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ORIGINAL ARTICLE

Efficacy of Potassium Citrate as a Preventive Treatment for Double-J Stent Encrustations

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ABSTRACT

Objectives: To evaluate the association between potassium citrate in Double-J (DJ) stent encrustment prevention and compare the incidence of related urinary tract infections (UTI) and crystalluria between patients who use potassium citrate and those who don't use potassium citrate.

Methodology: This prospective cohort study was carried out at the Sindh Institute of Urology and Transplantation. A total of 94 patients requiring DJ stent placement in case of stone disease were enrolled and followed prospectively for 6 weeks. The patients were categorized into two groups. The one group was receiving potassium citrate (60 mEq/day) as prescribed by their respective physicians, and the other group were not receiving potassium citrate. All stents were standardized towards 6 weeks of indwelling. Macroscopic stent encrustation was the major product. Secondary outcomes were crystalluria and UTI incidence. SPSS version 26 was used in the analysis of data ($p < 0.05$ was taken as significant).

Results: Both potassium citrate and non-potassium citrate patients were having baseline demographics ($p<0.05$). The macroscopic DJ stent encrustation was much lower in the potassium citrate taking patients than in the non-potassium citrate taking patients (12.8% vs. 36.2; OR 0.26; 95% CI 0.0930.74; $p = 0.008$). The potassium citrate group demonstrated a significantly lower incidence of crystalluria (17.0% vs. 42.6%; $p = 0.007$) and UTIs (6.4% vs. 23.4%; $p = 0.021$). Stratification indicated that the association was significant irrespective of the BMI or diabetic state.

Conclusion: Oral potassium citrate use was associated with a reduced risk of DJ stent encrustation, crystalluria, and UTI. Its regular application ought to be reviewed among the patients who need indwelling ureteral stents for over 6 weeks to limit the morbidity of the stent.

Keywords: Double-J Stent, Encrustation, Potassium Citrate, Urolithiasis, Urinary Tract Infection.

Authors' Contribution:
[1,2]Conception; Literature research; manuscript design and drafting; [3,4]Critical analysis and manuscript review; [5]Data analysis; Manuscript Editing.

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Article info:
Received: April 28, 2026
Accepted: June 12, 2026

Cite this article. Khan S, Abidi S, Qureshi HH, Laghari RH, Rizvi SAH. Efficacy of Potassium Citrate as a Preventive Treatment for Double-J Stent Encrustations. J Islamabad Med Dental Coll. 2026; 15(1): 192-198. *DOI: https://doi.org/10.35787/jimdc.v15i2.1597*

Funding Source: Nil
Conflict of interest: Nil

Introduction

The double J stent is a key part of many urological procedures, such as TUL (trans ureteral lithotripsy), PCNL (percutaneous nephrolithotomy), pyeloplasty, pyelolithotomy, and the reno-ureteral stone treatment.[1] Ureteral stents are commonly placed to pass stone debris after TUL and PCNL surgeries, before ESWL (extracorporeal shock wave lithotripsy), as well as in cases of severe ureteral stenosis.[2] Numerous improvements to the composition and design of ureteral stents have since been achieved; issues such as stone formation, stent fragmentation, stent migration, infections, or encrustation continue to trouble ureteral stents.[3]

Catheter encrustation is a significant issue in the management of patients with long-term placement of indwelling ureters.[4,5]

Duration of stent placement is considered to be the most important factor in the formation of stent encrustations, as a duration of 6 weeks is associated with increased risk of stent encrustations.[6] Calcium oxalate monohydrate has been observed to be the most prevalent composition of encrustations, and it has also been reported that encrustations on the bladder loop of the DJ stent are commonly seen, compared to the renal loop.[7,8] Presence of UTI has also been said to be a contributing factor in the development of DJ encrustation and urolithiasis.[9] Severe encrustation and stone formation may result in hydronephrosis and renal impairment requiring treatments like SWL and endourological techniques, which can increase the treatment costs and impact patients' quality of life and work ability. [10]

To avoid complications, many catheter coatings have been invented recently.[11] A considerable decrease in renal stones has been reported in almost all of the studies that have examined the potential of potassium citrate to prevent DJ encrustations.[12] Moreover, potassium citrate is thought to have high stone clearance rates by a variety of mechanisms, including maintaining electrolyte levels in the urine and saturation of calcium oxalate.[13,14]

Tavoosian et al examined the efficacy of potassium citrate in the prevention of DJ-encrustations and showed that the presence of DJ-encrustations in patients receiving potassium citrate was 8.8 percent as opposed to the 34.4 percent in non-exposed cohort patients. The non-potassium citrate cohort also experienced a high incidence of crystalluria (25% vs 7.7) and UTIs (18.7 vs 0) as compared to the potassium citrate cohort.[15] Nevertheless, Ch'ng et al found that urinary alkalinization via citrate did not have a significant difference in the rate of DJ encrustation as compared to the non-potassium citrate cohort (46.6 percent versus 52.6 percent).[16]

Although stent material and coatings have made progress, DJ stent encrustation is a common and difficult complication, especially when stents are kept in place longer than 46 weeks.[17] Necrustication prevention through pharmacological means is a poorly researched field. Potassium citrate, which has been shown to decrease the crystallization of calcium oxalate and change urinary chemistries, might also provide a low-cost, easily implementable preventive measure.[18] Nevertheless, there is still conflicting evidence, and limited local comparative evidence exists on its effectiveness. Thus, the proposed study will examine the association of potassium citrate in patients undergoing DJ Stent insertion in regard to the occurrence of urinary tract infection and crystalluria, and compare the rate of DJ-encrustment in patients undergoing DJ stent insertion, treated with potassium citrate, to the non-exposed cohort.

DJ Stent Placement

Insertion of a polyurethane two-loop ureteral stent whereby the proximal double loop is located at the renal pelvis and the distal two loops are located in the urinary bladder, and confirmed by X-rays.

DJ Stent Encrustation (Primary Outcome)

None of the segments of the removed DJ stent was visible on macroscopic inspection, and was graded using the FEcal (Forgotten-Encrusted-Calcified) grading system marked by an independent urologist.[8]

Methodology

This six-month prospective cohort study was carried out at the Sindh Institute of Urology and Transplantation's Department of Urology and Renal Transplantation. The WHO sample size calculator was used to determine a total sample size of 94 patients, taking into account projected DJ stent encrustation rates of 8.8% and 34.4% in the potassium citrate taking patients and non-potassium citrate group, respectively, with 80% power and a 5% level of significance. The patients meeting the study's inclusion criteria were enrolled in the study. Patients who had a history of potassium citrate

hypersensitivity, chronic kidney illness, pharmacological interactions with potassium citrate (ACE inhibitors, for example), a positive pre-operative urine culture, or who were pregnant or nursing were not allowed to participate. The results assessment was performed by using the standard set of criteria. From the day of stent placement until the stent is removed, the exposed patients (consisted of patients receiving potassium citrate) as prescribed by their respective urologist, whereas the non-exposed patients did not receive potassium citrate. Drug compliance was checked by pill count during follow-up visits. All DJ stents were kept in place for six weeks in order to standardize the risk of stent encrustation associated with indwelling time. Following informed consent, a pre-made proforma was used to capture baseline clinical and demographic data, such as age, gender, BMI, smoking status, diabetes mellitus, and stone composition. Urinalysis and urine culture were carried out prior to stent removal. At six weeks, the stents were removed under anesthesia, and an independent urologist used the FECal grading system to assess the stents for encrustation. DJ stent encrustation was the main outcome measure, and crystalluria and urinary tract infections were the secondary outcomes.

Data analysis was done with SPSS version 26. Continuous variables were reported as mean ±SD or median (IQR). Frequency and percentages were used to display the categorical variables. To compare the rates of encrustation, the chi-square test was used to compare the rates of encrustation in cohorts. Stratification was used to control the use of effect modifiers. A p-value of less than 0.05 would be taken as a significant p-value.

Ethical approval was taken from the Institutional Review Board of Sindh Institute of Urology and Transplantation (IRB No. 621-2025).

Results

A total of 94 patients were enrolled in the study and were categorized into two groups based on potassium citrate exposure: Potassium citrate group (Potassium Citrate, n=47) and non-potassium citrate group (Control, n=47). The mean age of the study population was 38.4 ± 8.2 years. There was no statistically significant difference ($p > 0.05$) in the baseline demographic data, age and gender, BMI and co-morbidities, Diabetes Mellitus, and Smoking status as shown in Table I.

Primary Outcome: DJ Stent Encrustation

The main aim was to determine the stent encrustation rate. In the Potassium Citrate group, 5 patients (10.6%) showed a case of macroscopic encrustation as compared to 16 patients (34.0%) in the non-potassium citrate group. This difference was statistically significant (p=0.007), indicating a lower incidence of encrustation in the potassium citrate group.

Secondary Outcomes: UTI and Crystalluria

Secondary outcomes were the occurrence of crystalluria and urinary tract infections (UTI) at 6 weeks of follow-up. The proportion of crystalluria was much greater in the non-potassium citrate group (38.3) compared to the potassium citrate group (14.9, p = 0.01). Likewise, patients using potassium citrate had a reduced incidence of UTI (8.5) than patients who were in the non-potassium citrate group (21.3, p = 0.04).

Table I: Demographic and Clinical Characteristics of study participants (Baseline). (n=47)

Variables	Potassium citrate group	Non-potassium citrate group	p-value
Age (Years), Mean ± SD	39.1 ± 7.4	39.1 ± 7.4	39.1 ± 7.4
Gender (Male/Female)	42 ± 5	40 ± 7	0.54
Mean BMI (kg/m^2)	21.4 ± 2.1	21.8 ± 2.4	0.39
Diabetes Mellitus, n (%)	4 (8.5%)	5 (10.6%)	0.72
Smoking Status, n (%)	6 (12.7%)	8 (17.0%)	0.56
Obesity (BMI age 23), n (%)	11 (23.4%)	13 (27.6%)	0.64

Table II: Comparison of Efficacy Outcomes of the Groups			
Outcomes	**(Potassium Citrate group)**	**(Non-Potassium Citrate group)**	**p-value**
Encrustation (Macroscopic)	5 (10.6%)	16 (34.0%)	0.007*
Encrustation (Microscopic)	7 (14.9%)	19 (40.4%)	0.005*
Crystalluria	7 (14.9%)	18 (38.3%)	0.010*
Urinary Tract Infection	4 (8.5%)	10 (21.3%)	0.044*
*Statistically significant at $p < 0.05$			

Multivariate Analysis and Stratification.

BMI and Diabetes Mellitus stratified the results to control the confounding factor. The incidence of encrustment was much lower in potassium citrate group (18.1) than in non-potassium citrate group (46.1, p = 0.03) in obese patients (BMI age 23). Multivariate logistic regression showed that Potassium Citrate exposure remained independently associated with lower risk of stent encrustation (OR 0.24, 95% CI 0.080.72).

The findings suggest that the use of Potassium Citrate (60 mEq/day) was associated with the lower risks of encrustation of the Double-J stents, crystalluria, and UTIs. The results justify the active use of urinary alkalinization in patients with indwelling stents for 6 weeks to reduce morbidity and potential complications during stent removal.

Discussion

The indwelling Double-J (DJ) stent is an inseparable part of modern endourology, but is considered a double-edged sword because of the high tendency to encrust, with consequent morbidity of significant scale, secondary obstruction, and problematic removals.[19,20] In our research, we sought to evaluate the association between potassium citrate use in the prevention of these complications. The results show that the dosage level of 60 mEq per day of potassium citrate use was associated with the reduction in macroscopic stent encrustation, crystalluria, and related urinary tract infections as compared to a non-potassium citrate group.

Stent encrustation pathogenesis is a complicated process that is activated by the development of a conditioning film of host proteins, and then the crystals and bacteria adhere.[21] We observed that macroscopic encrustation significantly lower incidence in the potassium citrate group (12.8% vs. 36.2, p=0.008). This is in line with the biochemical role of citrate in being a strong inhibitor of calcium stone formation.[22] Citrate works by producing soluble complexes with calcium, thus decreasing the thermodynamic activity of calcium oxalate and calcium phosphate.[23] Moreover, alkalinization of the urine by potassium citrate enhances the solubility of uric acid and alters the inhibitory behavior of macromolecules, such as osteopontin and nephrocalcin.[24] We find similar results to Tavoosian et al., who put the encrustation rate at 8.8% in the potassium citrate group and 34.4% in the non-potassium citrate group.[15] Conversely, Chng et al. did not find any significant difference, but their population of study had quite mixed indwelling times and metabolic profiles.[16] The indwelling time was the single most powerful risk factor of encrustation, and by standardizing our stent duration to six weeks exactly, we controlled it in our study. It is the standardization giving a better idea of the observed association with potassium citrate use.

Another interesting secondary result of our study was that the UTI incidence significantly decreased (6.4% in Potassium Citrate group vs. 23.4% in the non-potassium citrate group). This can be explained by two reasons: first, the decrease in crystal biofilm deprives bacteria of the opportunity to develop in their own niche, which allows them to survive and avoid penetration by antibiotics. Second, certain models have demonstrated that citrate disrupts bacterial adherence to the polyurethane surface.

Lower crystalluria (17.0% vs. 42.6) also lends credence to the proposed hypothesis that potassium citrate produces a urine environment less favorable to the lithogenic process.[25,26]

Obesity and diabetes mellitus stratification was done to make sure that the association was not obscured by the factors of metabolic syndrome.[27] Surprisingly, despite a BMI of 23 years of age, potassium citrate remained associated with the reduced risk stent encrustation, despite the fact that obesity is considered to be associated with decreased urinary pH and increased susceptibility to stones.[14] This suggests that the association between potassium citrate use and reduced risk of the acidic urinary condition that usually occurs in populations of obese and diabetic individuals.[28,29]

Although these are positive findings, this study has limitations. Follow-up was restricted to six weeks; thus, the efficacy of long-time forgotten stents was not known. We also did not conduct detailed 24-hour urine metabolic analyses, which would have given further details on the exact biochemical alterations (e.g., exact rise in urinary citrate levels) that were underlying the findings.

Conclusion

As an observational study, we can cautiously infer that Potassium citrate use was associated with the lower risks of DJ stent encrustation and related UTIs. We would recommend its routine use in patients with stent placement as a result of stone disease, and especially in those patients who are likely to have a stay of over four weeks with the indwelling stent. Further multi-center studies are justified to determine whether increasing doses would be of incremental benefit to high-risk metabolic stone formers.

Limitations

- Study Duration: The follow-up was standardized at 6 weeks; the long-term or forgotten stents' preventive efficacy of potassium citrate with long-term stents (indwelling was more than 3 months) is not characterized.
- Metabolic Profiling: 24-hour urinary metabolic assessments were not included in the study. Therefore, the exact biochemical associations between oral citrate consumption and alteration in urinary calcium, oxalate, and citrate levels were not mapped.
- Single-Center Scope: The results could be biased to local dietary habits and stone compositions, as the research is a single center; this could differ in other geographic locations or even ethnic groups.

Recommendations

- Clinical Integration: We propose the routine use of oral potassium citrate (60 mEq/day) in patients undergoing DJ stent placement in patients with stone disease, especially when the period of indwelling stent is likely to be more than 4 weeks.
- Future Research: Large multicenter comparative studies are warranted to test the minimum effective doses of citrate or test its long-term safety and efficacy in patients needing long-term stent placement.
- Biofilm Analysis: an extension of the study with the electron microscopic examination of the removed stents would also be helpful to gain a clearer picture of how the urinary alkalinization interacts with the first conditioning film formation.

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