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A RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF *PATHYAGOKSHURADI KWATHA* AND TO COMPARE IT WITH *SHATAVARYADI KWATHA* IN *PAITTIKA MUTRAKRICCHRA*

Megha Mirajkar[1*] and Surekha Pai[2]

[1]3rd Year PG Scholar, Department of Kayachikitsa, Alvas Ayurveda Medical College & Hospital Moodbidri, Karnataka, India.

[2]Professor, Department of Kayachikitsa, Alvas Ayurveda Medical College & Hospital Moodbidri, Karnataka, India.

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***Corresponding Author**
Megha Mirajkar
3rd Year PG Scholar, Department of Kayachikitsa, Alvas Ayurveda Medical College & Hospital Moodbidri, Karnataka, India.

ABSTRACT

Background and Objectives: Out of eight types of *mutrakricchra*, *paittika mutrakricchra* is the commonest type. It's symptoms resembles the signs and symptoms of acute infection of lower urinary tract. The management of UTI in modern contemporary science is mainly antibiotic therapy. Even though they are useful, they involve considerable amount of risk, side effects and are expensive. In this regard management of UTI by herbal drugs is safe and rational. Considering all the above facts, the study was selected to evaluate and compare the effect of *Pathyagokshuradi kwatha* and *Shatavaryadi kwatha* in patients suffering from *Paittika Mutrakricchra*. **Materials and methods**: In this clinical trial, 60 patients fulfilling the diagnostic and inclusion criteria were selected and were randomly assigned into two groups group A (*Pathyagokshuradi kwatha*) and group B (*Shatavaryadi kwatha*). **Results**: The effect of treatment was statistically significant in both the groups. When statistical comparison was done between the two groups, no significant difference was found. **Conclusion**: Both the kwathas are therapeutically effective in the treatment of Paittika Mutrakricchra individually and on comparison there is no significant difference in their effects. H_0 is accepted.

KEYWORDS: Mutrakricchra, Pathyagokshuradi kwatha, Shatavaryadi kwatha.

INTRODUCTION

The disease Mutrakricchra is an age old disease and has been described in all major classic text books of Ayurveda. Out of eight types of mutrakricchra, paittika mutrakricchra is the commonest type evokes greater attention due to its higher incidence and sudden onset. It's symptoms like daaha, peeta, sarakta, saruja mutrata, muhur mutrata[1] resembles the signs and symptoms of acute infection of lower urinary tract.[2] Urinary tract infection is a common medical complaint. It is the second most common infection, preceded only by respiratory infection.[3] UTI's are leading cause of morbidity and health care expenditures in the persons of all ages. It is estimated that between 50% and 60% of adult women will have at least one UTI in their life.[4] UTI is acute condition and reoccurs in many cases. The management of UTI in modern contemporary science is mainly antibiotic therapy. Even if they are beneficial, they come with a lot of side effects, and are expensive, and the causative organism will develop medication resistance. Hence, the present study aims to explore the efficacies of Pathyagokshuradi Kwatha[5] and Shatavaryadi Kwatha[6] in the management of Paittika Mutrakricchra.

MATERIALS AND METHODS

OBJECTIVES OF THE STUDY

1. To evaluate the efficacy of Pathyagokshuradi kwatha in the treatment of paittika mutrakricchra.
2. To compare the effect of Pathyagokshuradi kwatha and Shatavaryadi kwatha in the treatment of Paittika mutrakricchra.

SOURCE OF DATA

a. LITERARY SOURCE: All Ayurvedic, Modern Medical literatures, Contemporary texts including Journals and Websites about the disease and Medicine were reviewed and documented for the planned study.

b. DRUG SOURCE: Raw drugs required were identified and collected from the source of availability and the medicines were prepared according to the classical references at Rasashastra and Bhaishajya Kalpana Laboratory, Alva's Ayurveda Medical College, Moodbidri.

c. SAMPLE SOURCE: Patients diagnosed as paittika mutrakricchra were randomly selected from Kayachikitsa Out Patient Department and In Patient Department of Alva's Ayurveda Medical College and Hospital, Moodbidri, Medical camps and other referrals.

METHOD OF COLLECTION OF DATA

a. SAMPLE SIZE AND GROUPING: A minimum of 60 patients were randomly divided into 2 groups A and B comprising minimum of 30 patients in each group.

STUDY DESIGN: Parallel group comparative clinical study

BLINDING: Single blind

METHOD OF SAMPLING: Lottery method

b. PLAN OF STUDY

GROUP A	GROUP B
Pathyagokshuradi kwatha	Shatavaryadi kwatha
Dose 25ml thrice daily before food	Dose 25ml thrice daily before food
Anupana: madhu and sharkara	Anupana: madhu and sharkara
Duration- 7 days medication + 7 days follow up	Duration- 7 days medication + 7 days follow up

OBSERVATION PERIOD

- Treatment period: 7 days
- Follow up: 7 days after completion of treatment i.e; 14^{th} day
- Total Study duration: 14 days
- Days of assessment: Observation will be done at baseline, 4th, 8th and 14th day.

DIAGNOSTIC CRITERIA

Patients with classical symptoms of pittaja mutrakricchra like.

- peeta mutrata
- sarakta mutrata
- daaha mutrata
- rujayukta mutrata
- muhur mutrata

INCLUSION CRITERIA

- Patients fulfilling diagnostic criteria.
- Patients between the ages of 16 years to 60 years (Both ages inclusive).
- Patients with history of disease from one day to one month.
- Patients who are willing to give consent.

EXCLUSION CRITERIA

- Paittika mutrakricchra due to marmabhighata
- Due to congenital deformity
- Due to STD
- Secondary to disorders like Ashmari, BPH, acute renal failure, vesico-ureteric reflux, tumor, renal tuberculosis.
- Patients with other systemic disorders like diabetes mellitus, thyroid disorders, cardiac illness and other disorders which interfere with the treatment.
- Pregnant women and lactating mother.
- Patients who are not willing to give consent.

ASSESSMENT CRITERIA

SUBJECTIVE PARAMETERS

- Painful micturition (saruja mutrata)
- Burning micturition (daaha mutrata)
- Difficulty in micturition (mutra kricchrata)
- Frequency of micturition (muhur mutrata)
- Nocturia

OBJECTIVE PARAMETERS

Clinical

- Yellow coloration of urine (Peeta mutrata)
- Hematuria (Sarakta mutrata)

Laboratory

- Pus cells/ hpf
- Epithelial cells/ hpf
- RBC's/ hpf

INVESTIGATIONS

- Urine Routine.
- Routine haematological investigations.
- X-Ray / USG if necessary.

STATISTICAL TEST

Comparative analysis of the overall effect of the treatments in both the groups was done statistically with Mann-Whitney Rank Sum Test and within the group comparison with Wilcoxon Signed Rank Test.

RESULTS

Table no. Effect of Pathyagokshuradi kwatha in sunjective and objective parameters in Group A.

CRITERIA	Median BT	Median AT	%	S.D.	S.E.	WSRT Value	p value
Painful Micturition	2.0	0	84.5	0.450	0.082	465	<0.001
Burning Micturition	2.0	0	93	0.346	0.0631	465	<0.001
Difficulty in Micturition	2.0	1.0	67.28	0.568	0.104	378	<0.001
Frequency of Micturition	2.0	0	84.59	0.521	0.0951	465	<0.001
Nocturia	2.0	1.0	65.23	0.507	0.0926	276	<0.001
Yellow coloration of urine	1.0	0	84.61	0.407	0.152	406	<0.001
Haemeturia	1.0	0	100	0	0	3.0	0.5
Pus cells/hpf	2.0	1.0	68.65	0.535	0.0977	465	<0.001
Epithelial cells/hpf	1.0	0	77.21	0.379	0.0692	153	<0.001

Table no. Effect of Shatavaryadi kwatha in subjective and objective parameters in Group B.

CRITERIA	Median BT	Median AT	%	S.D.	S.E.	WSRT Value	p value
Painful Micturition	2.0	0	81.25	0.466	0.0851	378	<0.001
Burning Micturition	2.0	0	92.17	0.379	0.0692	465	<0.001
Difficulty in Micturition	2.0	0	80	0.498	0.091	465	<0.001
Frequency of Micturition	1.5	0	81.25	0.466	0.0851	276	<0.001
Nocturia	2.0	0	75.50	0.498	0.091	435	<0.001
Yellow coloration of urine	1.0	0	83.77	0.407	0.0743	351	<0.001
Haemeturia	1.0	0	100	--	--	1.0	1.0
Pus cells/hpf	2.0	1.0	60.94	0.648	0.118	435	<0.001
Epithelial cells/hpf	1.0	0	57.14	0.466	0.0851	78	<0.001

Table No. Comparative effect of Group A and Group B.

CRITERIA	Group A	Group B	t value	p value	Remarks
Painful Micturition	1.0	1.0	961.5	0.496	NS
Burning Micturition	2.0	2.0	845.50	0.307	NS
Difficulty in Micturition	1.0	2.0	760	0.022	SS
Frequency of Micturition	1.0	1.0	957	0.539	NS
Nocturia	1.0	1.0	834.5	0.236	NS

Yellow coloration of urine	1.0	1.0	940	0.716	NS
Haemeturia	0	0	930	0.829	NS
Pus cells/hpf	1.5	1.0	1009.5	0.164	NS
Epithelial cells/hpf	1.0	0	990	0.27	NS

ASSESSMENT OF RBC'S/HPF BY MEAN AND PERCENTAGE

Statistical analysis could not be done for objective parameter like RBC's/hpf as these values were present only in 1 subject in a group. Hence the improvement is assessed by the mean and the percentage of the score given. Only one patient in Group B had RBC's/hpf. The percentage of improvement was 100%.

Table no. Comparison between the percentage relief of Group A and Group B

Criteria	% of relief in Group A	% of relief in Group B
Painful micturition	84.5%	81.25%
Burning micturition	93%	92.17%
Difficulty in micturition	67.28%	80%
Frequency of micturition	84.59%	81.25%
Nocturia	65.23%	75.5%
Yellow coloration of urine	84.61%	83.77%
Hematuria	100%	100%
Pus cells/hpf	68.65%	60.94%
Epithelial cells/hpf	77.21%	57.14%

DISCUSSION

In the present study age limit for the selection criteria was between 16-60 years. Among them the maximum number of patients belonged to the age group 26-30 years (11 patients, 18.3%). UTIs occur during the years of maximum sexual activity, usually between the ages of 18 and 39.[7] In the present study maximum numbers of patients were females (47 patients, 78.3%). Women get UTIs more often because a woman's urethra is shorter than a man's. This makes it easier for bacteria to get into the bladder. A woman's urethral opening is also closer to both the vagina and the anus, the main source of many organisms that cause UTIs.[8] Majority of patients registered for the present study were married (40 patients, 66.7%). Due to the spread of infection through cohabitation, married patients are at high risk. Majority of the patients were officials (23 patients, 38.3%). The probable reason for this could be withholding of urine for a long time due to heavy work load. In present study, it was observed that patients who consumed mixed diet (35 patients, 58.3%) showed higher incidence of Paittika Mutrakricchra. Certain foods, including poultry and pork, act as food reservoirs for bacterial strains of *E. coli* called extraintestinal pathogenic *E. coli* (ExPEC), which account for 65–75% of all UTIs. This means that food reservoirs may be a vehicle for transmission of

ExPEC.[9] Maximum no. of patients was accustomed to Katu rasa (22 patients, 36.7%). More intake of spicy food will increase pitta prakopa which will further lead to Paittika Mutrakricchra.

Ingredients of Pathyagokshuradi kwatha contain Haritaki, Gokshura, Dhanvayasa, Lodhra and Aragwadha. Ingredients of Shatavaryadi kwatha are Shatavari, Kasha, Kusha, Gokshura, Vidari, Shali, Ikshu and Kasheruka. These drugs are having Madhura, tikta rasa pradhana, sheeta veerya and madhura vipaka which will help in pitta dosha shamana.

Drugs like Kasha, Kusha, Gokshura, Vidari, Shali and Ikshu are having mutrala property which will help in increased urinary output. Flavonoids, Saponins and Terpenoids which are present in Gokshura, Aragwadha, Lodhra and Dhanvayasa are responsible for diuretic activity by exerting favorable effects on physiological processes of the kidney such as by increasing potassium sparing capacity, binding with adenosine A1 receptor associated with diuretic activity or possibly by inhibiting tubular reabsorption of water and accompanying anions.[10] Drugs like Kasha, Shali, Gokshura and Kasheruka contains constituents like coumarins, flavonoids, phenolic, alkaloids, terpenoids, tannins and polyacetylenes which can be bactericidal, bacteriostatic or produce fungicidal effect on human pathogenic microbes.[11]

In kashaya kalpana, the water soluble and thermostatic active principles of the durgs are extracted out. As water is used as the base for the formulation it helps in better absorption, increases urine output and also cleans up the channels. Madhu and Sharkara are given as anupana in the study. Madhu[12] has properties like tridoshahara and yogavahi. It improves the properties of kwatha due to its yogavahi guna. Sharkara[13] is another adjuvant added to kwatha, it is daaha shamaka thereby reduces burning sensation. Time of administration of medicine is before food. As there is apana vata dushti in Mutrakricchra, medicine for apana vata dushti should be administered before food.

CONCLUSION

Paittika Mutrakricchra is one among 8 types of Mutrakricchra. It is the commonest type. It's symptoms like daaha, peeta, sarakta, saruja mutrata, muhur mutrata resembles the signs and symptoms of acute infection of lower urinary tract. Urinary tract infection is a common medical complaint. It is the second most common infection, preceded only by respiratory infection.

Clinically, both Pathyagokshuradi kwatha and Shatavaryadi kwatha were effective in the treatment of Paittika Mutrakricchra, while comparing the effects, clinically both groups were equally effective. On statistical evaluation within the group, both kwathas showed significant results before and after treatment with $p<0.001$. On comparison between two groups, it was found that there was no statistically significant difference, with $p>0.05$.

Hence null hypothesis H_0 is accepted. There is no significant difference between the effect of *pathyagokshuradi kwatha* and *shatavaryadi kwatha* in the management of paittika mutrakricchra.

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