above, creatinine level at baseline and group effect are significant variables on the change in creatinine level. The model is used to select the significant variables on the change in creatinine level rather than predicting change in creatinine level, since the R^2 value is low.

Table 5. Multivariate Linear Regression Model on Change in Glomerular Filtration Rate (GFR) From Baseline to 6 Months (R^2=0.093)

Variable	Correlation Coefficient (95% CI)	P Value
GFR at baseline	−0.217 (−0.304 to −0.129)	<.001[d]
Group effect	−5.568 (−9.653 to −1.482)[a]	.008[d]
Diuretics	−1.232 (−5.369 to 2.905)	.56
Diabetes	3.941 (0.083 to 7.799)[b]	.045[d]
Hypertension	2.611 (−6.055 to 11.278)	.55
ACEI/ARB use	−4.309 (−8.422 to −0.196)[c]	.04[d]

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; CI, confidence interval.

[a] The change in GFR for the treatment group is 5.57 units lower than that for control group when other variables remain constant.

[b] The change in GFR for the diabetes group is 3.94 units higher than that of the nondiabetes group when other variables remain constant.

[c] The change in GFR of the ACEI/ARB group is 4.3 units lower than that of the non-ACEI/ARB group when other variables remain constant.

[d] The response variable is change in GFR from baseline to 6 mo. Based on the multivariate linear regression model above, GFR at the baseline, group effect, diabetes, and ACEI/ARB use are significant variables on the change in GFR. The model is used to select significant variables on the change in GFR rather than predicting GFR change, since the R^2 value is low.

All of our patients had creatinine concentrations that were less than 1.5 mg/dL, the upper limit of normal for our laboratory. A patient may have a serum creatinine level that is at the upper limit of normal or barely above it and have a significant decrease in GFR if the serum creatinine measurement is the only test used to estimate renal function. This is demonstrated by the fact that we had patients with stage 3 CKD by the abbreviated MDRD GFR who had a serum creatinine level in our laboratory's normal range. The MDRD GFR is superior to the serum creatinine measurement in estimating renal function, especially in older individuals and in women.

The study group experienced a significant deterioration in GFR at 6 months, and there was a smaller drop in the GFR at 1 year. The magnitude of deterioration in creatinine was small by conventional standards. However, when absolute GFR is considered, it amounted to a loss of 6% of the total GFR over the period of 6 months and 8% of the GFR over a period of 1 year. Also, this is not a 1-time insult, since many people undergo these screening procedures every 5 to 10 years, which, depending on the life expectancy of the patients, could amount to 3 to 4 exposures in their lifetime.

In comparison, the control group of patients had a 1% loss of GFR from the baseline to 1 year, which is what is expected for their age distribution and comorbidities. The control population had a similar baseline creatinine value compared with the study group and also had a similar incidence of hypertension, diabetes, and use of ACEIs, ARBs, and diuretics as the study group. Previous studies have outlined hypertension as being a risk factor for APN. In our study, we found that 95% of the study group and 94% of the control group were hypertensive. Hypertension may not be a predisposing cause, but it is an associated condition based on its high incidence in this age group.

There is always a certain limitation with retrospective analysis about the other unidentified factors that might have influenced the outcomes. There may be as much as a 10% variability in the measurement of creatinine, which in the MDRD equation could translate to a significant change in the GFR. To minimize this error, we selected a large group of patients for analysis and used a control group of patients who had an age-expected decline in creatinine level and GFR.

Men are more likely than women to undergo screening endoscopic tests.[9,10] Our study group as well as the control groups had a distinct female preponderance. Of our population of 3013 patients who underwent colonoscopy, 58% were female, which is different from the national statistics.[9,10] This was a retrospective analysis, and the inclusion into the study involved the presence of laboratory results prior to the colonoscopy and at 6-month and 1-year intervals. It is possible that we may have further selected more female patients, since they are more likely than their male counterparts to be more compliant with office visits and laboratory work. Similarly, white patients are more likely to undergo screening tests, which accounts for their preponderance in our study and control groups.[9,10] Also, both groups involved patients older than 50 years, since these are the patients who undergo endoscopic screening procedures. Whether our results can be extrapolated to the male population and to different races and patients younger than 50 years needs to be analyzed further.

It is a matter of debate whether OSPS is the sole agent involved in the AKI or whether its nephrotoxic effects are evident in older patients who have some degree of underlying CKD and who are not compliant with the prescribed fluid intake for the OSPS. There are no data available concerning the fluid intake compliance of outpatients prescribed OSPS as a bowel cleansing agent who are not in a research study. Also, the safety studies on the use of OSPS for bowel cleansing did not monitor or

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test for the serum creatinine level or GFR, especially at 6 months. Furthermore, with the rising awareness regarding colon cancer screening, the number of patients undergoing the procedure has vastly increased and they are elderly.

The nephrotoxic effects may not be obvious in a regular physician's visit because the change in creatinine level may be trivial (eg, a change of 0.1 mg/dL). This may amount to a change in the GFR of 10%, especially when dealing with creatinine concentrations in the range of 0.5 to 1.5 mg/dL, as we did in this study. This loss of renal function is often not noticed by a primary caregiver, and because of this, these patients may not be recognized as having CKD. They may continue to be exposed to other nephrotoxic drugs or may have further elective exposure to OSPS, as more screening colonoscopies are done as the patient ages.

We are all aware of the risks of the OSPS bowel preparations in patients with advanced kidney disease.[11,12] Our study highlights the risk of OSPS preparation in patients with stage 1 to 3 CKD and its effects on their renal function. In our opinion, OSPS should not be used as the bowel cleansing agent in patients with stage 3 to 5 CKD who undergo elective or screening colonoscopy. Its status as a bowel cleansing agent for elective or screening colonoscopy at higher levels of GFR should also be questioned.

Because of these findings, our health care system has abandoned the routine use of OSPS as a bowel cleansing agent for elective colonoscopies. We have recommended PEG as the preferred cleansing agent for any patient with stage 3 to 5 CKD who has to have a bowel cleansing for colonoscopy. There may be circumstances in which PEG or other agents might not be indicated, and we recommend that the patient be informed of the risk if OSPS (or OSPT) is to be used. There are ample data in the literature about alternate colonoscopy preparation methods, including PEG and magnesium citrate, which have comparable efficacy of bowel cleansing as OSPS preparations, although magnesium salts should be avoided in patients with stage 4 to 5 CKD.[1,13]

A final concern is that OSPS is available as an over-the-counter medication. It is likely that OSPS and OSPT have good sales records, since they are very effective agents. Unfortunately, they are likely to be used by the populations most at risk: the elderly, women, and those with chronic medical or surgical conditions that require repeated bowel emptying or bowel cleansing. We believe that it is imperative for physicians to inquire about OSPS and OSPT use by their patients and that the safety of these agents and their over-the-counter status should be questioned.

In conclusion, the use of OSPS preparations is an underdiagnosed cause of AKI and may be responsible for CKD of unknown etiology. We are sure to diagnose more cases as the awareness of this entity increases in the general medical practice. If OSPS is used, the MDRD GFR measure should be used as a better guide than the serum creatinine level in estimating the renal function in women and elderly patients. Also, the importance of adequate hydration and avoidance of ACEIs and ARBs may be important, especially in patients with diabetes, to minimize the insult resulting from the phosphorus load with OSPS use. Increased awareness of this entity is therefore required not only by gastroenterologists and primary care physicians but by the general population as a whole.

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