

Protective effects of a natural substance from chicken gizzard as a novel application for the treatment of renal calculi: A randomized pilot study.

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Abstract

Background: In recent decades, multiple treatment strategies have been developed for the treatment of renal calculi. However, these are less convincing and cause side effects of the kidney.

Objectives: The main objective of this research is to study the use of a novel drug subtracted from chicken gizzard for treatment of renal calculi.

Methods: Twenty-three patients diagnosed with kidney stones by ultrasonography and radiography. All patients had the stone size of more than 5.0 mm and age >18 y old and these patients were randomly assigned by nephrology and urology specialists to one month treatment program with capsules (500 mg) filled by a substance of chicken gizzard (four capsules, 3 times daily within 24 h during one month).

Results: In general, 49 stones belonging to the 23 patients were used by chicken gizzard substance for treatment of nephrolithiasis. The mean of the stone size after treatment for 15 and 30 d groups were 6.2 ± 3.2 mm ($P=0.001$) and 5.6 ± 2.9 mm ($P=0.006$), respectively. As well as there were significant differences between groups. In 15 d group on 44 stones, 73% of stones were decreased and there was no seen exchange of their sizes in 20% of all stones, as well as 7% were excreted. In addition, only 18 remaining stones after 30 d with 84% of stones were reduced and 11% were excreted.

Conclusion: We found that chicken gizzard substance might be used to be safe for the treatment of nephrolithiasis in clinical settings and indicates that its administration can be reduced and prevented the growth of kidney stones. Therefore, chicken gizzard substance was helpful to prevent the primary stages of stone development.

Keywords: Chicken gizzard, Kidney, Stone, Treatment, Size.

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Introduction

Nowadays, kidney stones are still a worldwide issue with unknown pathophysiology [1-3]. Despite multifarious methods for its treatment, there are still no satisfactory medications to prevent and treat in modern medicine, which can dissolve the renal calculi and accordingly, for better relief, physicians stay to be depending on alternative medicine systems [4-6].

The prevalence of symptomatic kidney stone with a higher range is 9.2% for males and nearly, one in eleven people are affected by nephrolithiasis and in other words, it affects at least 10% of people and this high prevalence of stones indicates the need for optimal treatments [7-9].

At recent decades, multiple treatment strategies have been developed for the treatment of renal calculi. However, most of these therapies are surgical removal of stones, extracorporeal shock wave lithotripsy, and percutaneous nephrolithotomy.

These methods are expensive and not always widely available. Moreover, these are less convincing and cause side effects of the kidney [10-15].

The most of natural substances which happen in nature are substances. Many drugs have emanated from natural substances, and they contain relevant physiological active ingredients. Moreover, there are few reports of clinical studies of animal with naturally occurring kidney diseases [16,17]. In parallel, at the traditional medicine of Chinese, chicken gizzard substance has been utilized for about 2,000 y as an additional property for the treatment of various diseases such as kidney stones, but there are not any studies to confirm this matter for the excretion of kidney stones until now [18,19].

Based on this literature background, we hypothesized that chicken gizzard substance might be effective in nephrolithiatic condition. However, in clinical induced renal stone formation, there is no scientific study reporting its anti-nephrolithiatic

activity. To the best of our knowledge, the present study is the first report on the effect of natural substance from chicken gizzard on the treatment of renal calculi.

Materials and Methods

Ethical issues

The research followed the tenets of the Declaration of Helsinki. The research was approved by the Ethical Committee of Baqiyatallah University of Medical Sciences.

Essential composition (major components) of chicken gizzard substance collected

Components of chicken gizzard substance mainly contains total fat (3%), cholesterol (80%), sodium (2%), potassium (6%), calcium (1%), magnesium (3%), iron (13%), protein (18%), vitamin B12 (20%), vitamin (1%), vitamin B6 (5%), vitamin C (6%) and carbohydrate (0%).

Patients

Twenty-three patients diagnosed with kidney stones by ultrasonography and radiography at the Nephrology and Urology Research Center were selected for the present study as well as these patients were randomly assigned by nephrology and urology specialists to one month treatment program with chicken gizzard substance capsules. Furthermore, chicken gizzard substance capsule was administered at 2000 mg, 3 times daily within 24 h during one month.

On the other hand, during treatment, the patients had a regular ultrasound examination every 15 d and variations in the size and number of stones was recorded. Nevertheless, in the absence of changes on factors above and complications from stone or medication, standard treatment such as invasive procedure for the treatment of patients was conducted (surgical and etc.).

Evaluation measures

A demographic questionnaire was completed for all study participants through interviews. The questionnaire contained questions about age, gender, weight and family medical history etc.

The inclusion criteria for the study were included:

1. A written informed consent was taken from all the patients.
2. Age > 18 y.
3. Size > 5 mm in renal calyces (upper, middle and lower).
4. Absence of potential side effects of the kidney stones.
5. Non-pregnancy.

The exclusion criteria were:

1. Without written informed consent from the patients.
2. Age < 18 y, stone size \leq 5 mm.
3. Signs and symptoms of urinary tract infection, multiple stones, and renal dysfunction.

4. Pregnant patients.
5. The presence of recurrent renal colic.

Statistical analysis

Software of SPSS version 17 for Windows (SPSS Inc., IL and USA) was applied for analysis of variables. The differences between groups were analyzed using the t-test and ANOVA. The results were presented as a mean \pm standard error of the mean. Differences of repeated measure analysis between the data were considered significant at $P < 0.05$.

Results

In total 49 kidney stones of 23 eligible patients were enrolled into this randomized study. Forty-four renal calculi were treated by the drugs and 17 remained for 30 d of treatment. In Table 1, descriptive statistics are presented.

According to Table 1, results indicated there was significant difference between the stones size before entering the study for a period of 15 d ($P=0.001$) and 30 d ($P=0.006$) and the treatment process from the onset to 30 d indicates that the average size of the stones has reduced.

Table 1. Descriptive statistics.

	Stones count	Mean \pm SD
Before	49	7.214 \pm 2.661
15 d	44	6.218 \pm 3.179
30 d	17	5.588 \pm 2.895

Table 2 describes the various sizes of renal calculi on 14 stones since the beginning of the study. The average stone size, according to the duration of drug administration, there was significant difference between pre-treatment, 15 d and 30 d post-treatment groups with regard to be consumed of chicken gizzard substance (7.99 \pm 0.812 vs. 5.66 \pm 0.853 mm, $p=0.005$), respectively.

Table 2. Repeated measure analysis.

	N	Stone size (Mean \pm SD)/mm	Confidence interval		P*
			Lower	Upper	
Before	14	7.993 \pm 0.812	6.238	9.748	0.001
15 d	14	6.564 \pm 0.904	4.611	8.518	
30 d	14	5.664 \pm 0.853	3.821	7.508	

Note: *Repeated measure.

On the other hand, indicators (such as weight, height, BMI and history of renal stone) in the condition of the stone and its reduction has been ineffective ($p > 0.005$). Furthermore, according to Table 3, on the 15th d of the experiment on 44 stones, 73% of stones were decreased in their size (less or more than 3 mm) and 6.82% were excreted, and only 18 remaining

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stones after 30 d, 84% of stones were reduced (<or>3 mm) and 11.11% were excreted.

Table 3. Status of stones in 15 and 30 d after taking the drug.

	15 d		30 d	
	N	%	N	%
Stone excretion	3	6.818	2	11.111
No change in stone size	9	20.455	1	5.556
Stone size reduction<3mm	28	63.636	12	66.67
Stone size reduction>3mm	4	9.09	3	16.67
Total	44		18	

Discussion

To our knowledge, there are no studies that have previously examined the effects of chicken gizzard substance on renal stones. In the current study, we examined the following three points to elucidate the mechanism of kidney stone under the efficacy of chicken gizzard substance treatment as an therapeutic agent for kidney stones: (1) Changing the size of renal calculi in patients; (2) Expression changes and determining number of renal calculi; (3) Novel modifications of chicken gizzard substance in the kidney by using a statistical analysis.

On the other hand, we investigated the effectiveness of chicken gizzard substance on nephrolithiasis. We administered 2000 mg, 3 times a day of chicken gizzard substance to patients by oral to induce stones in the kidney. Based on the results of our observations, this high dose of this substance reduced the size of calculi in the treated groups (15 and 30 d) by 6.564 and 5.664 mm, respectively. Furthermore, treatment with chicken gizzard substance demonstrated a significant reduction on size of kidney stones, and the average stone size indicating a curative effect of 6.218 ± 3.179 mm and 5.588 ± 2.895 mm for groups 15 and 30 d, respectively. Statistically significant differences were found between the two groups. Results were consistent with our hypothesis that chicken gizzard substance would inhibit stones formation. To the best of our knowledge, this is the first evidence for the inhibitory effect of Stonex on stone size and or calcium oxalate crystal formation in patients. On the other hand, the precise mechanism underlying its effects remains unknown, and further experimental and clinical studies are required to elucidate the chemical constituents of the chicken gizzard substance and the mechanism is responsible for its pharmacological activities.

On the basis of evidence provided, few novel therapies have emerged over the past decade and the treatment of renal calculi is challenging, demanding and often requiring multiple procedures [20,21]. During the recent years, little medical improvements have been reported, and it is also possible that with development of new techniques of effective treatment. A profile of side effects is clearly evidence [22-24]. Importantly, at our study, no patients reported any side effects from chicken

gizzard substance. Therefore, we do not feel that utilization of this compound engenders inappropriate risk. However, we cannot provide any evidence of efficacy. Nevertheless, our findings are of sufficient interest to warrant investigation of this potential in human clinical trials.

Conclusion

To the best of our knowledge, the present study is the first report on the effect of chicken gizzard substance on the treatment of renal calculi. Information gained from the use of chicken gizzard substance therapies suggests that these natural products may play a role in complementing or expanding existing therapies for renal stones. Taken together from these results, it is believed that chicken gizzard substance might be used for the treatment of nephrolithiasis in clinical settings and indicates that administration of chicken gizzard substance reduced and prevented the growth of renal stones. Therefore, chicken gizzard substance was helpful to prevent the primary stages of stone development. Clinical trials of chicken gizzard substance should be designed for patients with recurrent nephrolithiasis and the findings of this study are awaiting confirmation by other investigators to accredit more extensively the importance of this novel therapeutic approach.

The Limitations of the Study

1. The absence of cooperation of all urologist specialists to refer the patient to Nephrology and Urology Research Center for participating in the project.
2. The absence of sufficient supply of medication for increasing number of patients in the project.
3. The absence of suitable cooperation of patients at follow-up, re-hospitalizations and timely medication administration.
4. The absence of perfect cooperation and optimal expected from other sectors to carry out diagnostic tests.

Conflict of Interest

None.

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