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Original Research Article

Drug utilization and prescribing pattern in the treatment of urolithiasis: a perspective on World Health Organization recommendations

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ABSTRACT

Background: Drug utilization research (DUR) is essential in promoting rational use of medicine, aimed at understanding the patterns of prescription, administration, and utilization of medications. It provides valuable insights into the actual drug usage patterns for specific disease conditions. To evaluate the current utilization pattern of drugs in patients of urolithiasis in the Department of General Medicine and Surgery at Integral Institute of Medical Science and Research Hospital, Lucknow.

Methods: Following the approval of the institutional ethics committee, a prospective observational study was conducted at Integral Institute of Medical Science and Research Department of general medicine and surgery over a six-month period. Urolithiasis patients' prescriptions were analyzed to study the prescribing patterns. Information about patient demographics, co-morbidities, and the number and types of medications prescribed were collected and analyzed.

Results: Out of 102 patients studied, a female preponderance over male patients was observed. The co-morbidities that are encountered most commonly were hydronephrosis, cystitis, and renal cyst. There is averaged 7 medicines per prescription, 15.25% of medicines written by the generic name, 83.33% of patients receiving antibiotics, 54.70% of patients receiving injections, and 83% of drugs prescribed are mentioned in the essential medicine list. Analgesics, antibiotics, nutritional supplements, antiemetic, alkalizing agents, and antispasmodics were among the class of medicines given.

Conclusions: This study highlights the current use of medicines and drug utilization in urolithiasis management. The findings show important insights for healthcare professionals to enhance medication therapy, encourage cost-effective healthcare delivery and improve quality of patient in urolithiasis management.

Keywords: Urolithiasis, Drug utilization, Prescribing pattern, Kidney stones, Prescribing indicators

INTRODUCTION

Occurring at estimated frequency varying from 1% to 13% in different regions of world, urolithiasis is among the most prevalent urologic illnesses globally.¹ Its rising incidence, prevalence, and related financial burden make it a serious public health concern. An estimated 19,000 deaths annually are related to kidney stone disease, which

affects about 12% of the global population.² There are various kidney stone kinds, however calcium oxalate or phosphate makes up 80% of them. Other stone forms besides those made of calcium oxalate or phosphate (80%) include those made of uric acid (9%), struvite (10%), and cystine (1%).³ Urinary tract stones are categorized usually based on their location: nephrolithiasis (presence of stones in the kidney), ureterolithiasis (in the ureter), and

cystolithiasis (in the bladder), or by their composition (calcium oxalate, uric acid, struvite, xanthine, cystine and other drugs).⁴ Patients receiving long-term therapy have been demonstrated with increased chance of developing stones when taking ceftriaxone.⁵

Urolithiasis patients have various co-morbidities and difficulties, such as hydronephrosis, cystitis, hypertension, diabetes mellitus, obesity, gout, and infection, and are endorsed an enormous number of prescriptions, including those that may change or interfere with the treatment approach and pose challenges for controlling urolithiasis.⁶ In cases of terminal stage kidney disease where nephrocalcinosis is present, nephrolithiasis accounts for 2–3% of cases.⁷ Geographic, socioeconomic, and climatic factors all influenced the global variations in urinary stone epidemiology. Age, sex, race, and diet also influence on the prevalence and rate of this condition. Urolithiasis risk factors include obesity and the metabolic syndrome. The aforementioned factors also influence on the kind of stones that form and how frequently they occur. Globally, calcium oxalate is still the main constituent in KS.⁸ Nonetheless, Studies has shown patients without a familial background of urinary stone formation had a three-fold lower chances of the condition, indicating a strong genetic propensity for urolithiasis and its associated variables.¹⁰

The management of urolithiasis often involves the prescription of multiple medications to address the symptoms, complications, and underlying causes of the condition. For example, pain management in urolithiasis typically involves use of paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs) such as aceclofenac, diclofenac and ibuprofen or opioids for severe pain.^{10,11} It is possible to administer antibiotics or anti-inflammatory medications for infections or inflammations. Additionally, antispasmodics and alpha-blockers like tamsulosin, drotaverine and dicyclomine are prescribed to facilitate the passage of stones through the urinary tract. Alpha-blockers act by relaxing the smooth muscles of the ureter, allowing stones to pass more easily. These medications can contribute to enhancing stone clearance and reduce intrusive techniques such as surgery or lithotripsy.¹² Despite receiving successful treatment, nephrolithiasis has returned in nearly half the patients.¹³ Polypharmacy is common among these patients, increasing the chances of drug-drug interactions and adverse drug reactions. Therefore, the appropriate selection of drugs and rational prescribing practices are vital to avoid unwanted effects and achieve optimal patient outcomes. There is currently disagreement in surgical management of urolithiasis and a lack of guidelines on exposure to radiation for both patients and practitioners.¹⁴

METHODS

The prospective, observational research was conducted in the department of general medicine and surgery at Integral Institute of Medical Science and Research, Lucknow, the study fully complied with the World Health Organization

(WHO) guidelines and was conducted subsequent to approval from institutional research and ethics committee, 102 patients of all ages both male and female have participated, the research was conducted over a six-month period.^{15,16} Individuals treated for urolithiasis were included, and their prescriptions were analyzed based on WHO prescribing indicators to know the prescribing patterns.¹⁶⁻¹⁸ Information about patient demographics, co-morbidities, and the number and types of drugs prescribed were collected and analyzed. In the process of patient selection, individuals in this study were chosen based on specific inclusion/exclusion criteria. Criteria for inclusion encompassed patients treated for kidney stones, ureteric stones, and bladder stones who met study criteria, including both genders and patients of all ages, along with those having urolithiasis and other comorbidities. Exclusion criteria involved mentally challenged and unconscious individuals and individuals unable or unwilling to comply. Data for the study was sourced from physicians' prescribing records, patient medication profiles, diagnostic reports, laboratory investigations, patient complaints and symptoms, as well as patient's progress reports. The evaluation parameters are based on WHO prescribing indicators and involved assessing various aspects such as types and percentage of medications prescribed in urolithiasis, medications amount per prescription, commonly used agents of a particular class, average ages of patients utilizing drugs, a comparison of medicines given by generic versus brand name, and the presence of concomitant diseased conditions.^{16,19} The data obtained was compared with standard value of the WHO core prescribing indicators to access the rationality of the drug use. Information regarding the usage of various drug classes, percentage of prescribing indicators and individual medications underwent statistical evaluations.

Descriptive analysis was evaluated using Microsoft excel 2016 and statistical package for the social sciences (SPSS) software. Variables were evaluated using descriptive statistics such as mean/median, other variables (categorized) were characterized by frequency and percentage. A probability (p) value below 0.05 was deemed statistically significant across all analyses. By assessing the drug utilization patterns in this specific patient population, valuable insights can be gained, resulting in the creation of strategies and establishment of guidelines that optimize drug therapy. For example, the study identifies the frequency of polypharmacy and the drug most frequently prescribed, which helps healthcare providers to develop guidelines for minimizing polypharmacy, drug-drug interactions and improving adherence to treatment guidelines.

RESULTS

Demographics (age and gender)

Patients were grouped into 6 groups based on their age. The largest proportion of patients fell within the age group of

31-40 years, comprising 26.90%, and the smallest representation was observed in the age group 11-20 years, accounting for 9.60%. On average, the age range of the patients is 32-42 years. 41(40.19%) were male and 61 (59.8%) were female patients. this shows a higher proportion of female patients in comparison to male patients (Table 1).

Table 1: Demographics distribution of patients' gender and age.

Demographics	Frequency	Percentage
Gender		
Male	41	40.19
Female	61	59.8
Total	102	100
Age group (years)		
11-20	10	9.80
21-30	19	18.6
31-40	28	27.45
41-50	18	17.6
51-60	15	14.70
61-70	12	11.76

Prescribing indicators

The WHO prescribing indicators are described in Table 2.

Table 2: WHO prescribing indicators.

Prescribing indicator	No. (%)	Recommended value (%)
Average number of drugs prescribed per encounter	7	≤3
Percentage of drugs prescribed by generic name	15.25	100
Percentage of patient with an antibiotic prescribed	83.33	≤30
Percentage of patient with an injection prescribed	54.70	≤10
Percentage of drugs prescribed from essential medicine list	83	100

Average amount of drugs used per prescription

Out of 102 patient's prescription studied, total 721 medicines were prescribed. averaging (7) per prescription. Analgesics accounted for the highest quantity of prescribed medications (23.43%) followed by antibiotics (19.55%) followed by PPIs (12.34%), then nutritional supplements and parenteral fluids (11.9%), antiemetics (9.1%), alkalizing agents (6.65%), antispasmodics (7.48%) and others: antihistamines, bronchodilators, and

anti- hypertensive (10.81%). Commonly used agents of every particular class are mentioned (Table 3).

Table 3: Class of drugs used and commonly used agents of each class.

Drug class	Frequency	Percentage (%)	Commonly used agent
Analgesics	169	23.43	Paracetamol
Antibiotics	141	19.55	Ceftriaxone
Alkalizing agents	48	6.65	Disodium hydrogen citrate
Antispasmodics	54	7.48	Drotaverine
Nutritional supplements	86	11.9	Multivitamins
Proton pump inhibitors	89	12.34	Pantoprazole
Antiemetics	65	9.01	Ondansetron
Others	78	10.81	Lactulose
Total	721	100	

Generic versus brand name prescription comparison

110 (15.25%) of the prescriptions are by their generic names and 611 (84.74%) by brand name (Figure 1).

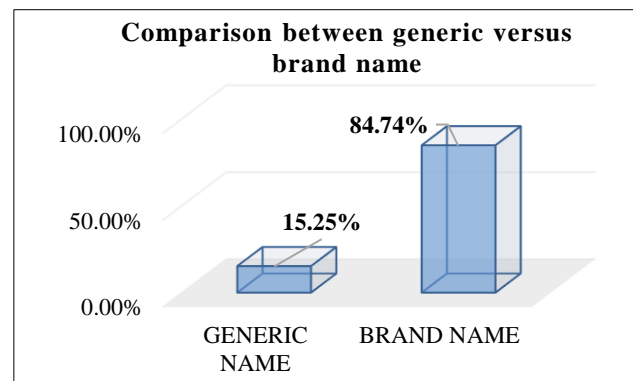


Figure 1: Comparison of drugs prescribed by generic versus brand name.

Antibiotics

Antibiotics were given 141 times, constituting 19.55% of the overall prescribed drugs (721 in total). They were found in 85 prescriptions, representing 83.33% of the total encounters with antibiotics. In 17 (16.66%) out of 102 prescriptions, no antibiotics were prescribed. Among the antibiotics, Ceftriaxone was the highest prescribed, accounting for 40.4%, followed by amikacin at 14.1%, metronidazole at 12%, and levofloxacin at 9.2% (Table 4).

Percentage of patients with injection prescribed

Injections were prescribed of 213 times, making up 29.54% of the overall prescribed drugs (721 in total). They

were included in 56 prescriptions, representing 54.70% of prescriptions with injectables given. Notably, 46 (45.09%) out of 102 have no prescribed injection.

Table 4: Antibiotics with their frequency.

Name of antibiotic	Category	Frequency	Percentage (%)
Ceftriaxone	Cephalosporin	57	40.4
Amikacin	Aminoglycoside	20	14.1
Levofloxacin	Quinolones	13	9.2
Metronidazole	Nitroimidazoles	17	12.05
Amoxicillin	Penicillin	9	6.3
Tazobactam	Beta-lactamase inhibitor	5	3.5
Cefixime	Cephalosporin	8	5.6
Piperacillin	Penicillin	5	3.54
Doxycycline	Tetracycline	2	1.41
Others*	Others*	5	3.64
Total		141	100

*Others: Azithromycin, Vancomycin, Meropenem, Linezolid and Faropenem (prescribed one time each)

Analgesics with their frequency in prescription

In the study, analgesics were prescribed 169 times in total among the participants. Paracetamol was the highest prescribed analgesic, constituting 43.19%, followed by aceclofenac at 21.3%, diclofenac at 18.9%, and tramadol at 15.9% of the total analgesics (Table 5).

Alkalinizing agents with their frequency in prescription

Alkalinizing agents were prescribed 48 times in total. The highest among was Disodium hydrogen citrate, accounting for 58.3% of this class, followed by magnesium/potassium citrate at 20.8%, allopurinol at 10.4%, and ursodeoxycholic acid at 8.3% (Table 5).

Antispasmodics with their frequency in prescription

Antispasmodic agents were prescribed 54 times totally. Drotaverine (46.2%) is the most prescribed, followed by tamsulosin (25.9%), dicyclomine (11.11%) and hyoscine butyl bromide (11.11%) (Table 5).

Percentage from essential drugs/NLEM lists

A notable majority, totalling 599, of the prescribed medicines are included in essential medicines/NLEM list, 28,29 making up approximately 83% of the total prescriptions, the remaining 122 were not listed as essential medicines.

Comorbidities

47 of the patients (46.07%) were observed with no comorbidities and 55(53.9%) patients had some comorbidities in which hydronephrosis (11.50%) was the highest comorbidity found in urolithiasis patients followed by cystitis (7.60%) and renal cyst (7.60%).

Table 5: Prescribing pattern of analgesics, alkalinizing agents and antispasmodics.

Name of drug	Category/class	Frequency	Percentage (%)
Analgesics			
Acetaminophen (paracetamol)	Analgesic antipyretic	73	43.19
Aceclofenac	NSAID	36	21.3
Diclofenac	NSAID	32	18.9
Tramadol	Opioid	27	15.9
Dextromethorphan	Opioid	1	0.59
Total		169	100
Alkalinizing agents			
Disodium hydrogen citrate	Urine alkalizer	28	58.3
Magnesium/Potassium citrate	Urine alkalizer	10	20.8
Allopurinol	Xanthine oxidase inhibitor	5	10.4
Ursodeoxycholic acid	Biliary agent	4	8.3
Sodium bicarbonate	Alkalinizing agent	1	2.08
Total		48	100
Antispasmodics			
Drotaverine	Antispasmodic	25	46.2
Tamsulosin	Alpha blocker	14	25.9
Dicyclomine	Anticholinergic	6	11.11
Hyoscine butyl bromide	Antispasmodic	6	11.11
Silodosin	Alpha blocker	2	3.7
Flavoxate hydrochloride		1	1.85
Total		54	100

DISCUSSION

The findings provide intriguing new information about the drug utilization in patients with urolithiasis. Among the 102 patients, 721 drugs were prescribed. The class of drugs commonly prescribed were (23.43%), antibiotics (19.55%), nutritional supplements and parenteral fluids (11.90%), proton pump inhibitors (12.34%), antiemetics

(9.01%), alkalizing agents (6.65%), antispasmodics (7.48%), and other miscellaneous drugs (10.81%), and the most used agents were paracetamol, ceftriaxone, A-Z (multivitamin), pantoprazole, ondansetron, disodium hydrogen citrate, drotaverine, and lactulose from each class respectively, the drugs prescribed aligned with the guidelines given by EAU guidelines on urolithiasis.²⁰ Furthermore, the study examined the age range of patients utilizing drugs, with the highest falling within the age range of 31-40 years. Gender wise distribution shows a higher proportion of female (60%) compared to male (40%), this shows a significant rise in the occurrence of the disease in women compared to men which is different from Zeng et al research, Faridi et al and that of Parvin Khalili et al which shows high male prevalence than female.²¹⁻²³

Comparing the prescribing practice by generic versus brand name, most of the drugs (84.74%) were prescribed by brand names and 15.26% by their generic names. Additionally, comorbidities were present in 53.9% of patients, with hydronephrosis being the co-morbidity most encountered, followed by cystitis and renal cyst. this is different from Liu et al study, that revealed hypertension the most encountered comorbidity.²⁴ these findings may be explained by the underlying pathophysiology of urolithiasis. The term "hydronephrosis" describes the kidney enlargement brought on by the restriction of urine flow (which may be brought on by urinary stones) causing the renal pelvis to dilate and eventually culminate in hydronephrosis. and subsequent hydronephrosis. Cystitis, on the other hand, is the inflammation of the urinary vesicle and is regularly associated with urinary tract infections.²⁵

Urolithiasis increases the risk of urinary tract infections by providing a nidus for bacterial growth and compromising the normal urinary flow, leading to stasis and subsequent infection. presence of stones in urinary bladder can irritate the bladder lining, leading to cystitis. Renal cysts, which are fluid-filled sacs that form in the kidneys, can also be associated with urolithiasis. While the exact relationship between renal cysts and urolithiasis is not fully understood, renal cyst growth may be facilitated by the presence of stones in the renal system. Additionally, both urolithiasis and renal cysts share certain risk factors, such as genetic predisposition and certain metabolic conditions, which may explain their co-occurrence. This study's goal was determined using WHO core indicators.¹⁶ Analyzing the outcomes of the current investigation with standard WHO core indicator values can help to prevent irrational medication treatment.²¹

When comparing the obtained values with the WHO prescribing indicators, the study found an average seven drugs per prescription, more than the recommended range (≤ 3), indicating a potential area for improvement. antibiotic encounter (84.61%) was significantly more than standard ($\leq 30\%$) WHO value, suggesting a potential issue of overprescribing antibiotics. Reducing antibiotic prescriptions is crucial to combat antibiotic resistance, a

pressing global concern that arises from overuse or misuse of antibiotics, jeopardizing the effectiveness of these medications in treating bacterial infections. The number of drugs written by generic name (13.85%) was less than the ideal goal of 100%. Moreover, the percentage of injections (88.46%) was substantially greater than ($\leq 20\%$) recommended value, indicating a possible need to reduce injectable drug usage.²⁶

On a positive note, medications from essential medicines or NLEM lists were 83%, reflecting adherence to essential drug guidelines to a certain extent, aligning with previous studies.²⁷ By comparing to other researches, it is essential to note that there may be variations across different studies and settings. However, in general, the findings align with some previous literature with respect to the prevalence of analgesics, antibiotics, and PPIs in the management of urolithiasis.^{28,29} The higher prescription of brand-name drugs and need of rationale use of antibiotic have also been highlighted in previous studies.²⁹⁻³²

Using multiple medications concurrently, is generally not recommended because of the risk of ADR, and potential drug interactions, and decreased medication adherence.^{33,34} However, in some cases, polypharmacy cannot be avoided, particularly in those with concomitant disease conditions. Among the analyzed patients it is likely linked to the higher comorbidities, as 53.9% of them have concurrent health conditions. Managing multiple health issues often requires the prescription of various medications, reflecting the need to address each comorbidity effectively. This connection highlights the challenge of balancing the therapeutic requirements for different conditions, leading to a higher number of prescribed drugs. The combination of analgesics and antispasmodics aims to enhance overall comfort during the passage of stone, providing symptomatic relief while the body naturally expels the stones.³⁵

Limitations

It is important to acknowledge the study's limitations. Firstly, the research was conducted at a single institution and with sample-size that is relatively small, this limits the generalizability of the findings. Secondly, the study relied on prescribing indicators and no evaluation of medication adherence or patient outcomes was performed.

Additionally, inability of follow-up with patients after discharge prevented a comprehensive assessment of treatment efficacy and long-term drug utilization pattern, inability to know the exact size and composition of the stones, thus, it is vital to establish facilities that can accurately determine the composition and size of urinary stones as it is significant in guiding the treatment approach and determining the appropriate tactics for urolithiasis patients. Various types of stones, including calcium oxalate, uric acid, calcium phosphate, and struvite require specific treatment modalities tailored to their characteristics.

CONCLUSION

The findings revealed several significant observations regarding the prescribing practices in this context, which add to the existing knowledge on drug utilization patterns in treatment of urolithiasis and give insightful information for healthcare professionals engaged in the management of this condition, by pointing out areas in need of improvement, including rationalizing antibiotic use, promoting the use of generic drugs, and offers potential benefits with regards to cost-effectiveness, patient safety, and optimal drug therapy. Overall, the evaluation of drug utilization pattern in patients with urolithiasis provides significant information for optimizing drug therapy and promoting sensible use of drugs in the management of this condition. The findings also emphasize the need for healthcare professionals on the proper use of medications.

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