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Research Article

A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF *CHARAKOKTA MUTRAVIRECHANIYA MAHAKASHAYA* IN *MUTRAKRICHRA* OR LOWER URINARY TRACT INFECTION

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ABSTRACT

Mutrakrichra the disease of Mutravaha Srotas is caused due to Sanga (obstruction). Mutrakrichra means difficulty in micturition. Mutrakrichra can be compared to lower urinary tract infection (LUTI) symptoms. LUTI is the most common infection known to mankind and a common condition seen in general practice. Urinary tract infection affects more than 150 million people every year worldwide. **Objective:** To evaluate the effect of *Mutravirechaniya Mahakashaya* in LUTI and to compare its efficacy with Tab. Norfloxacin. Methods: 45 patients of either gender with the symptoms of LUTI were randomized into three groups of 15 patients each. Group A- received Mutravirechaniya Mahakashaya 50ml. Group B- received Tab. Norfloxacin 400mg and Group C- Mutravirechaniya Mahakashaya and Tab. Norfloxacin in the above mentioned dose for ten days. Efficacy outcomes were assessed through subjective parameters and routine urine and microscopic examination. **Observation and results:** When compared all the groups showed better results in relieving the clinical symptoms of LUTI. Overall patients treated with Mutravirechaniya Mahakashaya and Tab. Norfloxacin showed better results, but there was no significant difference between the groups (P<0.351). Conclusion: Mutravirechaniya Mahakashaya was able to meet the efficacy outcomes measures in comparison to Tab. Norfloxacin. Clinical effects of Mutravirechaniya Mahakashaya were similar to Tab. Norfloxacin owing to its diuretic, analgesic and anti-inflammatory properties.

KEYWORDS: Ayurveda, Lower urinary tract infection, *Mutrakrichra, Mutravirechaniya Mahakashaya*, Norfloxacin.

INTRODUCTION

Dosha dhathu mala mulam hi shareeram, Dosha, Dhathu and Mala are the basic substratum of the Shareera (Body).^[1] Mala being one among them, Acharyas have given importance to their function and their different status in the body. Mutra is one among the Trimala^[2] and it plays a major role in Kledavahana. Mutravega is one among the Adharaniya Vegas^[3]. Basti which is the Srotomula of the Mutra is one among the Trimarma^[4]. All these factors highlight the importance of the Mutra.

Disorders related to *Mutra* have been elaborately explained by our *Acharyas* and *Mutrakrichra* is one among them. As the word itself denotes, it is characterized by *Kruchratha* in *Mutravahana* (difficulty in micturition). The *Samanya Lakshana* of *Mutrakrichra* has been mentioned in *Madhukosha* commentary of *Madhava Nidana* as *Kruchrarata* in *Mutravahana* i.e. difficulty in micturition.^[5] Other *Lakshanas* of *Mutrakruchra* varies according to the predominance of *Dosha* involved in pathogenesis like *Shula* (pain) in *Vataja Mutrakrichra, Daha* (burning sensation)in *Pittaja Mutrakrichra* and *Gourvata* (heaviness) in *Kaphaja Mutrakrichra* as predominant symptoms.

Lower urinary tract infection (LUTI) is the most common infection seen in general practice. In majority of LUTI, bacteria establish infection by ascending from urethra to bladder. The entry of uro-pathogens in to the urinary tract is often from peri-urethral colonisation in females and from preputial colonisation in uncircumcised males. Escherichia Coli and Staphylo Saprophyticus are the most common organisms involved in causing LUTI.^[6] Patients with LUTI present with symptoms such as abrupt onset of frequency of urination and urgency, dysuria- burning pain in urethra during micturition, nocturia, urge incontinence, suprapubic pain, sensation of incomplete bladder emptying due to spasm of inflamed bladder wall, urine having offensive smell, blood and cloudy appearance.^[7]

Mutravirechaniya Mahakashaya Gana is mentioned by Acharya Charaka, under Shad virechanashataashreetiya adhyaya.^[8] The combination includes- Vrukshadhani (Dendropthoe falcate ainn. F.), Swadanshtra (Tribulus terrestris), Vasuka (Osmanthus fragrans), Apamarga (Achyranthus aspera), Pashanabheda (Aerva lanata Juss.), Darbha (Imperata cylindrical Beau.), Kusha (Desmostachya bipinnata stapf.), Kasha (Saccharum spontaneum Linn.), Gundra (Typha elephentina Roxb.) and Itkatamula (Sesbania cannabina). Most of these drugs possess *Mutrakruchrahara* (relives symptoms of LUTI) and *Mutrala* (diuretic) property. Vrukshadhani, Swadanshtra and Pashanabheda has got anti-bacterial activity.

Norfloxacin belongs to the first-generation fluoroquinolones. Fluoroquinolones are basically quinolones antimicrobial and they have one or more fluorine substitution. Norfloxacin is primarily used for urinary and genital tract infection.^[9]

Hence the present study was intended to evaluate and compare the efficacy of *Mutravirechaniya mahakashaya* and Norfloxacin in *Mutrakrichra* vis-a-vis lower urinary tract infection.

MATERIALS AND METHODS

The study was a simple randomized controlled clinical study having three parallel arms (allocation ratio 1:1:1). Subjects diagnosed with *Mutrakrichra* or LUTI were recruited from OPD, IPD and special camps conducted at Sri Sri College of Avurvedic Science and Research Hospital, Bengaluru. The ethical clearance from the institutional ethical committee was obtained prior to the initiation of the research.

Eligibility Criteria:

Inclusion criteria:

Subjects aged between 18 to 70 years

Subjects presenting with one or more of the following symptoms of LUTI:

- Pain in lower abdomen
- Increased frequency of urination
- Burning micturition
- Pain during micturition

Subjects willing to give informed consent

Exclusion Criteria

- Subjects suffering from urinary calculi, pyelonephritis
- Subjects suffering from benign prostatic hypertrophy, prostatitis
- Subjects suffering from diabetes mellitus and sexually transmitted diseases
- Pregnant women
- Subjects who have participated in clinical trials within 6 months.

Diagnostic Criteria

Diagnosis was established based on the signs and symptoms of *Mutrakrichra* and LUTI further confirmed with laboratory investigation-Urine routine and microscopy for presence of bacteria and pus cells.

Intervention

- Group A- Patients were given Mutravirechaniya Mahakashaya 50ml, twice a day along with warm water, before food for 10 days.
- Group B- patients were given Tab. Norfloxacin 400mg 1 bid, after food for 10 days.
- Group C- Patients were given both Mutravirechaniya Mahakashaya and Tab. Norfloxacin 400mg with above mentioned dosage respectively for 10 days.

Assessment criteria

Subjective criteria

Pain in the lower abdomen

- a. Grade 0 (normal- absent)
- b. Grade 1 [mild- present but intensity is less (draws attention)]
- c. Grade 2 (moderate- present, intensity is high, able to do routine activities)
- d. Grade 3 (severe- present, intensity is severenot able to do routine activities)

Frequency of Urination

- a. Grade 0- less than 5 times
- b. Grade 1- 5-8 times
- c. Grade 2- 8-12 times
- d. Grade 3- more than 12 times

Burning Sensation

- a. Grade 0- absent
- b. Grade 1/ mild- occasional mild burning
- c. Grade 2/ moderate- moderate burning with every voiding
- d. Grade 3/ severe- severe burning with every voiding

Pain During Urination

- a. Grade 0- absent
- b. Grade 1/ mild- occasional mild pain
- c. Grade 2/ moderate- often moderate pain
- d. Grade 3/severe- severe pain

Objective Criteria

Urine microscopy was done before treatment and after the treatment (11th day)

Urine Microscopy

Pus cells

- 1. Grade 0- 0- 5/hpf
- 2. Grade 1- 5-15/hpf
- 3. Grade 2-15-25/hpf
- 4. Grade 3- 25-35/hpf
- 5. Grade 4- 35-45/hpf
- 6. Grade 5- 45-55/hpf

Bacteria

- 1. Grade 0- absent
- 2. Grade 1- present

Assessment schedule

Data was collected before treatment (0th day), on 5th day, 11th day (after completion of treatment) and 15th day (follow up). Urine routine and microscopy was done on 0th day and 11th day.

Statistical Analysis

The statistical analysis was done using the SPSS software version 20. Paired t -test and ANOVA test were applied to analyze parametric data within and between the groups. Wilcoxon signed rank test and Kruskall wall is test was applied to analyze non parametric data within and between the groups respectively.

OBSERVATIONS

Maximum incidence of *Mutrakrichra* was noticed in the age group of 18-29 years followed by 60-69 years. LUTI is most commonly seen in patients of reproductive and sexually active individuals. The same might be the reason for the incidence of *Mutrakrichra in* 18-29 years of age group in the study. Urinary incontinence is most commonly seen in elderly due to weak bladder muscles leading to lower urinary tract infection. The incidence of disease in different age group in the present study is shown in Table No. 1.

In the present study, incidence of gender showed that females were more prone to LUTI. The reasons behind this are short urethra and nearby structures like vagina and anus. Other than these reasons, *Mutravegadharana* (suppression of urge to micturate) was noticed in most of the female. Unhygienic toilet facilities in public places and work places might be the reason behind *Vegadharana*. The incidence of disease based on gender is given in Table No. 2.

Maximum number of patients had moderate physical activities with reduced water intake. Water intake disproportionate to physical activity was noticed, this might be the cause for dehydration, contributing to lower urinary tract infection. The physical activity and water intake of the patients in present study is given in Table No. 3 and 4.

Age	Group A			Group B			oup C		Total	
18-29	6	4		6	3			15 (33.33%)		
30-39	2	BU		2					10 (22.22%)	
40-49	1		at II	0					2 (4.44%)	
50-59	2		.S.	3 10.5					7 (15.50%)	
60-69	4			4 JA	3			11 (24.44%)		
Table 2: Showing the incidence of disease with relation to gender										
Gender	Group A		G	Group B		Group C		Total		
Female	15		1	15		13		43(95.50%)		
Male	0	0		0		2		2 (4.40%)		
Table 3: Showing the incidence of disease with relation to physical activity										
Physical activity		Group A		Group B		Group C		Total		
Sedentary		2		0		1		3(6.60%)		
Moderate 12			12		9		33 (73.33%)			
Vigorous	1			3		5		9 (20%)		
Table 4: Showing the incidence of disease with relation to water intake										
Water intake (per day)			Gro	Group A		Group B		рC	Total	
1 litre			5		4		7		16 (35 55%)	

Table 1: Showing the incidence of disease with relation to age

Water intake (per day)	Group A	Group B	Group C	Total				
1 litre	5	4	7	16 (35.55%)				
2 litres	7	10	7	24 (53.33%)				
3 litres	2	1	1	4 (8.88%)				
4 litres	1	0	0	1 (2.22%)				

Subject flow chart through the study



Analysis of the result of drugs within the groups, for pain in lower abdomen group B and C had significant result with a p value of 0.020, for increased frequency of urination group A and group C had significant result with a p value of 0.010 and 0.014 respectively, in burning sensation while urination, group A and C showed highly significant result with a p value of 0.001, in pain while urination group A showed significant result with a p value of 0.041. In objective parameters, in pus cells group B and C showed highly significant result with a p value of 0.005, in bacteria all the three groups showed statistically significant result with a p value of 0.000. The mean score with p value of group A, B and C are given in Table No. 5, 6 and 7 respectively.

Pain while urination

Mean P value On comparing the results between the groups, there was no statistically significant result in the subjective parameter. By analysing the mean value, group A had highest mean value in all the subjective parameters when compared to group B and C. The mean score with p value on comparing the results in between the group is shown in Table No. 8. In objective parameter, there was no statistical significance for pus cells with a p value of 0.269, whereas there was significant result for presence of bacteria in urine with a p value of 0.000. Though, clinically faster recovery and sustained therapeutic effect was better in group C compared to group A and B. This can be considered as an add-on effect of *Mutravirechaniya Mahakashaya*.

Symptoms		Mean score					P value	
			.T		AT			
Pain in lower abdomen	Pain in lower abdomen			.0	.00		0.157	
Increased frequency of urination			.87		.07		0.010	
Burning sensation while urination			1.93		.13		0.001	
Pain while urination			.73		.07		0.041	
Bacteria			1.00		0.40		0.000	
Pus cells			20 yurveda	1.	1.27		0.005	
Table 6: Showing the effect of medicine on subjective and objective criteria of group B								
Symptoms			Mean score			P value		
	2	1	BT 💦 🔰		AT			
Pain in lower abdomen	La	1	.80	CU.	.07		0.020	
Increased frequency of urination			.33	N.	.00		0.102	
Burning sensation while		4.00	3	.00		0.016		
Pain while urination			.33		.13		0.180	
Bacteria			1.00		0.20		0.000	
Pus cells			2.47		0.80		0.000	
Table 7: Showing th	ne effect of medi	iciı	ne on subjecti	ve an	d objective crit	eria	a of group C	
Symptoms			Mean score		Р	value		
		E	BT	AT				
Pain in lower abdomen			73	.00		.020		
Increased frequency of urination			.80		.00		.014	
Burning sensation while urination			1.80		.07		0.001	
Pain while urination			.13		.00		57	
Bacteria			1.00		0.13		0.000	
Pus cells			2.47 0.80)	0.000		
Table 8: showing the effect of medicine in between the groups								
Subjective criteria			Group A		Group B		Group C	
Pain in lower abdomen	Mean		22.50		24.00		22.50	
	P value				.368			
Increased frequency of	Mean		24.00		22.50		22.50	
urination P value			.368		.368		1	
Burning sensation	Mean		23.93 22.60				22.47	
while urination	P value		.470					

22.50

.351

23.00

21.50

DISCUSSION ON RESULTS Pain in Lower Abdomen

All the groups showed significant result on the symptom pain in lower abdomen. Most of the drugs in *Mutravirechaniva Mahakashava* possess *vatahara*.^[10-12], anti- inflammatory effect^[13] and spasmolytic effect^[14]. This might be the reason behind the relief of symptom in group A. Norfloxacin being an antibiotic has bactericidal effect and thus helps in LUTI which reduces cystitis. The combined effect of Mutravirechaniva Mahakashava and Norfloxacin reduced the symptom in group C.

Increased frequency of urination

The drugs in *Mutravirechaniyagana* like Tribulus terrestris^[15], Achyranthus aspera^[14], Aerva lannata^[16] and Saccharum spontaneum^[17] has got diuretic activity. Diuretic activity of the drugs helps in flushing out the bacteria and thus reducing sensitivity of bladder. Norfloxacin primarily being an antibiotic brings down the infection of lower urinary tract, this subsides the increased frequency of urination. The combined effect of Mutravirechaniya Mahakashaya and Norfloxacin effectively relieved this symptom in group C.

Burning Sensation While Urination

Most of the drugs in *Mutravirechaniva* Mahakashaya like Dendroupthoe falcate [18], Tribulus terristris^[15]. Achvranthus aspera^[14] Aerva lannata^[16] has got diuretic effect. Increased amount of urine output reduces the concentration of urine thus relieving the burning sensation while urination. bactericidal Norfloxacin possesses activity. Infection being the cause for symptoms in the diseases, with bactericidal activity of Norfloxacin, burning sensation will come down. The combined effect of Mutravirechaniva Mahakashava and Norfloxacin relieved this symptom effectively in group C.

Pain while Urination

In Mutravirechaniya Mahakashaya gana, there are drugs which have got analgesic and antiinflammatory activity. *Aerva lannata*^[16], *Typha elephentina*^[19] and *Achyranthus aspera*^[14] has got analgesic effect. *Tribulus terrestris*^[15], *Achyranthus* aspera^[14], Aerva lannata^[16] and Saccharum *spontaneum*^[13] has got anti-inflammatory effect. This might be the reason behind for relief of symptom pain during urination after the intake of Kashaya. Norfloxacin, reduces the inflammation of lower urinary tract, thus reducing the symptom pain while urination. The combined effect of the Kashaya and Norfloxacin relieved the symptom effectively in group C.

Bacteria in Urine

In Mutravirechaniya Mahakashaya gana, most of the drugs like *Dendropthoe falcate*^[18], Tribulus terrestris^[15], Achyranthus aspera^[14], Aerva *lannata*^[16] has got antibacterial activity. This might be the reason for absence of bacteria in urine microscopy after the intake of medicine. Norfloxacin, inhibits the enzyme bacterial DNA binding synthesis, bv to the enzyme-DNA complex.^[8] The antibacterial activity of Norfloxacin along with the antibacterial, diuretic and antiinflammatorv activitv of Mutravirechaniva Mahakashaya acted well against the bacteria, thus bringing down the infection effectively in group C.

Pus cells in urine

Most of the drugs in *Mutravirechaniya Mahakashaya* possess antibacterial and diuretic activity it reduces the number of pus cells. Norfloxacin is an antibiotic which has bactericidal activity. As the infection reduces the number of pus cells also reduces. The anti-inflammatory activity of the drugs in *Mutravirechaniya Mahakashaya* also helps in bringing down the pus cells. The diuretic effect flushes out the bacteria and pus cells.

On follow up on 15th day, group C showed statistically better results when compared to group A and B. This indicates that, Tablet Norfloxacin when taken along with *Mutravirechaniya Mahakashaya*, helped in effective management and prevention of further recurrence of infection.

CONCLUSION

Drug resistance and recurrence are common in LUTI. There was better recovery and sustained therapeutic effect in patients treated with Mutravirechaniva Mahakashava Tab. and Norfloxacin but there were no statistically significant results between the groups. Over all it can be concluded that, in subjective parameter, the Mutravirechaniya subjects treated with Mahakashaya had better results compared to Norfloxacin subiects treated with and Mutravirechaniva Mahakashava along with Norfloxacin. In objective parameter, subjects administered with Norfloxacin and Mutravirechaniya Mahakashaya along with Norfloxacin showed better result.

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