Original Article

Comparison of the Effects of Potassium Polycitrate with No Treatment on Microlithiasis of the Infants Referred to a Pediatric Nephrology Clinic

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Abstract

Background & Aims*:* Microlithiasis is a common increasing disorder, especially in infants and young children, defined as sonographic detection of hyperechogenic deposits in the pelvic area of the ureter and calyces which are less than 3 mm in diameter. Potassium citrate is one of the drugs used in nephrolithiasis. Citrate prevents the formation of calcium deposits. It also inhibits calcium oxalate crystals, which can be the nidus for kidney stones. The aim of this study was to compare the effect of potassium polycitrate versus no treatment in the infants with microlithiasis.

Materials & Methods: In this descriptive-retrospective study, 112 patients referred to a pediatric nephrology clinic were enrolled. Children less than two years old with microlithiasis in kidneys or urinary tract confirmed by ultrasonography imaging were included in the study. Patients were randomly divided into two groups: the first group received potassium citrate solution of 1-2 mEq/kg of body weight daily for two months, and the second group did not receive any specific medication. Follow-up was performed every two months for six months using ultrasound by a skilled radiologist with a fixed ultrasound device. To minimize drug side effects and treatment response, the allergic responses were measured once every two months, and the physician decided drug will or will not continue. Data analysis was done by SPSS 19. The P values <0.05 were considered significant.

Results**:** The mean age of the study population was 4.13 ± 2.27 months. The mean weight in the total study population was 6.62±1.36 kg and the mean birth weight in the total study population was 3±0.41 kg. According to the results of the study, the decrease in the size or number of stones in one or both kidneys was more in the recipients of polycitrate solution and the increase in the size or number of stones in one or both kidneys was more in the infants not receiving polycitrate (P<0.001).

Conclusions: Factors such as age, sex, current weight, birth weight and type of nutrition have no effect on improving and/or reducing the size and number of renal stones. However, in the group receiving potassium polycitrate solution, there was a significant reduction in the size and number of stones compared to the non-receiving group.

Keywords**:** Kidney Stone, Potassium Polycitrate, Infants, Microlithiasis

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Introduction

Microlithiasis is a common and increasing disorder, especially in infants and young children, which is defined as the sonographic detection of hyperechogenic deposits in the pelvic area of the ureter and calyces that are less than 3 mm in diameter (1-3). Increasing the knowledge of renal stone and microlithiasis, further use of ultrasound in children with exclusive and non-exclusive urinary symptoms, adventures in ultrasound devices, and further experiences in radiologists may cause increased rate (4). Urolithiasis is mainly seen in boys and girls in the first and second life decade (5). The main etiological factors for infantile microlitiasis include metabolic disorders, urinary tract infections, increased serum vitamin D levels, background diseases, and positive family history (6). The dietary factors, infections, and environmental etiologies are possible predisposing factors for stone formation in all age groups (7, 8). Vast majority of the children and infants with microlithiasis have one or more metabolic disorders including hypercalciuria, hypocitraturia, hyperoxaluria, and cystinuria (9). Microlithiasis is also a risk factor for renal stone in older ages including adulthood (4, 10). The clinical symptoms of microlithiasis and urinary stone are same, and also some cases are asymptomatic and spontaneous stone passage is also reported in some cases (11). The symptoms in infants may also be misdiagnosed with infantile colic (10, 11). The common symptoms in children include abdominal/flank pain, dysuria, vomiting, oliguria, hematuria, sterile pyuria, and urinary tract infection (11). Microscopic/macroscopic hematuria may be seen in ninety percent of the children with nephrolithiasis (9, 11, 12). Treatment goal in children and infants is reduction of stone formation, kidney function preservation, and prevention of recurrence/infection, and correction of metabolic/anatomic problems. However, sometimes surgical intervention is required. Initial diagnostic approaches for renal stones include physical examination and ultrasound imaging (13, 14). Medical treatments include increased fluid intake, decreased sodium consumption, and use of analgesics in persistent pain cases (15, 16). Non-medical treatments are proposed in the cases with first time of urinary stones and microlithiasis, and medical therapeutic are suggested for recurrent multiple stone formation cases and metabolic background diseases beside resistance to non-medical treatments. The surgical modalities are not required in the cases with microlithiasis because of little stones and lower risk for urinary stone obstruction (17). Potassium polycitrate is one of the utilized drugs in nephrolithiasis that prevents calcium deposition and inhibits oxalate calcium crystal formation which may be nidus for renal stones. Also, it can increase the urinary pH and inhibit uric acid and cysteine formation (18). Adverse effects include abdominal pain, diarrhea, nausea/vomiting, muscular weakness, rash, itching, and dizziness. Some studies showed good efficacy and safety for potassium polycitrate in conventional doses (19, 20). Despite various studies, there are scarce investigations in infants about renal stone prevention by potassium polycitrate or even non-medical approaches such as fluid therapy (21-27). Regarding non-expensive status of potassium polycitrate and importance of treatment for nephrolithiasis to reduce complications, this study was carried out to compare the effect of potassium polycitrate in microlithiasis versus non-pharmacological treatment in infants referred to pediatric nephrology clinic. To the best of our knowledge, this study is the first clinical trial conducted in Iran that compared efficacy of polycitrate in a group of children with nephrolithiasis compared to a control group receiving no treatment.

Materials & Methods

In this descriptive retrospective study, 112 consecutive children younger than two years referred to pediatric nephrology clinic since November 2019 to

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March 2020 with renal or urinary tract microlithiasis (opacity smaller than three millimeters) were enrolled.

Exclusion criteria included: urinary tract infection with urinary metabolic disorder (hypercalciuria, hyperoxaluria, uricosuria, cystinuria, hypocitraturia, and metabolic acidosis), hydronephrosis, admission history, prematurity, renal failure, anatomic disorder, surgical history of urinary stones, and loss to follow up.

After initial diagnosis of urinary stone by ultrasound assessment, the metabolic and infectious laboratory tests were done including blood (urea, calcium, phosphorous, alkaline phosphatase, uric acid, magnesium, and bicarbonate) urine (calcium, creatinine, oxalate, citrate, uric acid, and cysteine), as well as urinalysis and urine culture. The patients were randomly assigned to receive either 1-2 mEq/kg potassium polycitrate for two months or no treatment. The required dietary recommendation list including excess fluid use were developed for the parents. Follow-up was done bimonthly for six months by ultrasound assessment that carried out by a single experienced radiologist and single ultrasound device. In each two-month follow-up session, the adverse effects and therapeutic responses were checked and then decision was made by physician for continuation or discontinuation of the drug. Accordingly, subjects were subdivided to complete remission, unilateral and bilateral increase in stone size/count, lack of change in stone size/count in one or both kidneys, and unilateral and bilateral decrease in stone size/count. In non-altered or increased stone cases, the medical treatment was initiated.

Data analysis was done by SPSS (version 19.0) statistical software. The utilized tests included Z, ANOVA, Repeated measure, Kolmogorov-Smirnov, and Kruskal-Wallis. The P values less than 0.05 were considered statistically significant.

Results

Totally 59 cases (52.7%) had reduction of stone size and count and 53 ones (47.3%) had no change or even increase in the stone size and count. The mean (standard deviation) age was 4.19 (2.48) and 4.08 (2.06) in the intervention and control groups, respectively ($P > 0.05$). The mean age was 4.22 (2.23) and 4.04 (2.33) in the cases with and without improvement, respectively, without significant difference ($P > 0.05$). There were 62.5% and 42.9% female cases in the intervention and control groups, respectively ($P > 0.05$). There were 55.9% and 49.1% of the female cases with and without improvement, respectively ($P > 0.05$).

The mean (standard deviation) current weights were 6.79 (1.41) and 6.46 (1.31) in the intervention and control groups, respectively, and the mean birth weight was 2.99 (0.43) and 3.02 (0.38) in the intervention and control groups, respectively, without significant difference ($P > 0.05$). The mean (standard deviation) current weights were 6.68 (1.41) and 6.56 (1.32) in the cases with and without improvement, respectively, without significant difference ($P > 0.05$), and the mean birth weight was 3.03 (0.47) and 2.98 (0.33) in the cases with and without improvement, respectively, without significant difference ($P > 0.05$). As shown in Table 1, there was significant difference in feeding type across intervention and control groups ($P=0.007$). However, the feeding type was not differed between the cases with and without improvement, respectively, and there was not a significant difference ($P > 0.05$). The mean size and count are shown in Table 2.

Table 1. Feeding type across intervention and control groups

	Intervention	Control	P Value
Breastfeeding	34 (60.7%)	32 (57.1%)	
Formula	19 (33.9%)	10 (17.9%)	0.007
Both	3 (5.4%)	14 (25%)	

Table 2. Stone size and count across the study

		Baseline	2-month	4-month	6-month
Stone Size	Right	1.96 (0.98)	1.85 (0.78)	1.62 (1.03)	2.0 (1.30)
	Left	1.85 (.66)	1.77 (0.64)	1.65 (0.84)	1.87 (1.03)
Stone Count	Right	3.23 (2.25)	2.41 (1.37)	1.72 (1.12)	1.82 (0.98)
	Left	2.75 (1.87)	2.5 (1.85)	1.87 (1.63)	2.38 (1.40)

Table 3. Result of repeated measure analysis of Stone size across the study

Partial Eta Squared	p-value	F	Mean square	df	Sum of squares	Stone size	
0.18	0.001<	15.45	6.01	1.55	9.34	Right	Main effect(time)
.096	0.001	9.01	2.96	1.34	3.97	Left	
-	-	-	.39	11.90	43.51	Right	Error(time)
-	-	-	0.33	114.09	37.43	Left	
0.001	0.83	0.045	0.07	1	0.07	Right	Between-subject effects (treatment)
0.034	0.08	2.97	3.16	1	3.16	Left	
-	-	-	1.65	72	118.55	Right	Error(treatment)
-	-	-	1.06	85	90.42	Left	

In the right side, Mauchly's test indicated that the assumption of Sphericity had been violated, χ^2 (5) =132.23, p<0.001. Therefore degrees of freedom were corrected using Greenhouse-Geisser of Sphericity (ε=0.52).the results show that there was significant main effect (time) of stone size, F (1.55, 11.90) =15.45, p<0.001. These result suggested no significance of changes right side stone size between study groups, F (1, 72) =0.045, p=0.83.

In left side, Mauchly's test indicated that the assumption of Sphericity had been violated, χ^2 (5) =208.60, p<0.001. Therefore degrees of freedom were corrected using Greenhouse-Geisser of Sphericity (ε=0.45).the results show that there was significant main effect (time) of stone size, F (1.34, 114.09) =9.01, p=0.001. These result suggested no significance of changes left side stone size between study groups, F (1, 85) =3.16, p=0.08.

Table 4. Result of repeated measure analysis of Stone count across the study

Partial Eta Squared	p-value	F	Mean square	df	Sum of squares	Stone count	
0.325	0.001<	52.95	124.01	2.15	266.33	Right	Main effect(time)
0.306	0.001<	48.60	127.12	2.54	322.79	Left	
-	-	-	2.34	236.25	553.29	Right	Error(time)
-	-	-	2.62	279.33	730.58	Left	
0.542	0.001<	130.01	406.98	1	406.98	Right	

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0.006	0.43	0.636	1.63	1	1.63	Left	Between-subject effects (treatment)
-	-	-	3.13	110	344.34	Right	Error(treatment)
-	-	-	2.56	110	281.26	Left	

In the right side, Mauchly's test indicated that the assumption of Sphericity had been violated, χ^2 (5) =78.71, p<0.001. Therefore degrees of freedom were corrected using Greenhouse-Geisser of Sphericity (ε=0.72).the results show that there was significant main effect (time) of stone count, F (2.15, 236.25) =52.95, p<0.001. These result suggested significance of changes right side stone count between study groups, F (1, 110) =130.1, p<0.001.

In left side, Mauchly's test indicated that the assumption of Sphericity had been violated, χ^2 (5) =41.54, p<0.001. Therefore degrees of freedom were corrected using Greenhouse-Geisser of Sphericity (ε=0.85).the results show that there was significant main effect (time) of stone count, F (2.54, 279.33) =48.60, p<0.001. These result suggested no significance of changes left side stone count between study groups, F (1, 110) =0.64, p=0.43.

According to Table 5, the size was reduced significantly with higher measures in the intervention group in 2nd and 6th weeks (P=0.03 and P=0.02, respectively). The measurements were significantly reduced in all follow-up sessions for count in the polycitrate versus control group (P=0.001).

Table 5. Differences in size and count across the time in groups

	2-month	4-month	6-month
Intervention group	- 0.68	- 1.20	- 1.91
Control group	- 0.25	- 1.38	- 1.54
P Value for size	0.03	0.33	0.02
Intervention group	- 3.10	- 2.87	- 1.76
Control group	- 1.94	- 1.56	+ 0.05
P Value for count	0.001	0.001	< 0.001

Totally twelve cases (10.7%) had complete improvement. In the intervention group, there were significantly more cases with increased stone size and/or count (P < 0.001) (Table 6). Also, as demonstrated in Table 5, this difference was again significant in multivariate analysis (OR=0.15; CI95% 0.06-0.38; P < 0.001).

Table 6. Final outcome across the groups

	Intervention group	Control group	P Value
Complete remission	5 (8.9%)	7 (12.5%)	< 0.001
Reduction in size/count	36 (64.3%)	11 (19.6%)	
Increase in size/count	5 (8.9%)	34 (60.7%)	
No Change in size/count	10 (17.9%)	4 (7.1%)	

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Table 7. Odds ratio and confidence interval for various factors Variable

Variable	Subgroup	Odds ratio	CI95%	P value
Age	-	0.86	0.60-1.24	0.44
Body weight	-	1.25	0.68-2.28	0.46
Birth body weight	-	0.47	0.15-1.44	0.18
Sex	Female	-	-	0.81
	Male	1.10	0.46-2.62	
Feeding type	Breastfeeding	-	-	0.44
	Formula	1.53	0.44-5.29	
	Both	0.82	0.19-3.44	
Treatment	Control	0.15	0.06-0.38	< 0.001
	Intervention	-	-	

Discussion

Kidney stone is an important common urological challenge in the pediatric cases affected by geographical and genetic factors, and may have some subsequences such as failure to thrive, infection, urinary tract obstruction, and renal failure. These may be seen incidentally in imaging assessments (28-30). Potassium polycitrate is a medical agent helping for both patients with metabolic and non-metabolic stones, acting with increasing the citrate and potassium as main stone formation inhibitors (31, 32). Hence, in this study the effects of potassium polycitrate on infantile microlithiasis were assessed. In our study, the mean age in children was nearly four months. Also the age and sex were matched across the case and control groups and these factors were not related to therapeutic effects of potassium polycitrate. This matching was also done by Mohammadjafari et al. (27). Also the birth and current weight were matched across the groups to delete its intervening effects on the therapeutic response in our study. There was no significant difference for feeding type in our study.

Bozkurt et al. (33) reported significant difference for duration of breastfeeding between groups, which was shorter in the cases with therapeutic response. Also, exclusive breastfeeding was related to lower need to treatment. The differences may be due to longer follow-up and no assessment of various therapeutic modalities by them.

In our study, the size and count of stones were significantly reduced, showing the efficacy of potassium polycitrate. In the case of size, it was significant in the second and sixth month’s follow-up sessions but it was improved in fourth session without significant difference. The efficacy was also approved by regression analysis in our study. Conversely Mohammadjafari et al. (27) reported no efficacy for potassium polycitrate even after six months. Soygür et al. (22) reported recurrence in 34.6 and 7.6 percent of the cases without and with potassium polycitrate administration after extracorporeal shock wave lithotripsy (ESWL), which similarly showed significant efficacy of this treatment. Elderwy et al. (34) reported stone removal in 72.9 and 82.1 percent of the cases under potassium polycitrate treatment and lithotripsy modalities without significant difference. Their study showed encouraging results for medical modality that is in line with our findings. Tekin et al. (20) similarly reported high efficacy and good safety for potassium polycitrate, especially in recurrent renal stones in the children.

Totally, according to the results of our study, the factors such as age, sex, current weight, birth weight, and feeding type have no effect on improving and

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reducing the size and number of renal stones. But in the group receiving potassium polycitrate solution, there was a significant reduction in the size and number of stones compared to the non-receiving group. However, further studies with larger sample population and multicenter sampling can develop more applicable and definite results in this era.

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Conflict of interests

The authors declare that they have no competing interests.

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