



## **A Clinical Study to Evaluate the Effect of An Ayurvedic Formulation in the Management of Pittaja Mutrakrcha W.S.R To Urinary Tract Infection**

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### **ABSTRACT**

*Mutrakrcha* is one of the commonest ailments which causes significant morbidity in females in developing countries.. Approximately 40-50% of adult females were reported to have UTI's/*Mutrakrcha*. Almost every classical texts mentioned this disease in one or other way. Therefore, a clinical study was carried out as to explore *Mutrakrcha* from literary as well as management point of view, keeping in mind the scientific knowledge. In spite of voluminous work done on *Mutrakrcha* and its management in *Ayurveda*, it still remains a common serious problem related to fatal complications. Therefore, in the present research work ,an indigenous and cost effective drug “*Eladi churna* with *Shatavryadi kwatha*” was evaluated for its efficacy on scientific grounds to check or reduce the incidence of *Pittaja Mutrakrcha*. To evaluate the effect of “*Eladi churna* with *Shatavryadi kwatha*” in the management of *Pittaja Mutrakrcha*. It is a double blind randomized study which was carried out by registering 34 patients of *Pittaja Mutrakrcha*. *Eladi churna* was given in a dose of 5gm TID with *Shatavryadi Kwatha* in a dose of 50ml BID for 21 days. It was seen that though the trial was of 21 days but patients were relieved in 7-15 days interval symptomatically and the repeat urine tests were also sterile after 15 days. Therefore, it can be concluded that both these drugs are quite effective in *Pittaja Mutrakrcha* patients. However, the drug can be made more palatable by converting *churna* form into *vati*.

**Keywords-***Pittaja Mutrakrcha* , *Eladi Churan*, *Shatavryadi Kwatha*, UTI.

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## INTRODUCTION

*Mutrakrcha* is very well described under the disorder of *mutravaha strotas* in almost all ayurvedic texts. Most of the urinary disorders are described in the form of 8 types of *Mutrakrcha*, 13 types of *Mutraghata*, 4 types of *Ashmari* and 20 types of *Prameha*<sup>1</sup>. Therefore, it can be alluded that *Mutrakrcha* is a disorder of *mutravaha strotas* which includes those forms of urinary disorders where *krcha* is a cardinal feature<sup>2</sup>.

Illness, ignorance and poverty are some of the factors behind increasing prevalence rate (2<sup>nd</sup> in frequency after URTI) of this disease. It is commonly seen in pregnancy, diabetes mellitus, polycystic renal disease and immuno-compromised patients. Clinical presentation of *Pittaja Mutrakrcha* shows close resemblance to UTI's as described in modern texts especially with lower UTI i.e. Urethritis and Cystitis. Urethritis is manifested as inflammation of the urethra with symptoms of dysuria, frequency, stranguary and supra-pubic pain. burning pain during micturition is characteristic of acute urethritis<sup>3</sup>.

The common symptomatology explained of *Pittaja Mutrakrcha* by *Charak* are:-

- Passage of yellow or red coloured urine.
- Painful micturition
- Burning sensation
- Difficulty during micturition
- Increased frequency of micturition<sup>4</sup>.

Therefore, present study is an attempt to define *Pittaja Mutrakrcha* on scientific line vis-a-vis UTI and to promote the safety of prescription, maximize the drug effects and minimize the side effects. It affects both sexes and all age groups with particular impact on females of all ages and males at extremes of life<sup>5</sup>.

It is potentially a serious condition which may lead to fatal conditions also. As far as the treatment of UTI is concerned, use of urinary analgesics, urinary alkalizers, antibiotics and haemostatic drugs help to certain extent but are not much potents as ayurvedic drugs are. Ayurveda has ample options in the management of *Mutrakrcha*. There is vitiation of *Vatadi doshas* which leads to *dosha-dushya sammurchna* in *vasti*, ultimately causing *mutrakrcha*.

Therefore, increasing prevalence made it necessary to explore *Mutrakrcha* from literary as well as management point of view keeping in mind the scientific knowledge.

## MATERIALS AND METHOD

To fulfill all the aims and objectives, the research work has been carried out in the following

manner:-

### Conceptual Study:

Detailed conceptual study was done on the solid topic from available ancient and modern literature. Literature regarding drugs and the work done in the past were also thoroughly reviewed.

### Selection of the patients

Patients of *Pittaja Mutrakrcha* fulfilling all the inclusion criteria were registered from the OPD/IPD of Rajiv Gandhi Govt. Post Graduate Ayurvedic Hospital, Paprola, Distt. Kangra Himachal Pradesh. Most of the patients were managed at OPD level; however, few patients were admitted in IPD. Everything was explained to the patients in detail and written consent was taken before starting the treatment.

For diagnosis, a detailed medical history was taken according to both Ayurvedic and modern clinical methods. Diagnosis was based on 2 criterias i.e. subjective criterias and objective criterias. In subjective criteria, a special performa was prepared with gradation of symptoms like *Pita mutrata*, *Sarakta mutrata*, *Saruja mutrata*, *Sadaha mutrata*, *Krcha mutrta*, *Muhur-muhur mutrata*<sup>6</sup> and scoring system was adopted.

### Subjective Criteria

1. Pita mutrata (Change in colour of urine)	Grade
❖ No cloudiness/ clear urine	- 0
❖ Definite cloudiness, but no granularity, no flocculation	- 1
❖ Granular cloudiness but no flocculation	- 2
❖ Dense opaque cloudy flocculation	- 3
2. Sarakta mütratā (Haematuria)	
❖ No haematuria	- 0
❖ Smoky urine	- 1
❖ Reddish urine	- 2
❖ Frank haematuria	- 3
3. Saruja mütrata (Painful micturition)	
❖ No pain	- 0
❖ Mild pain (patient not complaining pain as a problem- or on interrogation patient complains slight pain).	- 1
❖ Moderate (patient complains of pain, needed some	

	medicine for relief)	-	2
❖	Severe (pain disturbing sleep and patient struggles due to pain and needs strong analgesics)	-	3
<b>4.</b>	<b>Sadaha mutrata (Burning micturition)</b>		
❖	No burning micturition	-	0
❖	Mild (patient not complaining of burning as a problem on interrogation patient complains of soreness)	-	1
❖	Moderate (patient complains of burning micturition & need medicine for relief)	-	2
❖	Severe (patient struggling with soreness & need internal medicine for relief)	-	3
<b>5.</b>	<b>Krchra mutrata (Difficulty in micturition)</b>		
❖	No difficulty	-	0
❖	Difficulty present at the beginning of the act	-	1
❖	Difficulty present at the beginning & partially during the rest of the act	-	2
❖	Difficulty present through out the act	-	3
<b>6.</b>	<b>Muhur-muhur mutrata (Frequency of micturition)</b>		
❖	Patient passing urine < 5 times a day	-	0
❖	Patient passing urine 6 - 10 times a day	-	1
❖	Patient passing urine 11 - 15 times a day	-	2
❖	Patient passing urine > 16 times a day	-	3

#### Investigational Assessment:-

Some of the laboratory findings were assessed by grading them and others were assessed simply evaluating the results obtained from them as follows:

<b>Pus cells in urine</b>		<b>Grade</b>
0-5 hpf	-	0
6-10 hpf	-	1
11-15 hpf	-	2
> 16 hpf	-	3
<b>RBC's in urine</b>		
0-5 hpf	-	0
6-10 hpf	-	1

11-15 hpf	-	2
> 16 hpf	-	3

**Criteria:-**

Urine culture reports were assessed before & after completion of clinical trial.

**Positive Urine Culture** was the main objective criteria for diagnosis and inclusion of patients in the clinical trial. Therefore, the patients were screened with respect to symptomatology, urine analysis, haematological and microbiological studies.

**Inclusion criteria**

- Patients willing for trial was the first and foremost criteria.
- Patients above 18 yrs of age.
- Patients who presented with signs and symptoms of *Pittaja Mutrakrcha* as mentioned in classical texts.
- Patients who had no serious organic or metabolic ailments.

**Exclusion criteria**

- Patients not willing for trial.
- Patients below the age of 18 yrs.
- Cases of associated obstructive uropathy such as BPH, renal or ureteric calculi etc.
- Patients with defects in voiding mechanism as incontinence of urine and atonic bladder.
- Patients suffering from chronic illness who had indwelling catheter.

**Posology**

**Eladi churna**<sup>7</sup> was given in a dose of 5gm thrice a day with plain water and

**Shatavaryadi Kwatha**<sup>8</sup> was given in a dose of 50ml twice a day

All the cases were subjected to clinical observation throughout the course of treatment to assess the efficacy of drug from time to time. The effect of therapy was assessed on the basis of relief observed over the pre-trial values and change in urine culture after the treatment. After 21 days, when the trial was completed, thorough examination of the patient was carried out including all investigations

**Assessment of overall effects of the therapy**

The results were classified into 4 groups on the basis of overall assessment of the therapy as listed below:-

- Cured
- Markedly improved
- Mildly improved

d. Unchanged

**a. Cured**

Absence of all the subjective and objective criteria of inclusion in trial was considered in this category.

**b. Markedly improved**

- (i) >75% of relief in the cardinal as well as the constitutional features
- (ii) Normal routine laboratory investigations
- (iii) Negative urine culture

**c. Mildly improved**

- (i) 50% relief in cardinal as well as other constitutional features
- (ii) Normal routine laboratory investigations
- (iii) Positive urine culture

**d. Unchanged**

- (i) <25% relief in cardinal as well as other constitutional features.
- (ii) Laboratory investigations remained unchanged.
- (iii) Urine culture remained positive.

**OBSERVATIONS**

In the present study 30 patients were registered, out of them 29 completed the study. Majority of patients (40%) were in the age group of 21-30 years, 76.7% were females and all the 30 patients were Hindu and belonged to rural area. 93% patients were married, 33% were house wives, 23% patients were uneducated, and 40% belonged to lower socio-economic group. 20 patients were on mixed diet and 10 were vegetarians. Only 11% patients maintained good hygiene, although 73% had no addiction. 70% patients complained of disturbed sleep due to increased frequency of urine at night. 16 patients were having *Vata-Pittaja prakriti*, 11 having *vata-kaphaja* and rest 3 were having *pitta-kaphaja prakriti*. 77% patients had normal appetite. Out of total 23 female patients, only 1 had history of abnormal vaginal discharge. 18 out of 30 patients did not have past history of UTI, while 12 had the history of UTI.

**Clinical Presentation**

Out of 30, 97% patients had *muhur-muhur mutrata*, 93% patients experienced *Sadaha mutrata*, followed by *Saruja mutrata* in 83%, *krichha mutrata* 60%, *pitta mutrata* 23% and only 7% had *sarakta mutrata*.

**Table 1: Signs and Symptoms of Pittaja Mutrakchra observed in 30 patients**

Clinical features	No. of Patients	Percentage
<i>Sadaha mutrata</i>	28	93.33
<i>Saruja mutrata</i>	25	83.33
<i>Krchra mutrata</i>	18	60
<i>Muhur-muhur mutrata</i>	29	96.67
<i>Pita mutrata</i>	7	23.33
<i>Sarakta mutrata</i>	2	6.67

### Constitutional Features

In the constitutional features, 73% (22 patients) complained of retention of urine, followed by urgency in 43.3%, straining was complained by 33.3%, constipation in 30%, anorexia 23.3%, hesitancy 16.7% and only 3.33% had fever. Urine analysis revealed that all the 30 patients had pus cells and positive urine culture. 6 patients had acidic urine and only 4 patients had RBCs and proteins in the urine.

### RESULTS AND DISCUSSION

All the data was collected and then statistically analyzed. The results were made on the basis of grades of various variables compared between pre trial and post trial values in terms of percentage, based on mathematical means and its difference. Values between variables were compared with student (t) test for dependent samples by using the degree of freedom p value. The results were expressed in terms of mean, standard deviation (S.D.) and standard error (S.E.)

- ❖ p < 0.0001 - Extremely significant
- ❖ p < 0.001 - Highly significant
- ❖ p < 0.01 - Moderately significant
- ❖ p < 0.05 - Significant

### Urine Analysis

In the present study, urine microscopic examination revealed pus cells and positive urine culture in all 30 patients (100%), where positive urine culture was the main inclusion criteria of the trial followed by RBC's and urine proteins present in 4 patients only i.e. 13.33%, urine reaction was acidic in 6 patients (20%) and lastly there was no patients who had urine output less than 1 litre.

**Table 2: Urine analysis findings observed in 30 Patients of Pittaja Mutrakchra**

Urine analysis finding	No. of Patients	Percentage
Pus cells	30	100
RBC's	4	13.33
Urine proteins	4	13.33
Urine Reaction (acidic)	6	20
Positive urine culture	30	100
Urine volume <1litre/24 hours	0	0

### Microbiological Findings

Microbiological studies of urine showed that the most common causative organism was *Escherichia coli*, which was present in 17 patients (56.67%) followed by *Staphylococci* which effected almost 9 patients (30%) , *E. coli* and *Staphylococci* in 2 patients (6.67%), *Proteus* was not detected in any patient, Gram negative Cocco-bacilli and others effected only 1 patient each (3.33%)

**Table 3: Microbiological Findings Wise Distribution of 30 Patients**

Micro-organism	No. of Patients	Percentage
E. Coli	17	56.67
E. Coli & Staphylococcus	2	6.67
Proteus	0	0
Staphylococcus	9	30
Gram –ve Cocco-bacilli	1	3.33
Others	1	3.33

### Blood Analysis Findings

In the blood analysis finding of 30 patients, leucocytosis was seen in 7 patients i.e. 23.33% and raised ESR in 19 patients i.e. 63.33%.

**Table 4: Blood Analysis Findings Observed in 30 Patients**

Blood analysis findings	No. of Patients	Percentage
Leucocytosis(TLC - >11,0000/cumm)	7	23.33
Raised ESR (Male - >5/mm fall in 1 <sup>st</sup> hr Female - >10/mm fall in 1 <sup>st</sup> hr)	19	63.33

### Effects of the Therapy

In this clinical study, total of 30 patients of *Pittaja Mutrakrchra* were registered. Out of them, only one patient was dropped out of the trial, as he did not turn up in time for re-evaluation. Remaining 29 patients completed the therapy, effects of which are mentioned in table 5.

**Table 5: Effects of the therapy on clinical features in 29 patients of *Pittaja Mutrakrchra***

Clinical features	N	Mean Score BT/AT	Difference	Percentage Relief	S.D±	S.E±	T	P
<i>Pita mutrata</i>	7	1/0	1	100	0.43	0.08	2.99	<0.002
<i>Sarakta mutrata</i>	2	1.50/0	1.50	100	0.40	0.076	1.361	<0.184
<i>Saruja mutrata</i>	25	1.56/0.038	1.52	97.43	0.76	0.14	9.27	<0.0001
<i>Sadaha mutrata</i>	27	2.18/0.185	1.99	91.28	0.74	0.13	13.50	<0.0001
<i>Krchra mutrata</i>	18	1.16/0	1.16	100	0.64	0.12	6.00	<0.0001
<i>Muhur-muhur mutrata</i>	28	1.14/0.178	0.96	84.21	0.52	0.09	9.4	<0.0001

### Effects of the therapy on urine microscopic findings

**Table 6: Effects of the therapy on urine microscopic findings in 29 patients**

Variables	N	Mean score BT/ AT	Difference	Percentage relief	S.D $\pm$	S.E $\pm$	T	P
Pus cells	24	1.17/0.13	1.04	88.88	0.44	0.087	11.89	<0.001
RBC'S	5	2.5/0.50	2.0	80	0.58	0.10	1.27	<0.05

### Effects of the therapy on urine culture findings

The mean score of urine culture positive patients was 1 before treatment and after treatment it came down to 0.13 giving 87% relief. The statistical analysis indicates extremely significant result i.e.  $p < 0.0001$ .

**Table 7: Effects of the therapy on urine culture findings of 29 patients**

Variables	N	Mean score BT/ AT	Difference	Percentage relief	S.D $\pm$	S.E $\pm$	T	P
Urine culture	29	1/ 0.13	0.87	87	0.35	0.06	13.23	<0.0001

### Overall effects of the therapy: Table 8

Out of 29 patients, 9 patients i.e. 72.41% were cured and became asymptomatic with respect to symptomatology and laboratory parameters. 3 patients i.e. 10.34% were moderately improved with  $\geq 75\%$  relief in clinical features and negative urine culture. 5 patients (17.24%) were mildly improved with 50% relief as far as symptomatology was concerned and their urine culture also remained positive after treatment in most of them. There was no patient who did not show any relief.

**Table 8: Overall effects of the therapy**

Results	No. of patients	Percentage
Cured	21	72.41
Markedly improved	3	10.34
Mildly improved	5	17.24
Unchanged	0	0

## DISCUSSION

The effects of the therapy on *pita*, *sarakta* and *krchra mutrata* showed highly significant result, statistically i.e.  $p < 0.002$  and  $p < 0.001$ , respectively. All three features were relieved by 100% after the clinical trial. The statistically highly significant results were seen symptomatologically because of *pitta-vatahar* property of the trial drug. Most of the trial drugs used in the trial also exhibit anti bacterial, anti inflammatory, anti septic, analgesic and above all diuretic and alkaliser properties.

Though, all the patients were subjected to haematological investigations like Hb gm%, TLC, DLC, ESR, FBS, Blood urea and Serum creatinine but there was no difference before and after the treatment.

### Discussion on over all Effects of the therapy

In the present clinical study, out of 30 patients, 29 completed the trial. The effects of the trial drug “*Eladi Churna* and *Shatavaryadi kwatha*” in recommended dose is evaluated over them. The overall results of the therapy were very encouraging as out of 29 patients , 72.41% patients were cured.10.34% patients were markedly improved and 17.24% patients were mildly improved.

### Probable Mode of Action of the trial Drugs

The fundamentals regarding treatment in *Ayurveda* are mainly based on the *dosha chikitsa*. In *Pittaja Mutrakrechra* the main *dosha* is *pitta*, which is vitiated and needed to be pacified. *Vasti* is the seat of *vata* and the micturition is under the control of *apana vayu*<sup>9</sup>. Therefore, *apana vayu*, *mutra* and *mutravaha srotas* are involved in the pathogenesis of this *pittaja vikara*. That’s why those drugs were selected in the trial which had *pitta shamaka*, *vata shamaka*, properties along with *vedana shamaka* and *mutra-virechaniya* action.

In *Ayurvedic* classics, *ela* is described in *katuskandha*, *sirovirechaniya gana* and has *katu*, *madhura rasa*; *laghu*, *ruksha guna*; *sheeta virya* and *madhura vipaka*. Due to all these properties, it pacifies *pitta* and *vata dosha*. It contains anti-aflatoxin substance which acts as very good anti-septic. N-hexane extract of seed exhibit anti-microbial activity against *Streptococcus*<sup>10</sup>. *Shilajita* has been described as *rasayana* drug which is *vrshya* and *tridoshghana*. Because, it has *tikta rasa* and *sheeta virya*, it pacifies *pitta dosha*. It has very good diuretic property, therefore manage UTI<sup>11</sup>.

In *Ayurvedic* literature, *pashanabheda* is explained under *mutra-virechaniya gana*, with similar *rasa* and *virya* as *shilajita* holds. Therefore, it is very good diuretic and very useful in dysuria, it also has lithotriptic activity<sup>12</sup>.

*Pipali* possesses *katu rasa*, *anusana shita virya* and *madhura vipaka*. By virtue of its unique property it pacifies both vitiated *pitta* and *vata dosha*. It is very good analgesic drug<sup>13</sup>. *Shatavari*, used in decoction, is a *rasayana* drug with multiple mode of action. It has *madhura*, *tikta rasa*; *shita virya* and *madhura vipaka* and *guru*, *snigdha guna* which is absolutely best drug in alleviating vitiated *vata* and *pitta dosha*. *Asparagus racemosus* has an anti-bacterial property, it relieves burning micturition and is also very beneficial anti-inflammatory property<sup>14</sup>.

*Gokshura* and *vidarikanda*<sup>15</sup> also holds similar properties as *shatavari*. *Gokshura*, additionally have very good anti-bacterial property. *Gokshura* is mainly used in renal and vesical calculi. *Gokshura* specifically is very useful against E.coli and Staphylococcus which are the most common culprit organisms in UTI<sup>16</sup>.

A very beneficial rejuvenator used in recent times is *amalaki*, widely described in *Ayurvedic* texts has *lavana rahit pancharasa; ruksha, shita, guru guna; sita virya* and *madhura vipaka*<sup>17</sup>. It is used as anti-oxidant, therefore very helpful in patients with low immunity. It is highly beneficial in all *pittaja vikara*. It also increases RBC count and regulates blood sugar level<sup>18</sup>.

Lastly, *kusha, kasa*<sup>19</sup> and *ekshu*, coming from the same group i.e. *trnapanchmula* and *mutra-virechaniya gana*. All three of them exhibit same pharmacodynamic properties i.e. *madhura, kashaya rasa; laghu, snigdha guna; shita virya* and *madhura vipaka*. They have very good diuretic property. They reduce burning micturition by pacifying the main *dosha* i.e. *pitta*<sup>20</sup>.

## CONCLUSION

The present clinical study revealed that “*Eladi Churna and Shatavaryadi Kwatha*” is very effective in the management of *Pittaja Mutrakrechra* w.Ss.r. to UTI. There were no untoward effects of the whole therapy in any patient within trial period of 21 days or after that too. Overall effects of the therapy revealed that 21 patients i.e 72.41% were completely cured, 3 patients i.e. 10.34% were markedly improved, 5 patients i.e. 17.24% were mildly improved and there was no patient who was not relieved. To conclude, it was seen that trial drug had very good efficacy, and was cost effective. This clinical trial was a sincere attempt in small number of patients in limited time and requires further work-up on large number but for shorter duration i.e. 15 days to prove its beneficial effects on patients. 15 days of trial is recommended as the matter of the fact and observation during the trial that patients were symptomatically improved considerably in 1<sup>st</sup> follow-up and fully recovered in next follow up.

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