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Case Study

EVALUATING THE EFFECTIVENESS OF *DURALABHADI KASHAYA* IN THE MANAGEMENT OF URINARY TRACT INFECTIONS

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ABSTRACT

Urinary tract infections are common bacterial infection affecting the urinary tract, with a higher prevalence in females. Urinary tract infections are defined as presence and multiplication of the bacteria. Around 50% of women will be treated for atleast one urinary tract infections during their lifetime. In Ayurveda, urinary tract infections can be correlated to *Pittaja Mutrakrichra* in which *Vata* and *Pitta Dosha* are vitiated. So drugs with *Pittavatahara*, *Sothahara*, *Krimighna, Mutrala,* and *Vatanulomana* are beneficial. So *Duralabhadi Kashaya* with *Sitha* as *Anupana* mentioned in *Gada Nigraha*, *Mutrakrichra Prakaranam* having above mentioned property was selected as trial drug. The present study aims to evaluate the effectiveness of *Duralabhadi Kashaya* in the management of urinary tract infection. Subjects of all gender from 20-60, satisfying the inclusion criteria were subjected to positive sampling and total of 26 subjects were selected for the study. The selected subjects were given *Duralabhadi Kashaya Choorna* packet 48gm per day, advised to take freshly prepared *Kashaya* 48ml along with *Sitha* 6gm as *Anupana* twice daily before food for 15 days and follow up was done after 15 days of treatment. Assessment of the subjects was done on 0th day, 6th day, 11th day, 16th day and follow up on 31st day with subjective and objective parameters. Based on the observations and results it has been found that subjective parameters and objective parameters got statistically significant result.

INTRODUCTION

In today's fast-changing world, people are very busy chasing after career goals and often forget completely about caring for their health. As a result, diseases emerge due to changes in lifestyle and environmental factors that impair immunity and increase vulnerability to infections. One of them is urinary tract infection which has significant impact on health. Urinary tract infections (UTIs) are one among the most common infectious diseases, affecting millions of people around the world in every year[1]. Urinary tract infections refer to those infections affecting the urethra, bladder, ureters, or kidneys, which forms the urinary tract[2].

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UTIs are common among people irrespective of all ages and genders. UTI is a prevalent disorder, accounting for 1-3% of all visits made to general medical practitioners. This is because 50% of women may have experienced at least one UTI in their lifetime. In childhood, around 1% of boys and 3% of girls will develop UTI[3]. Lack of personal and menstrual hygiene, sexual activity, and diabetes mellitus contributes to risk in getting UTIs[4]. Majority of the cases are due to anatomical or functional abnormalities of the urinary tract[5].

Based on symptomatology, urinary tract infections can theoretically and clinically correlate to *Pittaja Mutrakrichra. Mutrakrichra* is a disorder of *Mutravahasrotas* characterized by *Ruk, Krichra Mutrata, Peeta Mutra, Muhur Muhur Mutrata[6].* Drug possessing *Pittahara, Vatanulomana, Mutrala, Krimighna, Sheeta Virya, Snigdha Guna* should be given in the management of UTIs[7].

Even though many people regularly use antibiotics, there is more and more concern with these medication, as they are becoming antibiotic resistance. Therefore there is need to consider other alternatives. This study describes a clinical trial evaluating the effectiveness of *Duralabhadi Kashaya*, an Ayurvedic formulation, in the management of UTIs. This *Kashaya* is mentioned in *Gada Nigraha*, *Mutrakrichra Prakarana*. It contains *Duralabha*, *Pashanabheda*, *Harithaki*, *Kantakari*, *Yastimadhu*, *Dhanyaka* and *Sitha* as *Anupana*[8].

MATERIALS AND METHODS

Subject Inclusion Criteria

1) Subjects of either gender between age group 20-60 yrs.
2) Subjects diagnosed with pus cell/bacteria in urine routine examination.
3) Subjects diagnosed on basis of diagnostic parameters.
4) Subjects willing to sign the consent form and agreeing to follow the protocol of the study.

Subject Exclusion Criteria

1) Subjects with known case of impaired renal function.
2) Subjects with known case of malignancy or tuberculosis of urinary tract.
3) Subjects with known case of diabetes mellitus.
4) Subjects with known case of urolithiasis.
5) Women those who are pregnant and breast feeding

Case series

The present case series include 6 subjects, diagnosed with urinary tract infections satisfying the inclusion criteria who attended the OPD of Pankajakasthuri Ayurveda Medical College and PG Centre Hospital, Kattakada. After proper evaluation and clinical examination, trial drug was given to the subjects and result were analysed based on subjective and objective parameters.

Table 1: Clinical report of subjects

Case	Age	Gender	Complaints with duration
Case 1	44	Female	Increased frequency of micturition for 3 days Urgency of micturition for 2 days Suprapubic discomfort for 2 days
Case 2	28	Female	Increased frequency of micturition for 4 days Urgency of micturition for 2 days
Case 3	35	Female	Increased frequency of micturition for 2 days Urgency of micturition for 2 days Suprapubic discomfort for 1 days
Case 4	36	Female	Increased frequency of micturition for 4 days Urgency of micturition for 2 days
Case 5	40	Female	Increased frequency of micturition for 2 days Urgency of micturition for 2 days
Case 6	37	Female	Increased frequency of micturition for 4 days Urgency of micturition for 2 days

Therapeutic intervention, Follow-up and outcome

The selected subjects were given *Duralabhadi Kashayam* 48ml morning and evening before food with *Sitha* 6gm as *Anupana* for duration of 15 days. Follow up was done 15 days after the completion of intervention. Review was done on every 5th day. Assessment was done on 0th day, 6th day, 11th day, 16th day and 31st day with subjective parameters and urine routine examination. Urine culture was done on 0th day, 16th day and 31st day. Safety parameters were assessed on 0th day and 16th day.

Subjective parameters

Dysuria, increased frequency of micturition, urgency of micturition, suprapubic discomfort and fever.

Objective parameters

Urine routine examination and urine culture

Table 2: Grading of Subjective parameters Grading for Dysuria

Grade 0	No symptoms
Grade 1	Burning sensation during urination
Grade 2	Frequency burning or pain during urination
Grade 3	Continuous burning sensation or pain during urination

Grading for Increased Frequency of Micturition

Grade 0	Less than 5times
Grade 1	5- 8 times
Grade 2	8-12times
Grade 3	More than 12 times

Scoring for Urgency of Micturition

Score 0	Absent
Score1	Present

Scoring for Suprapubic Discomfort

Score 0	Absent
Score 1	Present

Scoring for Fever

Score 0	Absent
Score1	Present

OBSERVATION AND RESULTS

Improvement was observed in the subjective parameters and objective parameters.

The result were analyzed using subjective parameters and objective parameters on every 5th day.

Table 3: Effect of *Duralabhadi Kashaya* in subjective parameters

Case 1					
	BT	**6th day**	**11th day**	**16th day**	**31st day**
Dysuria	2	1	0	0	0
Increased Frequency of Micturition	2	1	0	0	0
Urgency of Micturition	1	0	0	0	0
Suprapubic Discomfort	1	0	0	0	0

Case 2					
	BT	**6th day**	**11th day**	**16th day**	**31st day**
Dysuria	2	1	0	0	0
Increased Frequency of Micturition	2	1	0	0	0
Urgency of Micturition	1	0	0	0	0
Suprapubic Discomfort	0	0	0	0	0

Case 3					
	BT	**6th day**	**11th day**	**16th day**	**31st day**
Dysuria	3	2	1	0	0
Increased Frequency of Micturition	2	1	0	0	0
Urgency of Micturition	1	0	0	0	0
Suprapubic Discomfort	1	1	0	0	0

Case 4					
	BT	6th day	11th day	16th day	31st day
Dysuria	2	2	1	0	0
Increased Frequency of Micturition	2	1	0	0	0
Urgency of Micturition	1	0	0	0	0

Case 5					
	BT	6th day	11th day	16th day	31st day
Dysuria	3	2	1	0	0
Increased Frequency of Micturition	2	1	0	0	0
Urgency of Micturition	1	0	0	0	0

Case 6					
	BT	6th day	11th day	16th day	31st day
Dysuria	2	1	1	0	0
Increased Frequency of Micturition	2	1	0	0	0
Urgency of Micturition	1	0	0	0	0

Table 4: Effect of *Duralabhadi Kashaya* in objective parameters

Assessment	BT	6th day	11th day	16th day	31st day
Case 1					
Urine albumin	Nil	Nil	Nil	Nil	Nil
Urine RBCs	Not seen	Not seen	Not seen	Not seen	Not seen
Pus cells	10-12	6-8	4-6	2-4	2-4
Epithelial cell	8-10	6-8	4-6	4-6	4-6
Bacteria	Present	Present	Absent	Absent	Absent
Urine culture	Staphylococcus 75,000CFU/ML	Staphylococcus 15,000CFU/ML	No bacteria	No bacteria	No bacteria
Case 2					
Urine albumin	Nil	Nil	Nil	Nil	Nil
Urine RBCs	0-1	Not seen	Not seen	Not seen	Not seen
Pus cells	10-15	4-6	4-6	1-2	2-4
Epithelial cell	10-12	6-8	4-6	4-6	4-6
Bacteria	Present	Present	Absent	Absent	Absent
Urine culture	E coli 50,000CFU/ML	No bacteria	No bacteria	No bacteria	No bacteria
Case 3					
Urine albumin	Nil	Nil	Nil	Nil	Nil
Urine RBCs	Not seen	Not seen	Not seen	Not seen	Not seen
Pus cells	8-10	6-8	2-4	1-2	1-2
Epithelial cell	8-10	8-10	4-6	4-6	4-6
Bacteria	Present	Present	Absent	Absent	Absent
Urine culture	Klebsiella 50,000CFU/ML	Klebsiella 20,000CFU/ML	Klebsiella 10,000CFU/ML	No bacteria	No bacteria

Case 4					
Urine albumin	Nil	Nil	Nil	Nil	Nil
Urine RBCs	Not seen	Not seen	Not seen	Not seen	Not seen
Pus cells	10-12	6-8	2-4	2-4	2-4
Epithelial cell	8-10	8-10	4-6	4-6	4-6
Bacteria	Present	Present	Absent	Absent	Absent
Urine culture	Staphylococcus 50,000CFU/ML	Staphylococcus 15,000CFU/ML	No bacteria	No bacteria	No bacteria
Case 5					
Urine albumin	Nil	Nil	Nil	Nil	Nil
Urine RBCs	Not seen	Not seen	Not seen	Not seen	Not seen
Pus cells	8-10	6-8	4-6	1-2	2-4
Epithelial cell	8-10	8-10	4-6	4-6	4-6
Bacteria	Present	Present	Absent	Absent	Absent
Urine culture	Staphylococcus 75,000CFU/ML	Staphylococcus 30,000CFU/ML	Staphylococcus 10,000CFU/ML	No bacteria	No bacteria
Case 6					
Urine albumin	Nil	Nil	Nil	Nil	Nil
Urine RBCs	Not seen	Not seen	Not seen	Not seen	Not seen
Pus cells	8-10	4-6	2-4	1-2	1-2
Epithelial cell	8-10	8-10	4-6	4-6	4-6
Bacteria	Present	Present	Absent	Absent	Absent
Urine culture	Staphylococcus 50,000CFU/ML	Staphylococcus 20,000CFU/ML	Staphylococcus 10,000CFU/ML	No bacteria	No bacteria

RESULT

Statistically significant changes were observed with p value <0.001 in the subjective parameters such as dysuria, Increased frequency of micturition, urgency of micturition and suprapubic discomfort and also in the objective parameters such as pus cell and urine culture. Pair wise comparison showed statistical significance between before treatment and 6th day; before treatment and 11th day; before treatment and after treatment; before treatment and after follow-up in the subjective parameters and objective parameters.

DISCUSSION

Hygiene plays an important role in maintaining health by preventing the spread of infection, and thereby enhancing the quality of life. This study examines several factors that increase the risk to the urinary tract infections like age, gender and also socio economic status. Moreover, a higher prevalence was seen in females of reproductive age. This may be due to the factors like sexual intercourse; poor personal and menstrual hygiene; and vaginal and rectal regions are close to the urethra. Since it is a bacterial infection, the causative organism identified includes Staphylococcus, E. coli and Klebsiella in the current study. These forms the underlying pathologies in UTIs lead to infections ranging from mild to severe depending on the bacterial load.

Based on symptomatology, urinary tract infections can theoretically and clinically be correlated to *Pittaja Mutrakrichra.* According to the etiopathogenesis of *Mutrakrichra, Nidana* described in the classics like *Teekshna, Ushna Guna, Amla, Lavana, Katu Rasa* vitiate *Pitta Dosha,* causing the *Agni Dushti* leads to *Saama Rasa* which in turn causes *Dushita Rakta* and produce *Mala Roopa Pitta Vriddhi.* Due *to Tikshna, Ushna Guna* of *Mala Roopa Pitta* causes *Kleda Soshana* in the *Drava Bhaga* of *Kitta* leading to vitiation of *Udakavaha Srotas.* Through this *Srotas* reaches the *Pakvashaya* causing *Mutravahasrotodushti* by *Teekshna, Ushna Guna* of vitiated *Pitta Dosha*. And as *Basti* being the residing place of *Apana Vayu.* This can result in *Apana Vayu Dushti.* The aggravated *Vata Dosha* by its *Ruksha Guna*, and *Chala Guna* resulting in decreased urine volume, increased urine concentration and impairment in the flow of urine. *Krimi* manifest at the *Pakvashaya* from the *Sama Rasa*. This leads to *Sotha* in *Mutramarga. Pratiloma Gati* of *Apana Vayu* occurs as a result of

Sotha which hampers from its *Mutra Nishkramana Kriya.*

When *Stanasamsraya* occur in *Mutravaha srotas,* produces *Lakshana* like *Ruk, Krichra Mutrata Peeta Mutra*, *Daha Muhur Muhur Mutrata.* So considering UTIs as *Pittaja Mutrakrichra,* here *Pittahara Chikitsa* can be adopted which is *Samprapti Vighatana.*

Probable mode of action of *Duralabhadi Kashaya*

The current study aims to evaluate the potential of *Duralabhadi Kashaya* as *Samana Oushadha* for clinical outcomes in UTIs. Vitiation of *Pitta Dosha*, *Udakavaha Sroto Dushti*, *Apana Vayu Dushti,* and *Mutravaha Sroto Dushti* are the pathogenesis involved in *Pittaja Mutrakrichra*. So *Pittahara, Vatanulomana, Mutrala, Krimighna, Sheeta Virya, Snigdha Guna* should be given. Here *Anupana* used is *Sitha,* with *Madhura Rasa, Madhura Vipaka, Sheeta Virya, Snigdha Guna* correct vitiated *Vata* and *Pitta Dosha.*

It's probable mode of action can be understood as follows.

On *Udakavaha Srotas*: *Madhura Tikta Rasa*, *Snigdha Guru Guna, Sheeta Virya* correct the *Teekshna, Ushna Guna* of vitiated *Pitta.* Thereby normalising the vitiated *Pitta Dosha. Madhura Rasa* with *Jala Mahabhuta* predominance helps in increasing the *Dravatvam.*

On *Mutravaha Srotas*: *Tikta Rasa, Sheeta Virya* counter act with the vitiated *Pitta* and chemical constituents like chebulinic acid, lupeol, and gallic acid found in this formulation, performs anti-inflammatory activity helps in reducing the inflammation, thereby correcting the *Gati* of *Apana Vayu.* Since, this formulation has *Mutrala Karma* and *Tikta, Kashaya Rasa* helps in cleansing the *Mutramarga.* Chemical constituents like kaempferol, D-Limonene and allatoin contributes to the diuretic activity, with this combined effect increasing the urine output as well as urinary electrolyte concentration. Quercetin, linalool, glycyrrhetinic acid contribute to anti-bacterial activity.

Sitha is one among the *Ikshu Rasa Vikara*, in which *Ikshu has* the property in production of *Mutra*. *Sitha* with *Madhura Rasa, Madhura Vipaka, Sheeta Virya,* and *Snigdha Guna* correct vitiated *Vata* and *Pitta Dosha.* This indicates its specific action in *Pittaja Vikara* and in *Mutra Roga.* By its *Madhura Rasa, Madhura Vipaka,* helps in the palatability. Chemical constituents like oleic acid, palmitic acid contributes to the antibacterial activity. Therefore *Sitha* used as *Anupana* has effect on *Vyadhi* by causing *Doshasamana* and increasing the palatability of the *Kashaya*.

While analysing the *Rasapanchaka* of each drugs, the properties of this formulation can described as *Madhura, Tikta, Kashaya Rasa, Snigdha Guna, Sheeta Veerya, Vata Pittahara, Mutrala, Sothahara, and Krimighna.* Based on the pharmacological actions, this formulation includes drugs that have been researched for their anti-inflammatory, analgesic, diuretic, and antimicrobial activities. Therefore, the combined effect of all these *Karma* acts on the curative level.

Discussion on Methodology

The study conducted was an intervention trial, where medicine was administered internally over a short duration. Pre and Post-test done with baseline assessment followed by assessments during the intervention and after treatment. Subjects aged 20- 60 years were selected due to high prevalence of UTIs observed. Both genders were included in the study, as they do not influence the treatment outcome. Time of administration of medicine is *Pragbhakta*, as treatment was planned in to address *Apana Vayu Dushti* occurs. Therefore to correct the *Stanika Dosha*, medicine is prescribed as morning and evening before food. Assessments were carried out on every 5th day to track the progress of infection, monitor the effectiveness of treatment through subjective and objective parameters and to know any adverse effect during the treatment. And follow-up was done to know the sustainability of the drug action. Safety parameters like LFT and RFT were assessed before and after treatment to evaluate that no adverse effect results from the treatment.

Sample size was 24 subjects including dropout as per the calculation, based on the previous study. Pus cell or bacteria present in the urine routine was included to ensure that the study selects the subjects with relevant UTI symptoms. Impaired renal function, malignancy or tuberculosis of urinary tract was excluded, mainly to focus on typical UTI cases. And also diabetes mellitus being excluded because *Sitha* as *Anupana* being used. Pregnant and lactating women were not taken as they belong to vulnerable group. Heavy metals and microbial impurities were done to ensure the quality and safety of the drug used in the study.

Discussion on Observation

In Ayurveda, *Sashoola Mutra* is one of the features of *Mutravahasrotodushti.* Here *Shoola* is due to *Ruksha Guna* of the vitiated *Vata.* The decreased in symptoms suggests that the trial drug contains *Vatapittahara*, *Madhura Rasa, Mutrala* properties. *Madhura Rasa* with *Jala Mahabhuta* predominance and *Mutrala Karma* helps in maintaining the volume and pH of the urine. Moreover, the administration of *Sitha* as *Anupana* with *Madhura Rasa, Madhura Vipaka, Sheeta Virya* counter act with the vitiated *Pitta* properties. Chemical constituents like solasodine, sapogenin contributes to analgesic activity which aid in reducing the pain.

Increased frequency of micturition is due to irritation and inflammation of the bladder which hampers the bladder capacity. In Ayurveda, *Muhur Muhur Mutra* is one of the *Lakshana* of *Mutrakrichra* due to *Chala Guna* and *Pratiloma Gati* of vitiated *Vata* refers to the increased frequency of micturition in UTIs. Here the symptoms got subsided due to combined action of *Madhura Tikta Rasa*, *Snigdha Guru Guna, Sheeta Veerya* counter act with the *Teekshna, Ushna Guna* of vitiated *Pitta*; while *Tikta, Kashaya Rasa* by its *Sodhana* effect helps in cleansing the *Mutramarga* thereby washing out bacteria in the tract. The presence of chebulinic acid, lupeol, gallic acid in this formulation which helps in reducing inflammation of the bladder, thereby reducing the pressure in the bladder which allow it to hold more urine and it also pacifying the irritation causing reduction in the sensation to urinate frequently; Kaempferol, D-Limonene and Allatoin contributes to the diuretic activity by increasing the urine output as well as urinary electrolyte concentration. This combined effect helps in reducing the condition.

Urgency of micturition is due to inflammation of the bladder which increases pressure within the bladder causing sudden urge to urinate. In Ayurveda, this condition is due to *Teekshna Ushna Guna* of vitiated *Pitta* causing an inflammation in the *Mutramarga* due to which *Pratiloma Gati* of *Vata* occurs, this hampers *Mutra Nishkramana Kriya* of *Apana Vayu*. *Tikta Rasa* counter acts with the *Teekshna Ushna Guna* of vitiated *Pitta* thereby producing *Sothahara* action leading to *Anulomana Gati* of *Vata*. Additionally, *Madhura Rasa* corrects the vitiated *Vata*. Chemical constituents present in this formulation contain chebulinic acid, lupeol, gallic acid reducing the inflammation which helps in smoothening the bladder lining and also reducing the pressure over the bladder thereby decreasing the feeling of urination. This highlights the efficacy of this *Kashaya*, particularly by addressing the underlying the vitiated *Dosha* and inflammatory condition.

The inflammation of the bladder causes irritation in the bladder lining or spasm of the bladder muscles causing uneasiness or pain in the lower abdomen which is perceived as suprapubic discomfort. Due to *Mutravegadharana* causes pressure as a result of distension of the bladder leading to the obstruction of *Vata* which causes spasm of the muscles. *Madhura Rasa* with *Jala Mahabhuta* predominance counter act with the vitiated *Vata*. Along with chebulinic acid, lupeol, and gallic acid which helps in pacifying the inflammation as a result reduction in the irritation causing easing in the condition. Solasodine, sapogenin helps in causing relief in pain or discomfort felt.

Presence of epithelial cells in the urine is due to the damage of the epithelial cells lining the tract caused as a result of inflammation. *Tikta Rasa, Sheeta Virya* counter acts with the vitiated *Pitta* aid in reducing the *Sotha. Tikta, Kashaya Rasa* helps in cleansing the *Mutramarga. Rasayana Karma* helps in regeneration of the cell lining the tract. Thereby inhibiting the growth of bacteria and also preventing the recurrence of the infection. Chebulinic acid, lupeol, and gallic acid found in this formulation helps in pacifying the condition. Kaempferol, D-Limonene and Allatoin contribute to the diuretic activity with this combined effect increasing the urine output. Quercetin, linalool, glycyrrhetinic acid act against bacterial growth by breaking their cell membrane. Linoleic acid, vitamin C performs antioxidant activity, thereby improving the immune response and aid in faster recovery.

Action on pus cell is due to *Madhura, Tikta Rasa* counter act with the vitiated *Pitta* reducing the *Sotha*. Chebulinic acid, lupeol, and gallic acid found in this formulation helps in pacifying the inflammation. Kaempferol, D-Limonene and Allatoin contribute to the diuretic activity with this combined effect increasing the urine output as well as urinary electrolyte concentration. *Tikta, Kashaya Rasa* having *Sodhana* effect helps in cleansing the *Mutramarga.* Thereby inhibiting the growth of bacteria and also preventing the recurrence of the infection. Quercetin, linalool, glycyrrhetinic acid inhibits the growth of bacteria.

Action on bacteria is due to *Deepana*, *Pachana* effect of *Tikta Rasa* counter act with *Samavastha*, thereby inhibiting the *Krimi* manifestation. *Kashaya Rasa* helps in cleansing the *Mutramarga. Mutrala Karma* helps in increasing the quantity of the urine which causes easy expulsion of the bacteria. Thereby inhibiting the growth of bacteria and also preventing the recurrence of the infection. Chebulinic acid, lupeol, and gallic acid found in this formulation, helps in reducing the inflammation. Kaempferol, D-Limonene and Allatoin contribute to the diuretic activity with this combined effect increasing the urine output as well as urinary electrolyte concentration. The chemical constituents present in this *Kashaya* destroy the cell membrane of microorganism by inhibiting the growth of Staphylococcus through Quercetin, Linalool, and Glycyrrhetinic acid; E.coli with Quercetin, Linalool and Klebsiella by Linalool. In addition to that *Sitha* with *Madhura Rasa, Madhura Vipaka, Sheeta Virya, and Snigdha Guna* helps in reducing the *Sotha.* Oleic acid, Palmitic acid against Staphylococcus species. This effect not only reduce the bacterial load but also prevent the further bacterial colonization.

CONCLUSION

The efficacy of *Duralabhadi Kashaya* in managing urinary tract infections has been presented clinically. The trial drug in gross possesses *Vata Pittahara, Mutrala, Krimighna,* and *Sothahara*

properties helps in alleviating the symptoms. *Sitha* used as *Anupana* has influence on *Vyadhi* and enhance the palatability of the *Kashaya*.

Utilizing these properties, subjects experienced significant improvement in subjective and objective parameters which indicates the clinical efficacy of *Duralabhadi Kashaya.* Importantly, no adverse effects were noted throughout the study. So considering its overall safety and clinical effectiveness, *Duralabhadi Kashaya* is effective and safe treatment for Urinary Tract Infections.

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