



Evaluation of citrate-based nutraceutical combinations and their impact on chemolysis in the management of urinary diversion device: a randomised double-blind placebo-controlled study on improved quality of life and clinical outcomes

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Abstract

Purpose We aimed to evaluate in a double-blind randomized placebo-controlled trial (RCT) the effectiveness of two citrate-based products in preventing ureteral stent encrustation in patients with severe urinary system damage requiring long-term stent placement and frequent replacements to prevent complications.

Methods Men and women aged 50–80, with severe urinary system damage were randomized to Product 1, Product 2 or Placebo. Efficacy points included encrustation prevention analyzed by mean normalized Kidney, Ureter and Bladder (KUB) score, ease of stent removal, and rate of emergency room (ER) visits.

Results Of 142 patients randomized (Product 1, $n=37$; Product 2, $n=62$; Placebo, $n=43$) 142 received treatment and 138 reached 9 months of follow-up. At 3 months Product 1 was associated with significant improvements vs. Product 2 by means of mean normalized KUB (mnKUB) score ($W=-5.75, p<0.001$). At 6 months both Product 1 and Product 2 were associated with significant improvements vs. Placebo ($W=-7.05, p<0.001$) and ($W=-6.55, p<0.001$) respectively. Similar results were obtained at 9 months (Product 1 vs. Placebo, $W=-4.84, p=0.002$; Product 2 vs. Placebo, $W=-4.15, p=0.009$). These outputs agree with that obtained for ease of stent removal, while no differences were found where evaluating the rate of ER visits in the three groups.

Conclusion This study emphasises the efficacy of a combination of potassium and magnesium citrates, *Phyllanthus niruri*, *Ceterach officinarum* and hyaluronic acid (Product 1) in managing long-term ureteral stent dependency, enhancing clinical outcomes and improving patient quality of life (QOL).

Keywords Urinary diversion devices · Citrates · KUB score · Hyaluronic acid · Chemolysis

Introduction

A significant number of oncological or functional urological conditions including endoscopic stone removal and reconstructive surgeries require treatment with urinary diversions, which are often non-continuous. These devices, such as nephrostomy tubes and ureterocutaneostomies (UCS), play a crucial role in ensuring proper urine drainage. Nevertheless, patients relying on these devices frequently experience various complications having a substantial impact on their QOL and general health [1].

Device-related issues, including malfunction, displacement or obstruction can lead to critical situations [2]. In

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particular, obstruction due to encrustation or calcifications can severely compromise urine flow, resulting in leakage or complete blockage [3, 4]. Such complications necessitate urgent medical intervention, often requiring an immediate visit to the ER to restore proper urinary drainage and prevent severe consequences such as acute kidney injury or life-threatening infections, including sepsis [5].

The strategies for preventing these complications may include dietary supplementation with pure substances or plant extracts with chelating and remodelling properties or substances able to alkalize urine and reduce crystal aggregation.

Among these, citrates are usually advised also by the European Guidelines for the management of patients with kidney stones, particularly for those prone to recurrent stone formation [6, 7]. Their role in alkalizing urine and reducing crystal aggregation makes it a valuable therapeutic option [8]. However, their potential benefits in patients with urinary diversion devices remain debated [9, 10].

Similarly, alkalizing therapy with potassium bicarbonate associated with citrates, could prevent or assist the treatment of certain types of uncomplicated kidney stones, by maintaining urinary pH at therapeutic values [11].

Furthermore, plant extracts with litholytic action has been a common way to assist the treatment of urinary stones in traditional medicine [12–14]. In details, *Phyllanthus niruri* and *Ceterach officinarum*, commonly found in the northern hemisphere and subtropical areas, are traditionally used to maintain urinary wellbeing and used in the treatment of various pathological conditions, including urolithiasis. Such extracts can act as crystal growth inhibitors due to their remodelling, diuretic, emollient, sudorific, depurative, and expectorant properties [15–17].

Finally, hyaluronic acid, also appears to be crucial in maintaining renal and urinary well-being as low urinary levels of glycosaminoglycans (GAG) are more common in patients with urolithiasis, suggesting a link between deficiency of this component and recurrence. Hyaluronic acid can also act as an inhibitor of stone aggregation by means of its chelating properties against alkaline-earth metals such as calcium. In addition, it encompasses mechanical, coating and moisturising actions, thereby ensuring the protection of the urothelium [18, 19].

The aim of this study is to evaluate the effectiveness of two different citrate-based products (Product 1 and Product 2) in a large cohort of patients with nephrostomy and UCS devices, comparing them with Placebo. The present study seeks to determine whether citrates together with other nutraceutical substances can play a role in improving the long-term management patients with severe urinary system damage treated with urinary diversions, by assessing their impact on device function and complication rates.

Materials and methods

Study participants

Participants were men and women aged 50–80 indwelling ureteral stents and/or nephrostomy tubes, able to understand and sign an appropriate informed consent to join the study. Participants were excluded for hyperparathyroidism and/or severe endocrinologic diseases or if they were allergic to one of the components of the study treatments.

Study design and setting

This randomized double-blind placebo-controlled trial consisted of enrolment and randomization visit after stent placement and 9 months of daily treatment.

Patients were randomly assigned to receive Product 1 (a sachet dissolved in a glass of water of a nutraceutical combination containing 1200 mg of potassium citrate, 1000 mg of magnesium citate, 150 mg of *Phyllanthus niruri* extract, 50 mg of *Ceterach officinarum* extract and 100 mg of hyaluronic acid), Product 2 (a sachet dissolved in a glass of water of a nutraceutical combination with 800 mg of potassium citrate, 800 mg of magnesium citates and 400 mg of bicarbonate) or Placebo (a sachet of only excipients dissolved in a glass of water).

Follow-up occurred at 3(T1), 6 (T2) and 9 (T3) months.

Outcomes

For each group, a radiography and a blood sampling was performed before the first cycle of therapy (T0), and at each follow-up visit (T1, T2 and T3). Moreover, BMI, Sex, Diabetes and Metabolic disorders were evaluated at T0.

Inter-group differences in terms of KUB score were considered the primary endpoint [20]. The mnKUB score was used to properly compare each treatment group since the procedure for stent application could be different due to ureteroscopy procedure conducted (e.g., unilateral or bilateral nephrostomy; unilateral or bilateral UCS; See *Supplementary Informations*).

Clinical and QOL outcomes expressed as the number of ER accesses for each patient between the T0-T1, T1-T2 and T2-T3 follow-up and the difficulty of devices replacement analyzed with a subjective score (from 1: no difficulty to 4: maximum difficulty) were considered secondary endpoints.

Ethics

The trial was conducted in accordance with the Declaration of Helsinki, Council for International Organizations of Medical Sciences International Ethical Guidelines, and

the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. All participants provided written informed consent at screening. The protocol was approved by the Ethics Committee of Riuniti Hospital in Foggia (approval n.177/C.E./2022, approval date: 12 February 2023).

Statistical analysis

For this preliminary study, the power analysis was performed with GPower 3.1 considering the primary endpoint, one-way ANOVA analysis with three groups, an effect size of 0.3, an alpha level of 0.05 and a power level of 0.8. With regard to a plausible 20% drop-out rate, a calculated size of 138 patients was deemed to be appropriate.

Statistical analysis of data was performed using Jamovi software and online chi-square calculator (<https://www.socscistatistics.com/tests/chisquare2/default2.aspx>).

Demographics, baseline characteristics, and efficacy endpoints were assessed in the per protocol (PP) population. Evaluation of data distribution confirmed a not normal distribution of the study dataset (Shapiro-wilk < 0.05; Table 1

Table 1 Anthropometric data of patients at baseline

	Group	Age	Weight (kg)	BMI
N	Placebo	42	42	42
	Product 2	59	59	59
	Product 1	37	37	37
Mean	Placebo	77.6	72.1	27.3
	Product 1	74.0	74.2	27.3
	Product 2	75.8	71.1	27.1
Std. error mean	Placebo	1.27	1.56	0.427
	Product 2	0.889	1.17	0.385
	Product 1	1.16	0.902	0.0158
Median	Placebo	78.5	70.0	27.0
	Product 2	75.0	70.0	27.0
	Product 1	75.6	70.0	27.0
Standard deviation	Placebo	8.20	10.1	2.77
	Product 2	6.83	9.02	2.96
	Product 1	7.07	5.49	0.0959
IQR	Placebo	10.8	4.43	0.00
	Product 2	10.0	10.0	2.00
	Product 1	2.43	0.00	0.213
Minimum	Placebo	48.0	60.0	23.0
	Product 2	52.0	53.0	18.7
	Product 1	59.0	60.0	27.0
Maximum	Placebo	91.0	105	39.0
	Product 2	88.0	107	35.0
	Product 1	91.0	100	27.2
Shapiro-Wilk W	Placebo	0.933	0.777	0.526
	Product 2	0.970	0.922	0.896
	Product 1	0.886	0.393	0.556
Shapiro-Wilk p	Placebo	0.017	< 0.001	< 0.001
	Product 2	0.153	0.001	< 0.001
	Product 1	0.001	< 0.001	< 0.001

and Supplemental Table 12). Data are presented as median with interquartile range (iQr) or mean $\pm$ standard deviation (Sd) in case of quantitative variables and frequencies in case of categorical variables. Differences between groups of patients were tested with the Kruskal Wallis One-Way analysis of Variance and chi-square test. Intergroup differences were evaluated with Friedman Analysis of variance. An alpha value of 5% was considered as the threshold for significance. Missing data were managed using mean imputation method. The Kruskal-Wallis test was conducted to assess the presence of significant differences among three treatment groups (Placebo, Product 1 and Product 2) in terms of the variable mnKUB score, difficulty in stent removal and number of accesses to the ER at T1, T2 and T3 respectively. The chi-square test was conducted to assess the relation between study groups and access to ER between T0-T1, T1-T2 and T2-T3.

Results

The study was conducted from February 2023 to January 2025 at Riuniti Hospital of Foggia. A total of 142 patients were initially enrolled and randomized (Product 1, $n=37$; Product 2, $n=62$; Placebo, $n=43$) Four patients were excluded for incomplete data due to lack of follow-up, giving 138 total patients (Fig. 1). Overall, there were 113 male and 25 female patients in the study. Mean age, BMI and weight of the cohort are listed in Table 1.

For the analysis of mnKUB Kruskal-Wallis test statistic (χ^2) was calculated (See *Supplementary information*, Supplemental Table 1), followed by post-hoc analyses performed to evaluate pairwise comparisons between groups at T1, T2 and T3.

In detail, Product 1 was associated with a significantly lower mnKUB than Product 2 ($W=-5.75$, $p<0.001$). At T2 both Product 1 and Product 2 were associated with significant improvements vs. Placebo ($W=-7.05$, $p<0.001$) and ($W=-6.55$, $p<0.001$) respectively. Similar results were obtained at T3 (Product 1 vs. Placebo, $W=-4.84$, $p=0.002$; Product 2 vs. Placebo, $W=-4.15$, $p=0.009$) (Table 2; Fig. 2a). These ultrasonographic results were confirmed by the clinical observation of difficulties of the surgeon during the substitution of stents at each follow-up (Table 3).

Kruskal-Wallis test statistic (χ^2) was also calculated for the evaluation of the difficulty on stent removal (See *Supplementary information*, Supplemental Table 2).

Post-hoc analyses revealed that at T1 significant differences exist between Product 1 and Product 2 ($W=-3.91$, $p=0.016$), while at T2 there is just a trend showing less difficulty in stent removal in Product 1 vs. Placebo ($W=-3.14$, $p=0.068$). Finally, at T3, only Product 1 was associated with

Fig. 1 Patient disposition. A total of 142 participants were randomized, 142 (100%) received the products, and 138 (97%) completed the study through 9 months

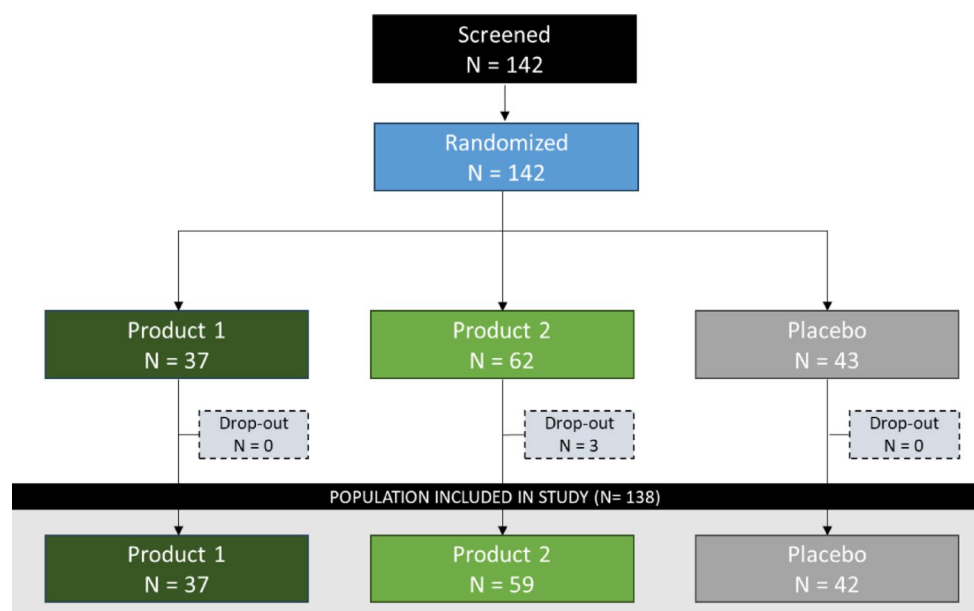


Table 2 Pairwise comparisons—mnKUB at T1, T2 and T3

Follow-up			W	p
T1 (3 months)	Placebo	Product 2	3.23	0.058
T1 (3 months)	Placebo	Product 1	-2.47	0.187
T1 (3 months)	Product 2	Product 1	-5.75	<0.001**
T2 (6 months)	Placebo	Product 2	-6.55	<0.001**
T2 (6 months)	Placebo	Product 1	-7.05	<0.001**
T2 (6 months)	Product 2	Product 1	-2.43	0.198
T3 (9 months)	Placebo	Product 2	-4.15	0.009*
T3 (9 months)	Placebo	Product 1	-4.84	0.002*
T3 (9 months)	Product 2	Product 1	-2.16	0.280

* $p < 0.05$; ** $p < 0.001$

significant easier stent removal vs. Placebo ($W = -3.59$, $p = 0.03$) (Table 3; Fig. 2b).

Differently, no significant differences were found either by analyzing the access or non-access to the ER (See *Supplementary information*, Supplemental Tables 3–5) or the number of accesses to the ER (See *Supplementary information*, Supplemental Tables 6–7 and Supplemental Fig. 1).

Table 3 Pairwise comparisons for difficulty in stent removal at T1, T2 and T3

Follow-up			W	p
T1 (3 months)	Placebo	Product 2	1.53	0.527
T1 (3 months)	Placebo	Product 1	-1.49	0.541
T1 (3 months)	Product 2	Product 1	-3.91	0.016*
T2 (6 months)	Placebo	Product 2	-2.67	0.142
T2 (6 months)	Placebo	Product 1	-3.14	0.068
T2 (6 months)	Product 2	Product 1	-1.25	0.652
T3 (9 months)	Placebo	Product 2	-1.39	0.586
T3 (9 months)	Placebo	Product 1	-3.59	0.030*
T3 (9 months)	Product 2	Product 1	-2.63	0.151

* $p < 0.05$; ** $p < 0.001$

Moreover, Friedman analysis of variance appears to show a progressive and maintained improvement of mnKUB clinical outcomes over time, both in Product 1 and Product 2, suggesting the long-term benefit of these treatments (See *Supplementary information*, Supplemental Tables 8–11, Supplemental Fig. 2–3).

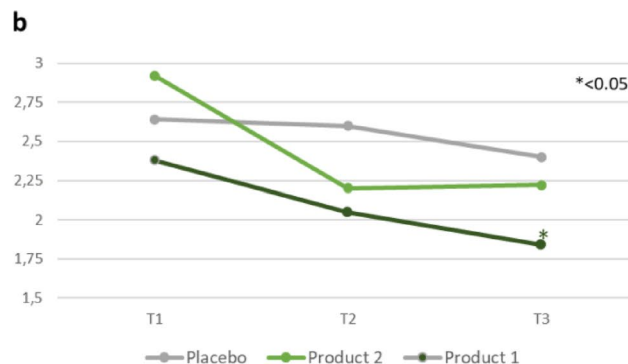
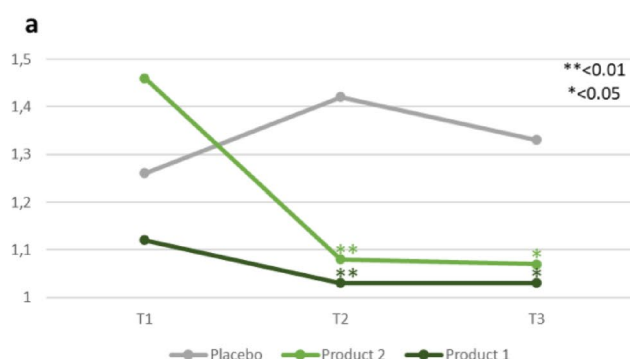


Fig. 2 **a** nmKUB score at T1, T2 and T3 in the three study groups. **b** Difficulty in stent removal at T1, T2 and T3 in the three study groups. Significance (* or **) was considered Vs Placebo

General descriptives of the study outcomes are listed in *Supplementary information*, Supplemental Table 12.

Discussion

Ureteral stents play a crucial role in urologic clinical practice. They are commonly used to facilitate urinary drainage following procedures such as endoscopic stone removal and reconstructive surgeries like cystectomy or pyeloplasty. Additionally, in emergency settings, they serve as a critical intervention to relieve acute obstructive renal failure [21, 22].

Typically, ureteral stents are removed within 4–12 weeks post-surgery, primarily through a retrograde cystoscopic approach. However, some patients with severe urinary system damage require long-term stenting, making these devices the only viable option for ensuring urinary drainage. In such cases, stents need to be replaced at least every three months [23].

Stent encrustation or malfunction significantly impacts patients' QOL and overall health, particularly in those requiring long-term use [1]. Our findings highlight that treatment with Product 1 (potassium and magnesium citrates, *Phyllanthus niruri*, *Ceterach officinarum* and hyaluronic acid, 1 sachet/day for 9 months) yielded the best clinical outcomes in preventing stent encrustation and facilitating stent removal. Our findings agree with the only comparable study by Mohammadi et al., who also found that potassium citrate after ureteral stent insertion significantly decreases the formation of calcium oxalate and uric acid encrusted material on Double-J stent [24]. These benefits translated into improved patient safety and QOL by reducing the incidence of infections, drug use, and hospitalizations [25–27]. Furthermore, the long-term use of citrate-based products may suggest progressive and maintained improvements of clinical outcomes over time.

These points are particularly important given that the majority of these patients are elderly with severe comorbidities. However, many patients in our cohort exhibited poor adherence to therapy, and four individuals succumbed to bladder cancer progression during follow-up. Consequently, incomplete follow-up posed a limitation in our study [28–30].

Although our results suggest that improving overall health outcomes could reduce public health costs, we were unable to statistically demonstrate this due to the limited cohort size. Furthermore, fluoroscopy-guided ambulatory stent replacement tends to underestimate the KUB score, which limits accurate encrustation evaluation. The chemical composition of encrustations is highly variable, and many urinary crystals are radiolucent, making tomography

the only reliable method for assessing encrustation grade. However, routine tomography is neither feasible nor cost-effective for patient follow-up due to radiation exposure and economic constraints [12].

Moreover, easier stent removal improves patients' QOL by reducing anxiety and pain associated with the procedure. Nevertheless, further prospective studies are necessary to better assess the effectiveness of potassium-citrate therapy in managing long-term stent-dependent patients. Notably, few studies in the literature have evaluated the QOL and overall health of this specific patient population, despite their significant representation in urological practice.

This study is however not without limitations. Although practical and accessible, the assessment of stent encrustation was conducted using KUB, this modality offers lower sensitivity and specificity compared to other methodologies, as computed tomography (CT), which may have provided a more precise evaluation of encrustation. Consequently, this could represent a study limitation in the data interpretation of clinical study. Secondly, a larger patient cohort and longer follow-up period could be two suggestions to be introduced into future studies in order to validate, assess the long-term efficacy and safety and have a better understanding of the benefits of both products, therefore further future studies are warranted to validate these results.

Conclusions

Overall, this RCT shows the efficacy of a combination of potassium and magnesium citrates, *Phyllanthus niruri*, *Ceterach officinarum* and hyaluronic acid (Product 1) in managing long-term ureteral stent dependency, enhancing clinical outcomes and improving patients' QOL. A similar product with lower concentrations of citrates and bicarbonate also shows significant improvements in the clinical outcomes vs. placebo in the long term but not in the early phase.

Expanded clinical studies are warranted to completely elucidate the beneficial effects of this treatment and the possible impacts on reduction of public health costs.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by N. S. and A.R. The first draft of the manuscript was written by A.R., N.S. and G. C. and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Competing interests The authors declare no competing interests.

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