Original Article
http://mjiri.iums.ac.ir
Medical Journal of the Islamic Republic of Iran (MJIRI)

Med J Islam Repub Iran. 2022 (28 Jun);36.70. https://doi.org/10.47176/mjiri.36.70

Effect of Polycitra-K and Bicitra in the Treatment of Pediatric Nephrolithiasis: A Double-Blind Randomized Trial

Mohammad Reza Razavi[1,2], Mostafa Vahedian[3], Fereshteh Motharinejad[2], Hojatollah Jafari[2,4], Mohsen Akhavan Sepahi[1, 2]*

Received: 23 Oct 202 Published: 28 Jun 2022

Abstract

Background: Urolithiasis is a common, sever, painful, and costly disease with a high probability of relapse. This study was performed to compare the effect of Polycitra-K containing potassium citrate and Bicitra containing sodium citrate in the treatment of kidney stones in children who referred to Hazrat Masoumeh hospital in Qom.

Methods: This double-blind randomized clinical trial study was carried out on 176 patients aged between 5 and 18 years old with kidney stones, hypocitraturia, and negative urine who referred to Hazrat Masoumeh hospital in Qom (Iran). Patients were divided into 2 groups of treatment (a dose of 1 mL/kg or 1-1.5 mg/ kg Polycitra-K) and control (Bicitra in the same dose). The results of kidney ureter bladder X ray (KUB) was followed and the 2 groups were compared. The chi-square test or the Fisher exact test was used to analyze qualitative values in the treated groups.

Results: Regarding bladder stones, there was a significant difference between the 2 treatment groups ($p = 0.025$), in which16 patients (18.2%) in the Polycitrat-K group and 29 patients (33%) in the Bicitra group had bladder stones. With respect to stone passage, 58 patients (65.9%) in the Polycitra-K group and 36 patients (40.9%) in the Bicitra group were recorded.

Conclusion: Oral Polycitrat-K is an effective preferential supplement against kidney stones in children due to urine alkalization, but the results of our study showed that both Polycitrat-K and Bicitra drugs have similar effects as therapeutic agents.
Registration code in the Iranian Registry of Clinical Trials: IRCT20190619043945N1

Keywords: Polycitra-K, Bicitra, Urolithiasis

Conflicts of Interest: None declared
Funding: This paper is part of the thesis of Fereshteh Motaharinejad No IR.MUQ.REC.1398.150, in Department of Nephrology, Qom University of Medical Sciences and Health Services.

***This work has been published under CC BY-NC-SA 1.0 license.**
Copyright© Iran University of Medical Sciences

Cite this article as: Razavi MR, Vahedian M, Motharinejad F, Jafari H, Akhavan Sepahi M. Effect of Polycitra-K and Bicitra in the Treatment of Pediatric Nephrolithiasis: A Double-Blind Randomized Trial. *Med J Islam Repub Iran.* 2022 (28 Jun);36:70. https://doi.org/10.47176/mjiri.36.70

Introduction

Urolithiasis has become more common in different populations over the past few decades (1-3). Urolithiasis is a common, sever, painful, and costly disease with a high

Corresponding author: Dr Mohsen Akhavan Sepahi, makhavan@muq.ac.ir

1. Department of Pediatric Nephrology, School of Medicine, Qom University of Medical Sciences, Qom, Iran
2. Pediatric Clinical Research of Development Center, Hazrat Masoumeh Hospital, Qom University of Medical Sciences, Qom, Iran
3. Department of Social Medicine, Faculty of Medical Sciences, Qom University of Medical Sciences, Qom, Iran
4. Department of Pediatric Gastroenterology, School of Medicine, Qom University of Medical Sciences, Qom, Iran

↑What is "already known" in this topic:
Urolithiasis has become more common in different populations over the past few decades. The reason for such an increase is not clear but is associated with a high probability of relapse. Kidney stones are one of the challenges in pediatric nephrology.

→What this article adds:
Potassium citrate is one of the drugs used for treatment of kidney stones, increasing inhibitors such as citrate and potassium in addition to alkalization of urine. However, there is no sufficient evidence to evaluate the effect of potassium citrate on the stones that do not have a specific metabolic background. Therefore, this study was performed to compare the effect of Polycitra-K and Bicitra solution in the treatment of nephrolithiasis in children.

[Downloaded from mjiri.iums.ac.ir on 2026-11-09]
[DOI: 10.47176/mjiri.36.70]

probability of relapse (4, 5). Development of stone in children depends on certain physicochemical factors. The suspected etiologies are anatomic abnormalities, urinary tract infection (UTI), metabolic disorder, lifestyle, malnutrition, dehydration, and drugs uses (1-6). Nephrolithiasis is one of the challenges in pediatric nephrology. About 7% of urinary calculi occur in children younger than 16 years old (5). Urolithiasis in children can lead to obstruction of the urinary system, UTI, growth retardation, and in severe cases, kidney damage and even kidney failure, which may also be a sign of other important underlying diseases (6). Several therapeutic methods are used to treat urolithiasis. The goal of treating nephrolithiasis in children is to eliminate stones, maintain kidney function, and prevent stone recurrence. Treatment of nephrolithiasis is based on protective and interventional measures (7).

Some therapeutic methods include increased fluid intake, dietary modification, analgesics and medical therapies, such as Polycitra-K and bacitra, and use of extracorporeal shock wave lithotripsy (ESWL), and finally surgery is used for treatment of urolithiasis (8-11). However, there are no comprehensive studies on the use of α-blockers as tamsulosin in children. Other medical treatments include salt restriction, increased potassium, magnesium intake, and herbal medicines (1-3). Despite the recommendation of thiazide diuretics (9, 10), other treatments for kidney stones, such as ESWL and surgery, are invasive and have been suggested especially for stones with complications or large size (5, 11). Potassium citrate is one of the pharmacological treatments used for treatment of kidney stones increasing inhibitors such as citrate and potassium in addition to alkalization of urine (6). However, there is no sufficient evidence to evaluate the effect of potassium citrate on the stones that do not have a specific metabolic background. The use of this drug in the treatment of stones in the field of metabolic disorders such as hypercalciuria and cystinuria has been proven. It is also used in cases without specific underlying causes in the urinary metabolic study, although its effect has not yet been studied and it needs further investigation (12, 13). Therefore, this study was performed to compare the effect of Polycitra-K containing potassium citrate and Bicitra containing sodium citrate in the treatment of kidney stones in children.

Methods

Design and Settings

The present study was a double-blind randomized clinical trial conducted in 2019. The Research Committee of Qom University of Medical Sciences (IR.MUQ.REC.1398.150) approved this study. To determine the sample size considering an alpha error of 5% and a power of 80% and according to the percentage of improvement in the intervention (77%) and control groups (57%), the sample size was determined as 83 patients in each group. Given the possible drop (attrition), finally 88 patients in each group and a total of 176 patients were included in this study. After obtaining informed consent, 176 patients were randomly assigned to the 2 groups. The patients aged 5 to 18 years referred to the nephrology clinic of Hazrat Masoumeh hospital in Qom were selected. Allocation was done using the permuted block randomization by the 6-block method. The random allocation sequences were computer generated in separate blocks for boys and girls. Participants and those measuring study outcomes were blinded to the interventions at all times. A Patients were anonymously reviewed by a person who had no idea what type of drug was being tracked, as well as the prescription and treatment outcome. All treatments for the 2 groups were delivered by a third individual who had the codes but was not directly involved in the trial and was supervised by a pediatric nephrologist who was blind to the type of codes. The interventions in the groups

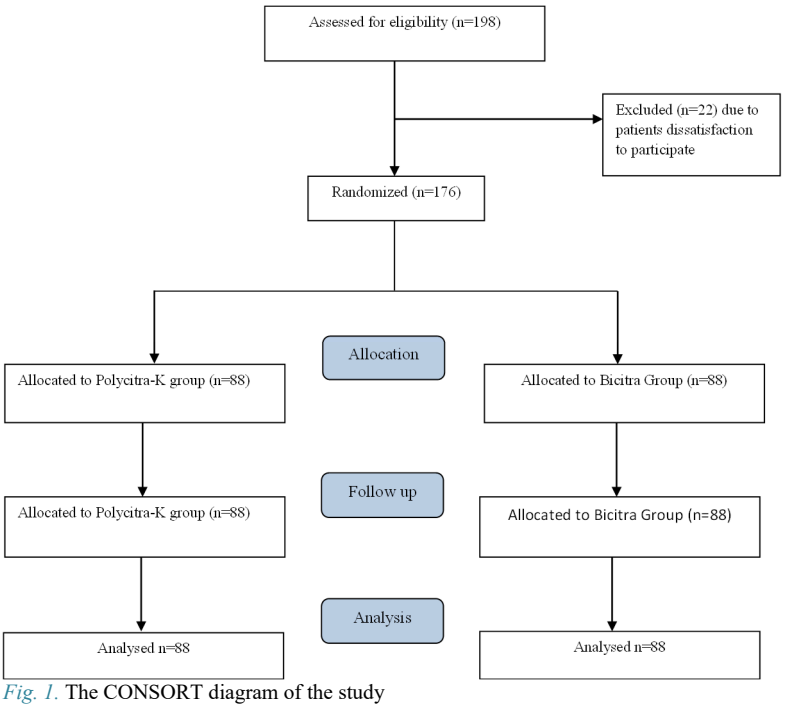

Fig. 1. The CONSORT diagram of the study

[Downloaded from mjiri.iums.ac.ir on 2026-11-09]

[DOI: 10.47176/mjiri.36.70]

included Polycitra-K and Bicitra (Fig. 1). The result was stone excretion or destruction, measured by ultrasound or imaging. These drugs are part of the routine treatment of kidney stones and did not impose any additional costs on the patient. Both drugs were in the form of powder and with the same taste, which was dissolved in water or fruit juice, and patients were not able to distinguish the type of drug. Polycitra-K was administrated with a dose of 1 mL/ kg or 1-1.5 mg/kg. In addition, Bicitra was given the same dose. Finally, the results of a kidney, ureter, and bladder X-ray (KUB) conducted at Shahid Beheshti Hospital and followed up 3 and 6 months later were compared.

Primary Outcome

The primary result of this study was stone removal, which was assessed using ultrasound 3 months after the commencement of treatment for all patients and compared between the 2 groups.

Inclusion and Exclusion Criteria

The intervention group of children aged 5 to 18 years with nephrolithiasis was confirmed by ultrasound or KUB (urinary stones in the size of 3-5 mm), without underlying or congenital disorders and not taking specific drugs and negative urine culture. Patients with cancer, immunodeficiency disorders that impact the patient's hemoglobin level, those with long-term corticosteroid use and improper collection were also excluded.

Statistical Analysis

The data were analyzed through SPSS Version 22. $P < 0.05$ was considered significant. Variables are presented as the frequency and percentage for qualitative variables, and mean and standard deviation for quantitative variables. The chi-square or the Fisher exact tests were used to analyze qualitative values in the groups.

Results

The mean age of the patients in the Polycitra-K and Bicitra groups was 7.41 ± 2.71 years and 6.61 2.5± 2.5 years, respectively ($p = 0.045$). In this study, 88 men and 88 women were studied and the 2 treatment groups were not significantly different in terms of gender ($p = 0.366$) In this study, stone in ureter ($p = 0.22$), stone in kidney ($p = 0.525$), no stone loss ($p = 0.485$), recovery after 3 months ($p = 0.289$), recovery after 6 months ($p = 0.15$), complete recovery after 3 months ($p = 0.647$), complete recovery after 6 months ($p = 0.876$), and stone size ($p > 0.999$) showed no significant difference between the groups (Table 1). None of the patients in the Polycitra-K group had UTI, the other group had 1 patient, but there was no statistically significant difference ($p > 0.999$). Also, dysuria was observed in 79 patients (89.8%) in the Polycitra-K group and in 60 patients (68.2%) in the Bicitra group, and there was a statistically significant difference between the 2 groups ($p < .001$). Pain was observed in 22 patients (25%) in the Polycitra-K group and 38 patients (43.2%) in the Bicitra group ($p = 0.01$). Frequency was observed in 54 patients (61.4%) in the Polycitra-K group and in 42 patients (47.7%) in the Bicitra group ($p = 0.07$) (Table 2).

Discussion

Urinary stones are still a major problem in healthy children. Its prevalence has increased due to dietary changes, lifestyle, and the use of some medications. The prevalence of this problem is 4.1% in women and 4-9% in men (14-

Table 1. Evaluation of senescence variable and patients' recovery in two groups

Variable	Groups	Polycitra-K	Bicitra	*P* value*
Stone_in_ureter	Yes	40 (45.5%)	32 (36.4%)	0.22
	No	48 (54.5%)	56 (63.6%)	
Stone_in_kidney	Yes	32 (36.4%)	28 (31.8%)	0.525
	No	56 (63.6%)	60 (68.2 %)	
Lake of stone destraction	Yes	9 (10.2)	12 (13.6)	0.485
	No	79 (89.8%)	76 (86.4%)	
Recovery after 3 months	Yes	43 (48.9%)	36 (40.9%)	0.289
	No	45 (51.1%)	52 (59.1 %)	
Recovery after 6 months	Yes	24 (27.3%)	16 (18.2%)	0.15
	No	64 (72.7 %)	72 (81.8%)	
Complete recovery after 3 months	Yes	36 (40.9%)	39 (44.3%)	0.647
	No	52 (59.1 %)	49 (55.7 %)	
Complete recovery after 6 months	Yes	19 (21.6%)	20 (22.7%)	0.876
	No	69 (78.4%)	68 (77.3%)	
Stone_size	1-5 mm	88 (100.0%)	87 (98.9%)	0.99
	5-10 mm	0(0%)	1 (1.1%)	
Calcium_oxalate_stone	Yes	54 (61.4%)	51 (58.0%)	0.645
	No	34 (38.6%)	37 (42.0%)	
Calcium_phosphate_stone	Yes	0 (0%)	2 (2.3%)	0.155
	No	88 (100%)	86 (97.7%)	
Uric acid stone	Yes	39 (44.3%)	31 (35.2%)	0.218
	No	49 (55.7%)	57 (64.8%)	
Cysteine stone	Yes	43 (48.9%)	40 (45.5%)	0.651
	No	45 (51.1%)	48 (54.5%)	

*: Chi-square test (or Fisher exact test)

[Downloaded from mjiri.iums.ac.ir on 2026-11-09]

[DOI: 10.47176/mjiri.36.70]

Table 2. Evaluation of clinical manifestation in two groups

Clinical Manifestation	Bicitra	Polycitrate-K		*P* Value*
Hematuria	33 (37.5%)	65 (73.9%)	Yes	000
	55 (62.5%)	23 (26.1%)	No	
UTI	1 (1.1%)	0 (0%)	Yes	1
	87 (98.9%)	88 (100%)	No	
Dysuria	60 (68.2%)	79 (89.8%)	Yes	000
	28 (31.8%)	9 (10.2%)	No	
Flank pain	38 (43.2%)	22 (25.0%)	Yes	0.01
	50 (56.8%)	66 (75%)	No	
Urinary frequency	42 (47.7%)	54 (61.4%)	Yes	0.069

*: Chi-square test (or Fisher exact test)

19). Potassium citrate is one of the medications, used in nephrolithiasis whose effectiveness is being studied. Citrate prevents the formation of calcium deposits. It also inhibits calcium oxalate crystals. In addition, citrate increases the pH of urine and prevents the formation of uric acid and cysteine stones (14). This study was performed to compare the effect of Polycitra-K and Bicitra solution in the treatment of kidney stones in children. The findings of our study showed a good effect of the 2 drugs in reducing the symptoms and recovery of patients, but in general, both treatment groups acted similarly on urinary stones. The only difference between the 2 groups was found in urinary stones, in such a way that in the Polycitra-K group, 16 patients (18.2%) had bladder stones and in the Bicitra group, 29 patients (33%) had bladder stones. There was also a significant difference between the 2 groups in terms of clinical symptoms, hematuria, dysuria, and flank pain. Zamonarski et al have shown that potassium citrate was completely safe. In addition, they found that the level of physiological citrate in urine was higher in the other inhibitory drugs. Therapeutic doses may cause mild metabolic alkalosis. In 70% to 75% of cases, improvement was observed by 1 year (15). In a cohort study by Technin et al, it was found that 1 mg/kg potassium citrate per day reduced stone recurrence and normalized urinary citrate levels in children aged 1 to 15 years (16). In a study by Sorkhi et al (17) on children with a mean age of 36.7 months, 78.7% of the patients had a complete response to polycitrate-potassium and 20 patients (22.7%) in the Bicitra group had complete recovery after 6 months, which could be due to environmental, nutritional, and other factors. Genetics, in addition to drug therapies, is also effective in treatment. Vulcan also found that high fluid intake, salt restriction, and Citrate-K treatment prevented the recurrence of kidney stones in 17 children with cystinuria (18). In general, many studies have been performed to prevent kidney stones and this study showed that effective treatment of kidney stones with polycitrate-K and Bicitra is very effective in children (19-22).

Conclusion

Oral Polycitra-K is an effective preferential supplement against kidney stones in children. The results of our study showed that both Polycitra-K and Bicitra drugs have good effects and efficacy in the treatment of urinary stones in children and in general, it can be said that the use of these drugs is useful for the treatment of urinary stones, but the results of our study shows that both drugs have similar effects in treatment.

Acknowledgment

We are grateful to Pediatric Clinical Research of Development Center, Hazrat Masoumeh Hospital, Qom University of Medical Sciences, Qom, and Mrs. Faeze Aghajanpour for their contribution to this study.

We thank all the patients and people who contributed to this study.

Conflict of Interests

The authors declare that they have no competing interests.

References

1. Mehrabi S, Askarpour E, Mehrabi F, Jannesar R. Effects of hydrophilic extract of Nasturtium officinale on prevention of ethylene glycol induced renal stone in male Wistar rats. J Nephropathol. 2016;5(4):123-127.
2. Mehrabi S, Manzouri L, Kohzadi A Mehrabi F. Efficacy of tamsulosin versus tamsulosin plus lithorex-B as medical expulsive therapy following extracorporeal shock-wave lithotripsy of renal and upper ureteric stones; a randomized clinical trial. J Nephropharmacol. 2017;6(2):79-84.
3. Mehrabi S, Behnam P, Manzouri L, Mehrabi A. Comparison efficacy and side effects of combined cystone and hydrochlorothiazide with cystone monotherapy in treatment and passage of upper urinary stones. J Renal Inj Prev. 2019;8(3):211-215.
4. Chizu Tanikawa, Yoichiro Kamatani, Chikashi Terao, et al .Novel Risk Loci Identified in a Genome-Wide Association Study of Urolithiasis in a Japanese Population. J Am Soc Nephrol. 2019 May;30(5):855–864.
5. Elder J S. Urinary Lithiasis. in: Kleigman RM, Behrman RE, Stanton BF Geme St, Schor NF, editors. Nelson Textbook of Pediatrics 21th ed. Philadelphia: Saunders. 2020; p. 2835-2840.
6. Dawn S. Milliner. Urolithiasis. In: Avner ED, Harmon WE, Niaudet P, et al. Pediatric Nephrology. 7th ed. Baltimore: Lippincott Williams & Wilkins. 2016; p.1405-30.
7. Tasian GE, Kabarriti AE, Kalmus A, Furth SL. Kidney stone recurrence among children and adolescents. J Urol. 2017;197(1):246-52.
8. Jung H, Andonian S, Assimos D, Averch T, Geavlete P, Kohjimoto Y, et al. Urolithiasis: evaluation, dietary factors, and medical management: an update of the 2014 SIU-ICUD international consultation on stone disease. World J Urol. 2017;35(9):1331-40.
9. Negri AL, Spivacow FR, Del EV. Diet in the treatment of renal lithiasis. Pathophysiological basis. Medicina. 2013;73(3):267-71.
10. Mohsen Akhavan Sepahi M, Sharifian M, Mohkam M, Vafadar M, Hejaz A. Biochemical risk factors for stone formation in healthy school children. Acta Med Iran 2012, Vol. 50, No. 12: 814- 818.
11. Telli O, Hamidi N, Bagci U, Demirbas A, Hascicek AM, Soygur T, et al. What happens to asymptomatic lower pole kidney stones smaller than 10 mm in children during watchful waiting? Pediat Nephrol. 2017;32(5):853-7.
12. Domrongkitchaiporn S, Stitchantrakul W, Kochakarn W. Causes of hypocitraturia in recurrent calcium stone formers: focusing on urinary

[Downloaded from mjiri.iums.ac.ir on 2026-11-09]

[DOI: 10.47176/mjiri.36.70]

potassium excretion. Am J Kidney Dis. 2006;48(4):546-54.
13. Stoller ML, Chi T, Eisner BH, Shami G, Gentle DL. Changes in urinary stone risk factors in hypocitraturic calcium oxalate stone formers treated with dietary sodium supplementation. J Urol. 2009;181(3):1140-4.
14. Soygür T, Akbay A, Küpeli S. Effect of potassium citrate therapy on stone recurrence and residual fragments after shockwave lithotripsy in lower caliceal calcium oxalate urolithiasis: a randomized controlled trial. J Endourol. 2002;16(3):149-52.
15. Zmonarski S, Klinger M, Puziewicz-Zmonarska A, Krajewska M, Mazanowska O, Dembińska E. Therapeutic use of potassium citrate. Przeglad Lekarski. 2001;58(2):82-6.
16. Tekin A, Tekgul S, Atsu N, Bakkaloglu M, Kendi S. Oral potassium citrate treatment for idiopathic hypocitruria in children with calcium urolithiasis. J Urol. 2002;168(6):2572-4.
17. Sorkhi H. Efficacy of Potassium Citrate Solation in Children With Renal Stone. Iranian J Kidney Dis. 2011;13:73–9.
18. Izol V, Aridogan IA, Karsli O, Deger M, Satar N. The effect of prophylactic treatment with Shohl's solution in children with cystinuria. J Pediat Urol. 2013;9(6):1218-22.
19. Izol V, Aridogan IA, Karsli O, Deger M, Satar N. The effect of prophylactic treatment with Shohl's solution in children with cystinuria. J Pediat Urol. 2013;9(6):1218-22.
20. Kobayashi T, Okada A, Fujii Y, Niimi K, Hamamoto S, Yasui T, et al. The mechanism of renal stone formation and renal failure induced by administration of melamine and cyanuric acid. Urol Res. 2010;38(2):117-25.
21. Guan N, Fan Q, Ding J, Zhao Y, Lu J, Ai Y, et al. Melamine-contaminated powdered formula and urolithiasis in young children. N Engl J Med. 2009;360(11):1067-74.
22. VanDervoort K, Wiesen J, Frank R, Vento S, Crosby V, Chandra M, et al. Urolithiasis in pediatric patients: a single center study of incidence, clinical presentation and outcome. J Urol. 2007;177(6):2300-5.

[Downloaded from mjiri.iums.ac.ir on 2026-11-09]

[DOI: 10.47176/mjiri.36.70]