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TITLE:

Open clinical study of *badrasashma pishti* (anubhut yoga) with and without *khas sharbat* in the management of *mutrakrichra* with special reference to dysuria

Abstract:

Now-a- days it is seems that, several patients are reporting to the hospitals regularly with affected from different disorders of *Mutravaha Srotas*. *Mutrakrichra* is one of the important diseases amongst this diseases. The term *Mutrakrichra* comes under the disorders of *Mutravaha Srotas*, and mainly deals with *Mutra* and *krichra*. In *Mutrakrichra*, the vitiated *Pita Dosha* along with *Vata* (mainly *Apana Vayu*) on reaching *Vasti* (bladder) afflicts the *Mutravaha Srotas* due to which the patient feels difficulty in micturation along with symptoms like *Pittta mutrata*, *Sarakta mutrata*, *Sadaha mutrata*, *Saruja mutrata* and *Muhur-muhur mutrata*.

Now, the present study to evaluation of the efficacy of *Badrasashma pishti yoga* with and without *khas sharbat* to assess the effect on *Mutrakrichra*.

Keywords:

Mutrakricrha, *Shool*, *krichra*, *Mutravaha Srotas*, *Badrasashma pishti yoga*, *khas sharbat*.

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Introduction

Ayurveda is a science of life aiming at disease free society. The objective of *Ayurveda* is to accomplish the physical, mental, social and spiritual well being by adopting, preventive and promotive approach as well as to treat the disease with various curative measures. In the very beginning classical *Ayurveda* is transmission of knowledge from to God sages and then to human physicians. *Ayurveda* therapies have varied and evolved over millennium and typically based on complex herbal compounds, minerals, metal substances. Ancient *Ayurveda* texts also taught surgical techniques, including rhinoplasty, kidney stone extractions, suturing, and the extraction of foreign objects^[1].

From an *Ayurveda* point of view *Mutrakrichra* and *Mutraghata* are two broad heads defining urinary tract diseases in classical text books of *Ayurveda*. Although the symptom of both headings seems to be overlapping but some *Acharyas* has differentiate them based on the predominance of *krichra* and *vibandhta*. *Mutrakrichra* is characterized with painful micturation associated with different grades of obstruction.

The term is comprised of two words *Muttra* and *krichra*. *Muttra* means urine, *krichra* means painful. Thus, dysuria and painful urination called as *Mutrakrichra*. In most of the *Ayurveda* classical texts any type of discomfort during urination and especially

lower tract infection problems are included under *Mutrakrichra*. *Mutrakrichra* can occur as an independent disease as well as *purvarupa* and *rupa* of some other systematic diseases. *Mutrakrichra* is classified into 8 types according to the *nidan* and *lakshanas*, *lakshanas* such as pain which can be annoying when one experience it every time on urination. It can be correlated symptomatically to dysuria^[1-2].

- In *Vataja Mutrakrichra*: Acute pain in lower abdomen and penis
- In *Pittaja Mutrakrichra*: Burning in bladder and penis, Painful micturation
- In *Kaphaja Mutrakrichra*: Heaviness in bladder, testis and penis, Painful micturation
- In *Sannipatik Mutrakrichra*: Burning in body, Pain in lower abdomen
- In *Abhighataj Mutrakrichra*: Acute pain in bladder, Distention of bladder
- In *shkrataj Mutrakrichra*: Flatulence, Obstruction of urine
- In *Ashmarija Mutrakrichra*: Chest pain, Pain in lumbar region and hypo gastric region.
- In *Shukraj Mutrakrichra*: Semen mixed urine, Pain in bladder and penis.

Modern treatment of dysuria comprises of antibiotics, antispasmodics, alkalizers which have their own side effects and limitations. A detailed description of dysuria is not available in classics so a lot of exploration is needed in understanding in treatment of dysuria whereas have ample of detailed

description of *Mutrakrichra* and number of *yoga's* in *Ayurveda* classics which are cost effective and giving good results. A number of formulations are mentioned in classics for treatment of *mutrakrichra* but some specific combination; suit all age groups, effective in *mutrakrichra* and readily available. In present study is the need of an attempt in direction of suitable drug in *mutrakrichra* to be used Thus for the same purpose *Badrasashma Pishti* with and without *Khas Sharbat* was studied.

Methodology:

Material and Methods:

The material and methods used in the study including criteria of selection of cases and parameters for clinical assessment have been described in detail followed by observations and results of the present work.

The present study comprises of two components as follows

- Demographic and clinical study on 60 patients of *Mutrakrichra*.
- Clinical evaluation of therapeutic trial of *Ayurvedic* drug in patients of *Mutrakrichra*.

Sample source;

- OPD/ IPD of PG School of Ayurveda and Research and Desh bhagat hospital Mandi Gobindgarh (PB).

For clinical study

a. Research Hypothesis: Null Hypothesis (H_0): There will be no significant difference between the efficacy of *Badrasashma Pishti Yoga* and *Badrasashma Pishti Yoga with*

Khas Sharbat in trial groups at 0.05 level of significance.

- Alternative Hypothesis (H_1): There will be significant difference between the efficacy of *Badrasashma Pishti Yoga* and *Badrasashma Pishti Yoga with Khas Sharbat* in trial groups at 0.05 level of significance.

b. Study Design:-

- Randomized, Parallel group and Open trial.

Sample:-

Total number of patients taken for study will be 60 excluding dropouts.

Sample Size:-

60 patients will be selected .30 for A group and 30 for B group.

c. Inclusion criteria:

- Patients willing for trial.
- Both male female patients age between 15 to 65 years.
- Patients having signs & symptoms of *Mutrakrichra* of any *Dosha Anubandha*.

d. Exclusion criteria:

- Patients unwilling to participate in the trial.
- Patient below 15 and above 65 years of the age.
- Patients suffering from major systemic illness.
- Any other state thought fit for exclusion.

e. Diagnostic criteria:

1. Patients having sign and symptoms of *Mutrakrichra* as described in the *Ayurveda* classics were included in study

- Frequent urination
- An intense urge to urinate
- Cloudy urine

2. **Grouping of patients:** 60 patients were randomly divided into two groups. So observation and result of 60 patients are represented here.

- Group A: *Badrasashma pishti yoga* with Luke warm water in the dose of 50 mg thrice a day was given to 30 patients of *mutrakrichra* for 60 days.
- Group B: *Badrasashma pishti yoga* with *khas sharbat* in the dose of 50 mg thrice a day was given to 30 patients of *mutrakrichra* for 60 days.

3. **Follow up study:** For the proper assessment of clinical trial. All patients are influenced to come for the follow up study after every 15 days i.e 0, 15, 30, 45, 60 days. During every visit proper assessment on the basis of objective (urine culture) and subjective parameter (frequent urination, an intense urge to urinate, cloudy urine).

f. Criteria of Assessment:

We have planned to study about 60 patients on the following criteria.

- **Subjective parameters:**
The Symptoms of *mutrakrichra* in classical text are:
 - Frequent urination
 - An intense urge to urinate
 - Cloudy urine
- **Objective parameters:**

Effect will also be assessed on changes in Urine parameters especially Urine culture.

- **Subjective parameter:** the following objective scale with numerical values was used to assess the severity of above mentioned subjective criteria.

Table -1: Showing Frequent Urination

Score	Frequent urination status
0	Absent
1	Mild
2	Moderate
3	Severe

Table- 2: Showing an Intense Urge To Urinate

Score	an intense urge to urinate status
0	Absent
1	Mild
2	Moderate
3	Severe

Table -3: Showing Cloudy Urine

Score	cloudy urine status
0	Absent
1	Mild
2	Moderate
3	Severe

g. Statistical Analysis

The scores of criteria of assessment were analyzed statistically in form of mean score B.T (Before treatment), A.T (After treatment), S.D (standard deviation). The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. The independent t test (for quantitative data within two groups) and paired t test (for quantitative data to compare before and after observations) were used for quantitative data comparison of all clinical indicators. Level of significance was set at $P \leq 0.05$.

- Highly significant - $p < 0.001$
- Significant - $p < 0.01$
- Insignificant - $p > 0.05$

Table- 4: Showing Urine Culture

Score	Urine culture status
0	Sterile
1	Infective

Overall assessment was established in terms of percentage relief obtained in criteria of assessment.

Table -5: Criteria for Overall Assessment

Complete remission	75-100% relief in sign and symptoms
Moderate improvement	60-74%
Mild improvement	31-60%
No improvement	0-30%

Result and Discussion:

Subjective parameters:

GROUP A

Table-6: Frequent Urination

	Mean	Std. Deviation	P Value	% relief
BT	2.26	0.73	0.001 (S)	36.7%
AT	1.43	0.62		

Among group A, before treatment mean score of excessive thirst was 2.26 and it was reduced to 1.43 after treatment which showed statistically significant results ($p=0.001$).

Table -7: An Intense Urge to Urinate

	Mean	Std. Deviation	P Value	% relief
BT	2.36	0.66	0.001 (S)	42.3%
AT	1.36	0.66		

Among group A, before treatment mean score of heaviness was 2.36 and it was reduced to 1.36 after treatment which showed statistically significant results ($p=0.001$).

Table- 8: Cloudy Urine

	Mean	Std. Deviation	P Value	% relief
BT	2.26	0.69	0.001 (S)	44.2%
AT	1.26	0.58		

Among group A, before treatment mean score of gatra stab dhata was 2.26 and it was reduced to 1.26 after treatment which showed statistically significant results ($p=0.001$).

Objective parameters:**Table- 9: Urine Culture**

		AT		Total
		Absent	Present	
BT	Absent	7	0	7
	Present	9	14	23
Total		16	14	30

Chi-square test, P value=0.001 (S)

Among group A, before treatment mean score of urine culture was 23 present and it was reduced to 14 present after treatment which showed statistically significant results (p=0.001)

Subjective parameters:**GROUP B****Table -10: Frequent Urination**

	Mean	Std. Deviation	P Value	% relief
BT	2.13	0.73	0.001 (S)	75.1%
AT	0.53	0.68		

Among group B, before treatment mean score of excessive thirst was 2.13 and it was reduced to 0.53 after treatment which showed statistically significant results (p=0.001).

Table -11: An Intense Urge to Urine

	Mean	Std. Deviation	P Value	% relief
BT	2.26	0.78	0.001 (S)	75.2%
AT	0.56	0.67		

Among group B, before treatment mean score of heaviness was 2.26 and it was reduced to 0.56 after treatment which showed statistically significant results (p=0.001)

Table -12: Cloudy Urine

	Mean	Std. Deviation	P Value	% relief
BT	2.13	0.62	0.001 (S)	71.8%
AT	0.6	0.67		

Among group B, before treatment mean score of *gatrastabdhata* was 2.13 and it was reduced to 0.6 after treatment which showed statistically significant results (p=0.001)

Objective parameters:**Table - 13: Urine Culture**

		AT		Total
		Absent	Present	
BT	Absent	10	0	10
	Present	15	5	20
Total		25	5	30

Chi-square test, P value=0.001

Among group B, before treatment mean score of urine culture was 20 present and it was reduced to 5 present after treatment which showed statistically significant results (p=0.001)

Table- 14: Pre comparison of study variables among group (inter-comparison)

		Mean	SD	Std. Error	P value
Excessive urine	A	2.26	0.73	0.13	0.48
	B	2.13	0.73	0.13	
An intense urge to urine	A	2.36	0.66	0.12	0.59
	B	2.26	0.78	0.14	
Cloudy urine	A	2.26	0.69	0.12	0.43
	B	2.13	0.62	0.11	

Table showed before treatment comparison of study variables among group (inter-comparison). Group A showed slightly high mean treatment score among all study variables as compared to group B which showed statistically non-significant results.

Table -15: Shows Urine Culture

		urine culture		Total
		Absent	Present	
Groups	A	7	23	30
	B	10	20	30
Total		17	43	60

Chi-square test, P value=0.39

Before treatment group A showed 23 patients as compared to group B (20) which showed statistically non-significant results (p=0.39)

Table -16: Post comparison of study variables among group (inter-comparison)

		Mean	SD	Std. Error	P value
Excessive urine	A	1.43	0.62	0.11	<0.001 (S)
	B	0.53	0.68	0.12	
An intense urge to urine	A	1.36	0.66	0.12	0.01 (S)
	B	0.56	0.67	0.12	
Cloudy urine	A	1.26	0.58	0.106	0.01 (S)
	B	0.6	0.67	0.12	

Table showed after treatment comparison of study variables among group (inter-comparison). Group B showed less mean treatment score among all study variables as compared to group A which showed statistically significant results. Group B showed more effect on patients which provide good results.

Table No-.17: Shows Urine culture

		Urine culture		Total
		Absent	Present	
Groups	A	16	14	30
	B	25	5	30
Total		41	19	60

Chi-square test, P value=0.01 (S)

After treatment group A showed 14 patients as compared to group B (5) which showed statistically significant results (p=0.01). Group B showed more improvement than group A.

The group A is not so much effected than the group B. hence the Badrasashma Pishti combined with Khas Sharbat is given the best results than the Badrasashma Pishti alone.

The above studies shows the 41% of group A patients got relief from the disease and 74% of group B patients got relief from the disease. So Group B showed more effect on patients which provide good results.

Conclusion:

It may be concluded from the present clinical study that the *Badrasashma Pishti* with *khas sharbat* has more effect than the *Badrasashma Pishti* alone.

Statistically, the drug in both group individually showed highly significant results. On the basis of all the observation of the study, we can conclude that *Badrasashma Pishti yoga* is effective in relieving most of the sign and symptoms of urinary problem, but when it is given with *khas sharbat* results found are more effective in solving urinary related problems.

On the basis of Descriptive statistics included computation of percentages, means and standard deviations. The independent t test (for quantitative data within two groups) and paired t test (for quantitative data to compare before and after observations) were used for quantitative data comparison of all clinical indicators. Level of significance was set at $P \leq 0.05$. the values came after treatment is very significant according to the $p < 0.001$.

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