

## Effect of Sugar Free Chewing Gum as a Supplemental Approach Instructions to Control Serum Phosphorus Level among Hemodialysis Patients

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### Abstract

**Background:** Hyperphosphatemia is common among hemodialysis patients, and independently associated with high mortality risk in those patients.

**Aim:** To examine the effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level among hemodialysis patients.

**Research design:** A quasi-experimental research design.

**Setting:** Kidney Dialysis Unit at Assiut University Hospital, Egypt.

**Sample:** 120 patients were randomized in two groups, experimental and control and met the inclusion criteria. Patients in the experimental group were instructed to chew two pieces of gum, for 60 min, during fasting periods in the morning and the afternoon and to use of phosphate binder with meals for 4 weeks.

**Tool:** The interview questionnaire sheet involved two parts:

**Part I:** Demographic characteristics for patients:

**Part II:** Clinical data of patients:

**Results:** Serum phosphorus level was significantly lower in the experimental group than in control after 4 weeks of using sugar free chewing gum ( $8.200 \pm 1.34$  to  $5.30 \pm 0.94$  ( $p < 0.0001$ )).

**Conclusion:** The use of sugar free chewing gum as a supplemental approach instructions was effective in controlling serum phosphorus level.

**Recommendation:** The study was highly reinforced the need for sugar free chewing gum to be used by hemodialysis patients for its positive effect on controlling serum phosphorus level.

**Keywords:** Hyperphosphatemia; Hemodialysis; Supplemental approach; and Sugar free chewing gum.

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### I. Introduction

Phosphorus is an essential component and the second most abundant anion in the human body after calcium. A normal adult has roughly 600 grams of phosphorus stored in the body, and the majority 85% of that is found in bone and teeth. Phosphorus is likewise present in soft tissues, erythrocytes, and around 1% is found in the extracellular fluid (Cupisti and Kalantar-Zadeh, 2013).

Phosphorus assumes an essential role in different biological functions, including cell signaling, bone mineralization, carbohydrate metabolism and energy metabolism. Likewise, it is significant for the normal generation of red blood cells, white blood cells and platelet function. Daily dietary phosphorus intake is approximately 800 to 1,200 mg. Ordinary phosphorus homeostasis is kept up by its subsequent appropriate excretion including the kidney (Penido and Alon, 2012).

Most end stage renal disease (ESRD) patients on long-term maintenance hemodialysis create hyperphosphataemia, because of extreme phosphorus consumption, reduced clearance of phosphorus, and conditions of bone remodeling (Guerra-Guerrero et al., 2012). Elevated serum phosphate levels among people who received chronic dialysis are associated with increased risk of cardiovascular disease (CVD) (Hasegawa et al., 2010). Furthermore, increased risk of death in this population is related to changes in the calcium and phosphate digestion (Carvalho and Cuppari, 2011) & (Shi et al., 2013).

Hyperphosphatemia stays ongoing challenge in clinical management of ESRD patients. Accessible treatments for the control of phosphorus in ESRD incorporate dietary restriction, the utilization of appropriate phosphate binders, and dialysis (Custodio et al., 2013).

Dialysis is the cornerstone of homeostatic electrolyte management for ESRD patients. However, the currently available dialysis techniques are usually ineffective in expelling abundance phosphate to the level of normalising phosphate concentration (Cupisti et al., 2012). Thus, the utilization of appropriate phosphate binders and phosphorus dietary restrictions correlative strategies for accomplishing prescribed levels of serum phosphate in hemodialysis(HD) patients.

Unfortunately, while studies have demonstrated that this three-pronged technique for serum phosphate control is powerful in accomplishing desired serum phosphorus level, it is estimated that as many as 50% of HD patients are not adherent to their dietary regimen. Also, up to 80.4% of HD patients report not utilizing their phosphate binders, further making them at risk for hyperphosphatemia (Kugler et al., 2011).

Dietary phosphorus management remains especially troublesome difficult and complex in hemodialysis patients. It has been as of late underlined that dietary manipulation is an underappreciated tool for decreasing serum phosphorus levels. Patients' education by renal dietitians remains a major component of the effort to control serum phosphorus, and restriction of dietary phosphorus intake is needed to allow a successful phosphate binder action. Moreover, HD nurses may assume an important role in the reinforcement of adherence and in instructing patients regarding the consequences of high serum phosphorus and the significance of dietary phosphorus control (Benini et al., 2011) & (Daugirdas, 2010).

A few studies have demonstrated the chewing gum is another weapon in phosphate control. the salivary phosphorus content being at least five times the serum phosphorus level. Salivary phosphate has been appeared to be conversely associated with glomerular filtration rate (GFR) in ESRD patients, in this way as the GFR decreases, salivary phosphorus concentration increases. In deed, HD patients have increased salivary phosphorus excretion contrasted with healthy controls. Restricting salivary phosphorus could decrease the body phosphorus burden and thus lower serum phosphorus (Block et al., 2013).

#### **Significance of the study:**

From clinical researcher's experience; it has been observed that hyperphosphatemia develops in the majority of patients with ESRD. Unfortunately, dietary phosphorus restriction and phosphate binders are ineffective ways to control serum phosphorus level (Fukagawa et al., 2017) & (Noori et al., 2010). Therefore, a close control of serum phosphate remains a cornerstone in the management of dialysis patients to improve their long-term prognosis. Consequently, this study was carried out to examine the effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level among hemodialysis patients.

#### **Aim of the study:**

The point of study was to examine the effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level among hemodialysis patients.

#### **Research question:**

Is there effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level among hemodialysis patients?

#### **Research design:**

Aquasi-experimental research design has been utilized to answer the research question.

**Setting:** The study was conducted in Dialysis Unit at Assiut University Hospital, Egypt.

**Sample:** The study sample included 120 patients, that were randomized in two groups, experimental and control (each group=60), and met the inclusion criteria, which were: receiving hemodialysis thrice-a-week for not less than 12 month, for a period of four hours; serum phosphorus level greater than 6.0 mg/dl, daily receiving treatment with phosphate binder at meals. Patients in the experimental group were instructed to chew two pieces of gum, for 60 min, during fasting periods in the morning and the afternoon and to use of phosphate binder with meals for 4weeks, while the control group patients used phosphate binder treatment only.

#### **Sample size:**

Total numbers of patients in dialysis unit at Assiut University Hospital in Egypt during November 2018 to December 2018 was 180 patients. Total numbers of selected patients according to inclusion criteria were 120 patient. The sample size was calculated utilizing the following Equation according to Steven K. Thompson (2012)

$$n = \frac{N \times p(1-p)}{\left[ \left[ N - 1 \times (d^2 \div z^2) \right] + p(1-p) \right]}$$

N=total patient population size

Z = confidence levels is 0.95 and is equal to 1.96

D= The error ratio is = 0.05

P= The property availability ratio and neutral = 0.50

**Tools:** Tool was utilized to collect data pertinent to the study :

**1-Interview questionnaire patient sheet:**

This tool was designed and developed by the researcher, after passing through an extensive and relevant literature review and consulting expertise in medical and nursing field, it was designed in English language.

**The interview questionnaire sheet involved two parts as the follows:**

**Part I:** Demographic characteristics for patient's age, sex, level of education, occupation, and marital status.

**Part II:** Clinical data of hemodialysis patients: This part covered the following information: Question related to treatment time on hemodialysis and laboratory investigations results at baseline such as serum phosphorus, and calcium.

**Sugar free chewing gum:**

Pre and post sugar free chewing gum was used to examine the effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level. Patients in the experimental group were instructed to chew two pieces of gum , for 60 min, during fasting periods in the morning and the afternoon and to use of phosphate binder with meals. The effect on serum phosphorus level was evaluated after 4 weeks, while the control group patients used phosphate binder treatment only.

**Procedure:**

**phase (1): Preparatory phase:**

- The study tools were formulated after extensive national and international literature review.
- The content validity was established by panel of 5 expertise in fields of Medical Surgical Nursing & Medical "Nephrology" fields who reviewed the study tool for clarity, relevance, comprehensiveness, understanding, and applicability.
- An official permission was obtained from the head of the kidney dialysis unit at Assiut university hospital.
- Each patient was informed with the purpose of the study. The investigator emphasized that the participation is voluntary and confidentially and anonymity of patients were assured through coding of all data, and protection of the patient from hazard. Verbal consent was obtained from each patient prior to his/her contribution in the present study.
- A pilot study carried out in November 2018 to test the feasibility and practicability of the study tools on a group of (10%) patients. It had also provided an estimate of time needed to fill out the tools, no change was done in the study tool, so the (10%) patients selected for the pilot study were included in the main study.

**Phase (2): Implementation phase:**

- Some patients are attending to the dialysis unit 3 times per week (Saturday, Monday, and Wednesday), other patients (Sunday, Tuesday, and Thursday).
- The researchers were visited the dialysis unit twice a week; Saturday for the control group and Sunday for the experimental group until data were completed.
- The experimental group received sugar free chewing gum. First collection of demographic, clinical data was done and blood samples were drawn to measure serum phosphate, and serum calcium as a baseline. Each patient was met for one session, which took about 20 minutes for every patient.
- For the experimental group; after filling the interview questionnaire. The researchers were instructed the patient to chew two pieces of gum , for 60 min, during fasting periods in the morning and the afternoon and to use of phosphate binder with meals for 4 weeks. The control group was received phosphate binder treatment only.
- The data were collected from November 2018 to December 2018.

**Phase(3): Evaluation phase:**

- After 4wks evaluation was carried out through introducing tool I for the studied sample "both control and experimental group" and blood sample was also obtained to examine the effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level. It was done in the dialysis unit and this session took about 15 minute.

**Data analysis:**

Data were collected and entered by SPSS version (21) used for statistical analysis of data. The frequency used to calculate count and percentage of qualitative data (e.g. sex), where descriptive used to calculate the mean + standard deviation for quantitative data (e.g. Age). Chi-square test used to test the relation between qualitative variables where T-test used to test the relationship between quantitative.

**Analysis of the results:**

**Table (1)** Frequency distribution of demographic characteristics in the experimental and control groups

Characteristics	Experimental (n.60)		Control (n.60)		P. value
	N.	%	N.	%	
<b>Age</b>					
• 18 – 35	14	23.3 %	13	21.7 %	0.849 n.s
• 36 – 50	20	33.3 %	23	38.3 %	
• 51- 65	26	43.4 %	24	40.0 %	
<b>Mean ±SD</b>	46.8167±12.75518		46.2833±12.61300		
<b>Sex</b>					
• Male	33	55.0 %	38	63.3 %	0.229 n.s
• Female	27	45.0 %	22	36.7 %	
<b>Level of education</b>					
• University ed.	2	3.3 %	1	1.6 %	0.967 n.s
• Secondary	8	13.3 %	9	15.0 %	
• Preparatory	14	23.3 %	13	21.7 %	
• Read & write	17	28.3 %	19	31.7 %	
<b>Occupation</b>					
• Office work	3	5.0 %	1	1.7 %	0.602 n.s
• Machinery work	18	30.0 %	24	40.0 %	
• Farmer	6	10.0%	8	13.3%	
• House wife	27	45.0%	22	36.7 %	
• Retired	6	10.0 %	5	8.3 %	
<b>Marital status</b>					
• Single	8	13.3 %	5	8.3%	0.279 n.s
• Married	52	86.7 %	55	91.7 %	

- Chi-square test                      -n.s not significance

Table (1) presents the demographic characteristics of the studied patients. It was found that there was predominance of male in both groups (55.0%, 63.3% respectively), The highest percentage of age (43.4%, 40.0% respectively) was regarding to patients that their age ranged from 51-65 yrs in both groups, with a mean age of (46.8±12.7, 46.3±12.6 respectively). Also it was found from the same table that (30.0%, 40.0 % respectively) of patients were machinery work in both groups. Concerning education; it was found that 31.7% of the experimental group were illiterate while 31.7% of the control group were read and write.

**Table(2)** Frequency distribution of the both groups regarding to their clinical data

Clinical data	Experimental (n.60)		Control (n.60)		P. value
	N.	%	N.	%	
<b>Treatment time on hemodialysis:</b>					
• 1 – 3 yrs.	10	16.6	10	16.6	0.571 n.s
• 4- 6 yrs.	35	58.3	37	61.6	
• 7-9 yrs.	13	21.7	13	21.7	
• 10-13 yrs.	2	3.3	0	0.0	

-n.s not significance

Table (2) Summarizes that; clinical data of 120 patients included in the study. Concerning treatment time on hemodialysis; it was found that( 58.3%, 61.6% respectively) of patients was between 4-6 years.

**Table(3)** Comparison between laboratory investigations' results at baseline and after 4 weeks for both groups (n.120)

Lab. Results	Experimental	Control	P. value
▪ At baseline: - Phosphorus level	8.0200 ±1.34829	8.0867 ±1.70368	0.010
- Calcium level	8.1833 ±1.0320	8.5417±1.0289	0.059
▪ After 4 weeks: - Phosphorus level	5.3050 ±.94177	7.6767±1.49784	0.0001***
- Calcium level	9.5517 ±.71580	8.9883±.74858	0.0001***

**Mann-Whitney test \*\*\*highly statistically significant difference at P. value <0.000**

Table (3) shows the results of laboratory investigations of patients. A statistically significant reduction in the mean serum phosphorus and elevation in mean serum calcium were identified, after 4 weeks of using sugar free chewing gum (p <0.0001).

**II. Discussion**

Poor control of serum phosphorus persists despite the implementation of phosphate binders as standard therapy in dialysis patients. Dietary restriction of phosphate is difficult because many foods have high phosphate contents (such as organ meat, dairy and bean products, whole grain, and seeds)(Askar,2015).

This study aimed to examine the effect of sugar free chewing gum as a supplemental approach instructions to control serum phosphorus level among hemodialysis patients The result of this study verifying the research question and showed that there was a statistically significant reduction in the mean serum phosphorus and elevation in mean serum calcium after using of sugar free chewing gum.

In respect to demographic characteristics; our study reported that a predominance of male in both groups, more than two fifth of both groups their age ranged from 51-65 yrs, with a mean age of (46.8±12.7, 46.3±12.6 respectively). This coincides with the results of (Stumm et al.,2017) who found in their study that hyperphosphatemic patients had a predominance of male retirees, with a mean age of 58.87 years, with a low level of education. This was on the contrary with the result of the current study which stated that less than one third in both groups were illiterate and read and write.

This too is inconsistent with the findings of this article which revealed that less than one third in the experimental group and two fifth in control group were machinery work. Concerning marital status, the findings of this study indicated that the majority of patients in both groups were married. Similar finding was revealed by (Agbelese,2016) who found that two third of patients were married. This too is consistent with the results of this paper which mentioned that less than one third in the experimental group and two fifth in control group were machinery work.

As regard to clinical data of patients , it was found that less than two third of patients in both groups was on hemodialysis between 4-6 years. Our data are inconsistent with prior study achieved by (Guida et al.,2011) which revealed that their study sample had a mean dialysis age (months) 20.3±19.5,19.7±16.3 respectively in both groups.

Concerning laboratory investigations' results; our data reported that increased serum phosphorus level in hemodialysis patient despite undergoing dialysis three times a week and being regularly treated with phosphate binder for at least 12 months at study entry and before using sugar free chewing gum. This study identified a significant reduction in the serum levels of phosphorus, after 4weeks from using sugar free chewing gum, showing this intervention was effective. It could be suggested that sugar free chewing gum, once solubilized into the stomach at acidic pH, could be retained onto the gastrointestinal mucosa for a prolonged time thereby exerting further phosphorus binding.

Similar finding was revealed by (Savica et al., 2009) reported in their preliminary study that serum phosphate significantly decreased during the first week of chewing gum; by the end of 2 weeks, serum phosphate decreased 31% from baseline (7.60 \_ 0.91 to 5.25 \_ 0.89 mg/dl; P \_ 0.00001).

As well,(Stephens et al., 2011) mentioned that salivary flow rate values were significantly lower in dialysis patients than in healthy controls. Sugar-free chewing gums should prescribe to these patients to increase the flow rate.

Moreover, (Bossola et al. 2012) found that the use of sugarless chewing gum significantly reduced the severity of xerostomia (Xerostomia Inventory scores decreased from 29.9 ± 9.5 to 28.1 ± 9.1). The researchers reported that the majority of study participants rated sugarless chewing gum as a beneficial therapy, but they did not report how this beneficial effect was assessed.

(Bayoumi, 2010) & (Van et al., 2011) pointed that numerous studies have demonstrated that educational interventions are helpful in assisting hemodialysis patients accomplish better wellbeing outcomes by enhancing hemodialysis adherence to both dietary phosphorus control and the utilization of phosphate binders.

As regard to increase in serum calcium in the present study, it was found that there was a statistically significant between the means ( $p < 0.0001$ ), comparing before beginning of the intervention and 4 weeks after the completion of using sugar free chewing gum. This finding was in agreement with the Stockholm study results achieved by (Araujo et al., 2010) which revealed that there was significant differences between the means of calcium, urea, potassium, hemoglobin, and hematocrit during these different periods of the intervention.

#### **Limitations of the study:**

- Nursing researches in this area were inadequate.
- The sample size was limited in generalizability because the sample was selected from one geographical area in Arab Republic of Egypt.

### **III. Conclusion**

The study revealed that the use of sugar free chewing gum as a supplemental approach instructions was effective in controlling serum phosphorus level and elevation of serum calcium among hemodialysis patients.

### **IV. Recommendations**

Recommendations were derived from the results of the study

- The study was highly reinforced the need for sugar free chewing gum to be used by hemodialysis patients for positive effect on controlling serum phosphorus level.
- Replication of the study using a larger probability sample acquired from different geographical areas.

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