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Comparative study of clinical evaluation of Tab. Bhumiamalaki Ghanavati and Tab. Norfloxacin in the management of Pittaja Mootrakruccha w.s.r. to Urinary Tract Infection

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ABSTRACT

Background: Prevalence and incidence of urinary tract infection (UTI) is higher, and caused by the invasion of microorganisms in the genitourinary tract. Most common causative organism is E-coli. Occurring commonly in females due to short urethra. UTI can be correlated with Mootrakruccha (dysuria) which is elaborated by Acharya Charaka in Trimarmiya Chikitsa Adhyaya. Pittaja Mootrakruccha occurs due to vitiation of Pitta Dosha, mostly seen in patients receiving Pitta Prakopaka Ahara and Vihara. Common symptoms are Sadaha (burning), Sashula (painful) and Muhurmuhu (frequency) Mootrapravritti (micturation). Aim: To do comparative study of clinical evaluation of Bhumiamalaki Ghanavati and Tab. Norfloxacin in the management of Pittaja Mootrakruccha w.s.r. to UTI. Materials & Methods: In this study, 60 patients were equally divided by simple random sampling method into Group A administered with Bhumiamalaki Ghanavati (250mg-2 BD) having cooling, antispasmodic, analgesic property and Tab. Norfloxacin (400mg - BD) to Group B for 10 days, respectively. The primary outcomes were measured by chi-square test and run test for interpretation of subjective and objective criteria. Observation and Results: Findings of 30 patients in each group revealed that in group A, relief of 63.63%, 65% and 56.86% was observed in Sadaha, Sashula and Muhurmuhu Mootrapravritti complaint, respectively. Conclusion: Administration of Bhumiamalaki Ghanavati shows significant improvement on subjective and objective criteria.

Key words: Pittaja Mootrakruccha, Bhumiamalaki Ghanavati, Urinary Tract Infection, Sadaha Mootrapravritti, Sashula Mootrapravritti.

INTRODUCTION

Urinary tract infection is disorder of urogenital system in which multiplication of organisms is seen in urinary tract. It is second most common infection in human.^[1] It has been reported that more than 150 million people are affected by UTI globally and it accounts approximately 35% of all nosocomial infection and also been estimated that the implication of E. coli in UTI

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infection is about 80-85%.^[2] Women are more prone to UTI than men due to short urethra due to which the invasion of bacteria in urinary tract is easy. Retrograde assent of bacteria from the perineum is the most common cause of acute cystitis in women.^[1] There are some other causes like certain medications, consumption of alcohol, tropical climate, lack of water intake; unhygienic lifestyle etc. 40-50% of women will suffer from UTI at least once during their lifetime.^[2] It affects daily activities and also has an impact on physical and mental health of the person. In contemporary, medicine choice of treatment is antibiotics. Due to lack of awareness about treatment and high cost, patients don't take treatment properly. Hence in modern times, there is an increasing resistance to antibiotics, chances of reinfection and relapse even after long term therapy is seen. Acute UTI is one of the most important causes of morbidity, occasionally becoming life threatening, forcing the general population to seek medical attention, and accounting for considerable health care costs. It may

lead to many serious conditions like chronic pyelonephritis, chronic renal failure etc. Common symptoms of UTI are Burning micturation, Painful micturation, and abdominal pain.^[3] Being undergone such a challenging situation regarding UTI, there is a necessity of continuous searching for a good and cost effective treatment modalities. On the basis of its sign and symptoms, UTI can be correlated with Mootrakruccha (Dysuria) in Ayurveda, which means difficulty in micturation. Acharya Charaka described this disease elaborately in Trimarmiya Chikitsa Adhyaya (management of disease of the 3 vital organs).^[4] In particular, it resembles with *Pittaja* Mootrakruccha, in which vitiated Pitta (heat) along with Vata (air) localized in Basti (bladder) and affects Mootravaha Strotas (channel carrying urine). Sadaha (Burning micturation), Mootrapravritti Sashula Mootrapravritti (pain during micturation), Alpa Varanvar Mootrapravritti (frequency of micturation) are cardinal symptoms of Pittaja Mootrakruccha.^[5] It is caused by Pittakara Ahara Vihara, Ativayam (Excessive physical exertion), Teekshna Aushadha (intake of drugs having sharp quality), Atimadyapana (habitual intake of alcohol), Adhyashana (food intake before digestion of previous food), Ajirnashana (chronic indigestion).^[4] Avurveda have both curative and preventive treatment for it.

Hence, in this study Bhumiamalaki Ghanavati was selected for the treatment of Mootrakruccha. Ghanavati (semisolid form of Kwatha) is a secondary form of Kwatha (decoction).^[6] Which is easily available and also cost effective. Its shelf life period is 2yrs and is convenient for patient.^[7,9] consumption Bhumiamalaki (Phyllanthus urinaria Linn.) belongs to Euphorbiaceae family. It has Mootral (diuretic property) so it is named as urinaria. It is mainly used in liver diseases, diabetes, jaundice, gonorrhea, intestinal infection, UTI.^[10] Bhumiamalaki is described by Charaka under Shwashara and Kasahara Gana. Tikta (bitter), Kashaya (astringent), Madhura (sweet) Rasa (taste), Madhura (sweet) in Vipaka (post digestive effect), Sheeta Virya (cool in potency) having Vatapittashamaka (alleviates Vata and Pitta Doshas) property.^[11] This herb is known to pacify the

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aggravated Vata Dosha and treat numerous Vatarelated diseases. Bhumiamalaki is also used in pacifying Pitta and Kapha Doshas, thus acts as Vedanasthapana (relieving pain) and Dahashamaka (relieving burning sensations) caused due to the aggravation of these two Doshas. It is easily available and cheap drug, palatable to all age group and thus fulfilling all criteria of Uttam Bheshaja (good medicine). Taking all the points into consideration, attempts have been made in the present work to provide better alternative diagnosis to the problem. In this study 60 patients were selected and randomly divided into 2 groups equally. Bhumiamalaki Ghanavati was administered to Group A and Tab. Norflox in group B for 10 days. In the present study, an attempt has been made to find an inexpensive and effective treatment of Pittaja Mootrakruccha (UTI).

ΑιΜ

Comparative study of clinical evaluation of *Bhumiamalaki Ghanavati* and Tab Norfloxacin in the management of *Pittaja Mootrakruccha* w.s.r. to Urinary Tract Infection.

OBJECTIVES

- 1. To study the *Mootrakruccha* (Dysuria) *Vyadhi* (Disease) and Urinary Tract Infection in detail.
- 2. To review the plant *Bhumiamalaki* (*Phyllanthus urinaria* Linn.) in detail.
- 3. To study the relief in the symptoms of *Pittaja Mootrakruccha* such as; *Sadaha Mootrapravritti* (Burning micturation), *Sashula Mootrapravritti* (pain during micturation), *Muhurmuhu Mootrapravritti* (frequency of micturation).

MATERIALS AND METHODS

Ethics

The study was approved by institutional ethical committee and MUHS (Maharashtra University of health science) on 17/3/2016. Prior informed written consent was obtained from each patient including in the study.

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Design

A prospective, randomized, single blind, controlled clinical trial was conducted on 60 patients. Simple random sampling method used for selection of patient.

Diagnostic criteria

A total of 63 patients having symptoms of *Mootrakruccha* (Dysuria) were selected from OPD and IPD of Ayurveda Seva Sangh hospital, Nashik irrespective of sex, religion, economical status, education, and occupation. Among them 3 patients were dropped out. Thus, 60 patients were studied in the present investigation. A detailed clinical research proforma, incorporating all the points of history taking, examination and treatment was recorded for analysis.

A) Inclusion criteria

Cases were randomly selected irrespective of their sex, occupation and socio-economic conditions, showing the following signs and symptoms of Pittaja Mootrakruccha; i.e., Sadaha Mootrapravritti (Burning micturation), Sarakta Mootrapravritti (Hematuria), Sashula Mootrapravritti (Painful micturation), of Muhurmuhu Mootrapravritti (Frequency micturation), Sheetpurvaka Jwara (Fever with or without chills). Patients with age group between 20-60 years and having Pus cells with or without RBC on Urine Examination were studied.

B) Exclusion criteria

Patients with Diabetes Mellitus, Immune compromised patient, Urinary Tract malignancy, Renal Calculi, Renal failure, Renal abscess, Pregnancy, Azotemia, Oligouria, CAUTI (Catheter associated UTI).

Drug administration details

Grouping and Posology

Randomly selected 60 patients were equally divided into 2 groups. As this was single blind randomized study here 30 patients were treated by drug Tab. *Bhumiamalaki Ghana* while the remaining 30 patients were treated by Tab. Norfloxacin.

Trial drug and procedure details of *Bhumiamalaki Ghanavati*

Content - Bhumiamalaki

Latin name - Phyllanthus urinaria Linn.

Family - Euphorbiaceae Rasa - Tikta, Kashaya, Madhura Vipaka - Madhura Veerya - Sheeta

Method of preparation of Bhumiamalaki Ghanavati

Bhumiamalaki Panchanga (all parts) was taken as a raw drug procured from GMP - certified pharmacy (Chaitnaya Pharmacy, Nashik, Maharashtra) was boiled with sixteen parts of water and reduced upto one eighth. Kwatha (decoction) was separated with the help of centrifuge machine, and then boiled back again for 8-12 hrs, until reduced to semi solid followed by drying at 60-70 degree using a vacuum tray dryer with the help of water bath. Coarse powder particles were prepared from dried Kwatha (decoction), which were later converted to granules with the help of multi mili instrument. No binding agent was used during this procedure. Finally, tablets were prepared using rotary tablet making machine. Thus, black color Bhumiamalaki Ghanavati is ready. Hardness and disintegration time observed.^[6,9]

Group A (experimental group)

30 Patients treated with Bhumiamalaki Ghanavati

Matra (quantity): 2 tabs (500 mg) 2 times a day

Anupana (vehicle): Shrutsheet Jala (lukewarm water)

Aushadha Sevan Kala (Time of drug administration): Apankala (before meal)

Duration: 10 days

Group B (control group)

30 Patients treated with Tab. Norfloxacin

Matra (quantity): 1 tab (400 mg) 2 times a day

Anupana (vehicle): Shrutsheet Jala (lukewarm water)

Aushadha Sevan Kala (Time of drug administration): Paschatbhaktha (after meal)

Duration: 10 days.

Investigation

Hematological examination (Hb%, TLC, DLC and ESR), Urine routine and microscopic examination were carried out before and after treatment. Nikita Sanjay Nigal. Clinical evaluation of Tab. Bhumiamalaki Ghanavati in Pittaja Mootrakruccha

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Criteria for assessment of result

The efficacy of the therapy was assessed on the basis of subjective and objective criteria.

Subjective criteria: Improvement in sign and symptoms obtained in the patient were considered for the assessment.

Table 1: Subjective criteria for assessment

Score	1. Sadaha Mootrapravritti (Burning Micturation)
0	Absent
1	Burning only during micturation
2	Burning persist upto 1 hour after micturation
3	Burning continuous even after 1 hour
Score	2. Sashula Mootrapravritti (Painful Micturation)
0	Absent pain
1	Pain at the time of micturation
2	Pain persistent upto 1 hour after micturation
3	Pain persistent and not relieved even after 1 hour
Score	3. <i>Muhurmuhu Mootrapravritti</i> (Frequency of Micturation)
0	1 -5 times/day
1	6 -10 times/day
2	11 -15 times/day
3	More than 15 times/day

Objective criteria

Table 2: Objective criteria for assessment

Score	1. Sheetpurvak Jwara (Fever)			
0	Normal Body temp			
1	Body temp. 99-100°f			
2	Body temp. 101-102°f			
3	Body temp. >102°f			

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Score	2. No. of pus cells
0	0-5/hpf
1	6-10/hpf
2	11-15/hpf
3	15/hpf & more
Score	3. <i>Sarakta Mootrapravritti</i> (Hematuria)
0	Below 5RBC/hpf
0	
	Below 5RBC/hpf

Statistical Analysis

Statistical analysis was done for the interpretation of the observation. Total 60 patients were enrolled for the study in Case Proforma for regular follow-up and separate criteria was prepared for their assessment. The data was analyzed with the help of 'Chi-square test for subjective and objective criteria', Run test was used for *Sarakta Mootrapravritti* (Hematuria) criteria before and after treatment'. The obtained results were interpreted as:

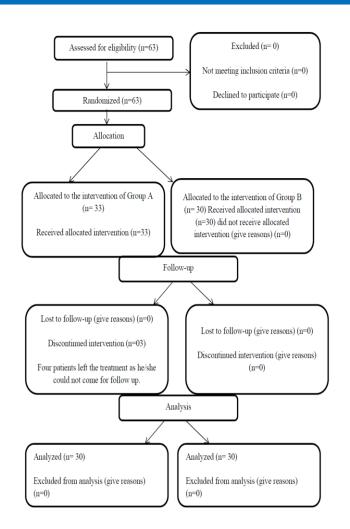
Not significant: P>0.05, Significant: P<0.05

OBSERVATION

Patient for the present clinical trial were registered between the periods of June 2016 to May 2017. After 1 year of the clinical study, registration of the patients was closed having to submit the thesis work to the institute. A total of 60 patients were registered for the present study and were randomly divided into two groups to evaluate the *Bhumiamalaki Ghanavati* and Tab. Norfloxacin in the management of *Pittaja Mootrakruccha*. 60 patients completed the treatment successfully. In this trial, 30 patients were allocated to group A and 30 patients were allocated to Group B. 30 patients in each group could complete the course of treatment, while 03 patients in Group A could not complete the treatment and follow-up. [Flow chart 1]

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Flow chart 1: CONSORT flow diagram

In the present study, a maximum of 61.66% of patients were in age group 41-60 years, of which 65% of the patients were female, 90% were married, 21.66% of patients were found to be housewife, 66.66% of patients were found to be literate, 55% of patients were having mixed diet, and 46.66% patients were having Kaphaja Pittaja Prakriti (constitution).

RESULT

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In the present clinical study, *Sadaha Mootrapravritti* (Burning Micturation), *Sashula Mootrapravritti* (Painful Micturation), *Muhurmuhu Mootrapravritti* (Frequency of Micturation) symptom, *Sheetpurvaka Jwara* (fever), pus cells in urine and *Sarakta Mootrapravritti* (hematuria) symptom was reduced to 63.63% and 65%; 56.86% and 43.90%; 73.21% and 76.78%; 84% and 77.27%; 84% and 77.27% and 95.23% and 90.56% in Group A and Group B, respectively.

In this study, the numbers of patients showing the symptom Sarakta Mootrapravritti (hematuria) was very less as many factors which cause hematuria were excluded. Thus, a non-parametric Run test was applied for these criteria. According to this test, both groups reduced Sarakta Mootrapravritti (hematuria) but there is no significant difference in result by comparing these two groups. In Subjective criteria, a significant difference was observed on Sadaha mootrapravritti (Burning Micturation), Sashula Mootrapravritti (Painful Micturation) while in Objective criteria, a significant difference was observed on Sheetpurvaka Jwara (fever), Pus cells and Sarakta Mootrapravritti (hematuria) while no significant difference was observed on Muhurmuhu Mootrapravritti (Frequency of Micturation). Overall effect of therapy in both the groups are as shown in Graph 1. After studying all the data thoroughly, it was observed that out of 30 patients of group A, 14 patients (46.66%) received complete relief, 12 patients (40%) received moderate relief, and 4 patients (13.33%) received mild relief and 0 patient shows unchanged. Where as in control group, 11 (36.66%) patient's received complete relief, 15 (50%) received moderate relief and 4 (13.33%) received mild relief and 0 patient shows unchanged. No adverse drug reaction was observed in any groups throughout the study period.

Effect of therapy on sign and symptoms

Table 3: Effect of therapy on subjective criteria Gr. Avs. Gr. B

Chief complai nt	X2		df		Table X ² value		Prob abilit Y	Significance	
	D 0	D 11	D O	D 11	D 0	D 11		D0	D11
Sadaha Mootra pravritti	4. 6 4	6. 2 2	1	1	3. 8 4	3. 8 4	<0.05	Signi fican t	Signi fican t
Sashula Mootra pravritti	0. 0 4	7. 8	1	2	3. 8 4	5. 9 9	<0.05	Not Signi fican t	Signi fican t

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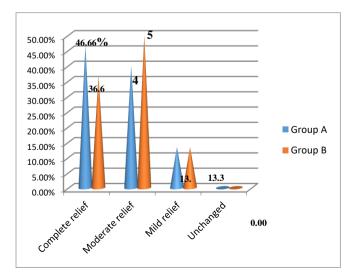
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Table 4: Effect of therapy on objective criteria Gr. A vs. Gr. B

Chief compl aint	Х ²		df		Table X² value		Proba bility	Significance	
	D O	D 11	D 0	D 11	D O	D 11		D0	D11
Sheet purvk a Jwara	0. 2 8	5. 1 6	1	1	3. 8 4	3. 8 4	<0.05	Not Signif icant	Signif icant
Pus cells in urine	9. 1 2	5. 0 6	2	1	5. 9 9	3. 8 4	<0.05	Signif icant	Signif icant

Table 5: Effect of therapy on Sarakta Mootrapravritti(Hematuria) criteria Gr. A vs. Gr. B

Sarakta Mootrapravritti	Group n		SD	Р	Result	
(Hematuria)	A	7	1.898	<0.05	Significant	
	В	4	1.191	<0.05	Significant	



Graph 1: Distribution of patients according to Overall effect of Therapy

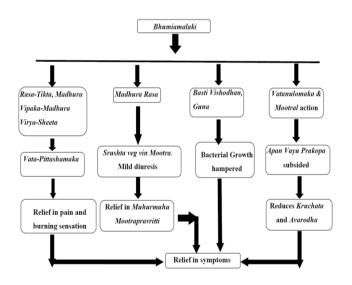
DISCUSSION

Trial drug i.e., Group A (*Bhumiamalaki Ghanavati*) is effective in the treatment of *Pittaja Mootrakruccha*. 61.66% patient was between 41-60yrs of age; which is *Pittapradhan Dosha Avastha* (*Pitta* dominance condition). 55% of patient had mixed diet, non-veg aggravates *Pitta*, which is another important factor in pathogenesis of *Mootrakruccha* (Dysuria). The efficacy of *Bhumiamalaki Ghanavati* on the *Vyadhi* (disease) *Mootrakruccha* (Dysuria) needs to be explored more. During the study, there was no evidence of any adverse reaction. The study was carried out for short period of time and on small sample size. So, the topic is open for further study on large number of subjects and for a long duration - for observing and preventing recurrence.

Probable mode of action of drug

Bhumiamalaki Ghana has Vaatpittashamaka (alleviates Pitta and Vata) property. Tikta Rasa (bitter taste) Kashaya (astringent), Madhura Rasa (sweet taste), Madhura Vipaka (post digestive effect) & Sheeta Veerya (cool in potency), thus acts as Dahashamaka (relives burning sensation). Tikta Rasa (bitter taste), Kashaya Rasa (astringent taste), Laghu (lightness), and Ruksha Guna (unctuousness) and have the properties of *Vedanasthapana* (analgesic).^[11] The Madhura Rasa has property of Srushta-Vega-Vinmootrata, hence proves to possess mild diuretic action. So, relief in Muhurmuhu Mootrapravritti.[12] It has Vatanulomaka & Mootrala properties, due to all these, it subsides Apana Vayu Prakopa which is useful to reduce Kruchhrata (difficulty) and Avarodha (obstruction). Tikta (bitter taste) and Kashaya Rasa Pradhana (astringent taste dominant), both of which are Pitta Kaphahara (alleviates Pitta and Kapha) Laghu (lightness), and Ruksha Guna (heat). Thus, acts as Kleda Shoshaka (absorbs putrefaction). The bacterial growth is hampered which may be due to its 'Basti Visodhana Gunas' and mild diuresis.^[12] Hence Bhumiamalaki is useful in the natural phenomenon of urinary secretion and abolishes the symptoms of Dysuria, suppression of urine, pain, fever and dribbling due to bacteriuria.

Bhumiamalaki has antimicrobial property against gram +ve & gram -ve bacteria. This plant was able to control the growth of Escherichia coli, Enterococcus faecium, Pseudomonas aeruginosa, Staphylococcus aureus and Mycobacterium smegmatis. ^[13,14] It's biomarkers phyllanthin and hypophyllanthin were able to modulate the innate response to phagocytes. Leaves and steam contain alkaloids phyllanthoside with strong anti-spasmodic activity which helps in relieving pain.^[10] These isolate from Phyllanthus Urinaria Linn. may be useful for the treatment of cell-mediated immune disease and acts as anti-inflammatory action also.^[15] This drug is diuretic to a great extent and thus concentrates in urinary system; it does not disturb the bacterial flora of bowel and is well tolerated by the most of the patients. Hence Bhumiamalaki (Phyllanthus urinaria Linn.) acts on urinary systems and relives the symptoms of Pittaja Mootrakruccha i.e., UTI.





Safety of trial drugs

No adverse effect of drugs was observed during the entire clinical trial.

CONCLUSION

On the basis of clinical trial conducted for the study. It can be interfered that in this study trial group i.e., *Tab. Bhumiamalaki Ghanavati* was showing safe and better results in *Pittaja Mootrakruccha (UTI)*.

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