

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1	The effect and factor analysis of potassium sodium hydrogen citrate on the formation of double j tube wall stones after ureteral stone surgery.
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1	Background: Double-J (DJ) ureteral stent encrustation is a frequent complication after .ureteroscopic lithotripsy (URS), leading to infections, obstruction and difficult stent removal. Potassium sodium hydrogen citrate may reduce encrustation by alkalinizing urine and increasing urinary citrate excretion. Objective: To evaluate the effect of potassium sodium hydrogen citrate on DJ stent encrustation and to identify biochemical, clinical and microbiological predictors following ureteral stone surgery. Method: This retrospective comparative study included 110 adults undergoing URS with DJ stenting. Group A (n=55) received potassium sodium hydrogen citrate for 4 weeks, while Group B (n=55) served as control. Patients were followed for urinary parameters, complications and stent encrustation graded at removal. Multivariate regression and ROC analyses identified predictors of significant encrustation. Results: Grade 0

				encrustation was higher in Group A (65.45% vs. 36.36%; p=0.003). Urinary pH and citrate were higher in Group A (p<0.001). Low urinary citrate, low pH and positive urine culture predicted Grade ≥ 2 encrustation. Urinary citrate showed strongest predictive value (AUC 0.821). Conclusion: Potassium sodium hydrogen citrate reduces DJ stent encrustation severity by modifying urinary biochemistry and may enhance postoperative outcomes.
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2	Double- J (DJ) ureteral stent encrustation is a frequent complication after ureteroscopic lithotripsy (URS), leading to infections, obstruction and difficult stent removal. Potassium sodium hydrogen citrate may reduce encrustation by alkalinizing urine and increasing urinary citrate excretion.
Objectives	3	State specific objectives, including any prespecified hypotheses	2	To evaluate the effect of potassium sodium hydrogen citrate on DJ stent encrustation and to identify biochemical, clinical and microbiological predictors following ureteral stone surgery.
Methods				
Study design	4	Present key elements of study design early in the paper	3	This retrospective, observational and comparative study.
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3	The Department of Urology at a teaching hospital for tertiary care was the setting for this

				retrospective, observational and comparative study. Stent dwell time was uniformly maintained at 28 ± 2 days for all patients.
Participants	6	<p>(a) <i>Cohort study</i>—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</p> <p><i>Case-control study</i>—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls</p> <p><i>Cross-sectional study</i>—Give the eligibility criteria, and the sources and methods of selection of participants</p>	3	<p>Inclusion criteria: People in the study were adults 18–70 years old who had a confirmed diagnosis of only one unilateral ureteral stone (near the kidney, in the middle or near the bladder) obtained with non-contrast computed tomography of the kidney and bladder. The patients were set up for URS with DJ stenting and all had normal renal function (creatinine below 1.5 mg/dl and eGFR over 60 mL/min/1.73 m²). Anyone included in the study had to have a negative urine culture plus be willing to follow the required treatments and testing. Exclusion criteria: Patients were excluded if they had bilateral stones or stones affecting multiple renal units requiring multiple procedures, as well as those with ureteral stents or nephrostomy tubes, active urinary tract infection or urosepsis, or chronic kidney disease stage 3 or higher. People with problems affecting the liver, those with uncontrolled diabetes, those born with or having acquired urological complications (including pelvi-ureteric junction obstruction and ureteral strictures), pregnant or lactating women, those known to be sensitive to citrate</p>

				<p>compounds and those with a history of diseases that cause metabolic stones (like cystinuria or primary hyperoxaluria) were not considered for this study. Anyone who had recently used citrate or thiazide treatment was not enrolled in the research.</p>
		<p>(b) <i>Cohort study</i>—For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i>—For matched studies, give matching criteria and the number of controls per case</p>	3	<p>When URS and stenting were successfully done, patients were randomly assigned to either group by a computer. Group A (n=55) received potassium sodium hydrogen citrate for 4 weeks, while Group B (n=55) served as control.</p>
Variables	7	<p>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</p>	4	<p>The main outcome of the research was the occurrence and severity (grade) of stent encrustation in the intervention and control groups. Encrustation was graded using the Griffith Visual Scale, where Grade 0 indicated no visible encrustation, Grade 1 indicated mild deposits involving less than 25% of the surface, Grade 2 indicated moderate deposits involving 25–50% of the surface and Grade 3 represented severe encrustation involving more than 50% of the surface or luminal obstruction.</p>
Data sources/ measurement	8*	<p>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</p>	4	<p>No patient was excluded from the study and all had a set of parameters recorded. Interpreted values were: serum creatinine, uric acid, calcium, phosphate, electrolytes, complete blood count and fasting glucose. Spot urine pH, urine routine</p>

				<p>microscopy, urine culture and sensitivity and a 24-hour urine collection for calcium, oxalate, citrate, uric acid, magnesium and volume were part of the urine analysis. Second urine pH, 24-hour urinary analysis and urine culture were performed at the time of follow-up. Upon removal, each DJ stent was thoroughly rinsed with sterile saline and subjected to gross visual examination under magnification for colour change, surface irregularities and mineral deposits. Selected stents underwent light microscopy and scanning electron microscopy (SEM) for surface characterization. Where sufficient deposits were found, compositional analysis of encrustations was performed using Fourier-transform infrared spectroscopy (FTIR).</p>
Bias	9	Describe any efforts to address potential sources of bias	3	<p>The Institutional Ethics Committee gave ethical approval before the study started. Every patient who joined the study was informed regarding what the study hoped to achieve, how it would be done, what outcomes might result and what dangers they could face. The informed consent provided by every patient gave them the option to withdraw at any moment and still receive the usual level of care.</p>
Study size	10	Explain how the study size was arrived at	3	<p>The sample size was calculated</p>

				to detect a minimum expected difference of 25% in moderate to severe stent encrustation rates between the citrate and control groups. With a power of 80% and a two-sided α of 0.05, the required sample size was 50 patients per group. To compensate for possible dropouts, 55 patients were recruited into each group.
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Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5	Continuous variables such as urine pH, citrate concentrations and stone dimensions were reported as mean \pm standard deviation (SD) or median with interquartile range (IQR), contingent upon their distribution.
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5	All gathered data were put into Microsoft Excel 2021 and analysed utilising SPSS version 26.0 (IBM Corp., Armonk, NY). Categorical variables, including sex, presence of encrustation and incidence of symptoms were represented as frequencies and percentages and compared across groups utilising the Chi-square test or Fisher's exact test. A multivariate logistic regression model was utilised to ascertain independent predictors of stent encrustation.
		(b) Describe any methods used to examine subgroups and interactions	5	Correlations between urine parameters and stent encrustation grades were evaluated using Pearson or Spearman correlation coefficients.
		(c) Explain how missing data were addressed	5	No patient was excluded from the study and all had a set of parameters recorded.
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	3	Stent dwell time was uniformly maintained at 28 ± 2 days for all patients and stent removal was scheduled accordingly.
		(e) Describe any sensitivity analyses	-	-
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	3	There were 110 participants in the study, all adults aged 18 to 70 with radiopaque ureteral stones who were set for elective ureteroscopy, with a stent placed afterward.
		(b) Give reasons for non-participation at each stage	3	Patients were excluded if they had

				<p>bilateral stones or stones affecting multiple renal units requiring multiple procedures, as well as those with ureteral stents or nephrostomy tubes, active urinary tract infection or urosepsis, or chronic kidney disease stage 3 or higher. People with problems affecting the liver, those with uncontrolled diabetes, those born with or having acquired urological complications (including pelvi-ureteric junction obstruction and ureteral strictures), pregnant or lactating women, those known to be sensitive to citrate compounds and those with a history of diseases that cause metabolic stones (like cystinuria or primary hyperoxaluria) were not considered for this study. Anyone who had recently used citrate or thiazide treatment was not enrolled in the research.</p>
		(c) Consider use of a flow diagram	-	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5	<p>The demographic attributes of both research cohorts were analogous, indicating effective randomisation. The average age of patients in the citrate group was 44.20 ± 10.60 years, whereas it was marginally greater in the control group at 45.80 ± 9.80 years. Nonetheless, this disparity was not statistically significant ($p = 0.420$), suggesting age uniformity across both groups. The male-to-female distribution was virtually equal, with Group A exhibiting a ratio of 36:19 and Group B a ratio of 34:21 ($p = 0.684$), indicating an absence of</p>

				<p>gender bias. The BMI, a possible determinant in metabolic disorders and stone formation, was comparable between the groups ($25.40 \pm 3.20 \text{ kg/m}^2$ vs. $25.70 \pm 3.50 \text{ kg/m}^2$; $p = 0.610$), excluding obesity as a confounding variable. A same percentage of patients in Group A (49.09%) and Group B (47.27%) had a prior history of urinary stone disease ($p = 0.839$), indicating equivalent recurrence risk in both groups. The familial history of nephrolithiasis was comparably dispersed (25.45% in Group A vs 29.09% in Group B; $p = 0.671$), indicating an equivalent genetic risk. The occurrence of common comorbidities, including hypertension (23.64% vs. 27.27%; $p = 0.665$), diabetes mellitus (16.36% vs. 18.18%; $p = 0.800$) and gout/metabolic syndrome (9.09% vs. 10.91%; $p = 0.744$), exhibited no significant differences between the groups.</p>
		(b) Indicate number of participants with missing data for each variable of interest	5	No patient was excluded from the study and all had a set of parameters recorded.
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	3	Stent dwell time was uniformly maintained at 28 ± 2 days for all patients and stent removal was scheduled accordingly.
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7	In Group A (citrate), 36 patients (65.45%) had Grade 0 encrustation, compared to only 20 patients (36.36%) in Group B (control), a statistically significant difference ($p = 0.003$). Mild encrustation (Grade 1, <25% surface) occurred in 21.82% of Group A and 30.91% of

				Group B, while moderate encrustation (Grade 2, 25–50%) was seen in 9.09% of the citrate group versus 20.00% in controls. Severe encrustation (Grade 3, >50% surface area or stent obstruction) occurred in only 2 patients (3.64%) in the citrate group, compared to 7 patients (12.73%) in the control group.
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	-	-
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	-	-
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8	The likelihood of developing Grade ≥ 2 encrustation was 2.87 times greater in participants from the control group than in those from the citrate group (95% CI: 1.12–7.41; $p = 0.028$). A urinary pH of less than 6.0 correlated with a heightened likelihood of encrustation (AOR = 3.22; 95% CI: 1.38–7.48; $p = 0.007$). Low urine citrate (<400 mg/24h) emerged as a robust independent predictor (AOR = 3.91; 95% CI: 1.62–9.43; $p = 0.002$). A positive urine culture independently forecasted encrustation (AOR = 2.74; $p = 0.049$).
		(b) Report category boundaries when continuous variables were categorized	8	A cut-off of <400 mg/24h yielded 84.37% sensitivity and 74.14% specificity ($p < 0.001$). An optimal cut-off value of <6.1 yielded 81.25% sensitivity and 70.73% specificity ($p < 0.001$).
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	-	-

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Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	5	Correlations between urine parameters and stent encrustation grades were evaluated using Pearson or Spearman correlation coefficients. Multivariate regression and ROC analyses identified predictors of significant encrustation.
Discussion				
Key results	18	Summarise key results with reference to study objectives	10	The present study demonstrates that potassium sodium hydrogen citrate favorably alters urinary biochemistry and substantially reduces the severity of DJ stent encrustation following ureteroscopic lithotripsy. Citrate therapy therefore represents a low-cost, safe and physiologically targeted strategy that complements existing stent technologies.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10	This was a single-center study with a relatively small sample size, which may limit the generalizability of the findings. The follow-up duration was restricted to 6 weeks, potentially underestimating late-onset encrustation. Stone composition analysis was not standardized across all cases. Patient compliance with hydration and dietary advice was self-reported and may have introduced bias. Moreover, microbial biofilm assessment was not done through advanced molecular methods.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9	The findings of the present study demonstrated a clear reduction in stent encrustation among patients treated with potassium sodium hydrogen citrate. This aligns with the known biochemical role of

				citrate in inhibiting calcium-based crystal aggregation and modifying urinary pH. Rather than repeating the numerical results, these findings collectively support the concept that biochemical optimization is a key determinant of stent performance. The protective effect remained significant even after adjusting for confounders, reinforcing the metabolic contribution to encrustation risk.
Generalisability	21	Discuss the generalisability (external validity) of the study results	10	This study contributes to the existing evidence by incorporating a uniform stent dwell time, standardized surgical technique and comprehensive biochemical assessment, thereby minimizing key confounders seen in earlier studies. These strengths support the reliability of the observed effects and highlight the value of integrating short-term metabolic optimization in routine postoperative care.
Other information				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	10	Funding None

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.