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Clinical Study to Evaluate the Effect of Shubhdeep Kidney Care Pill in the Management of *Mutrakricchra* w.s.r to UTI

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ABSTRACT:

Introduction *Mutrakricchra* (Urinary tract infection) is a prevalent illness that affects people of all ages. Disease incidence and prevalence differ by age and gender. Urinary tract infection and its treatment are critical since it can result in immediate morbidity as well as long-term problems such as hypertension and chronic renal insufficiency.

Materials and methods 30 subjects had a 45-day clinical assessment of the test drug. Patients visiting the O.P.D. and I.P.D. of the P.G. Department of *Kayachikitsa*, Subhdeep Ayurveda Medical College & Hospital (P.G Institute), Indore, participated in an open clinical study. Based on inclusion and exclusion criteria, patients of both sexes between the gender of 20 and 50 years were chosen. 500mg of the trial medication were administered twice daily with lukewarm water before meals. For the purpose of observing and evaluating the therapeutic effect, a case record form was created. Results were evaluated using both subjective and objective criteria. The paired "t" test was used to statistically analyze the demographic and clinical data.

Results It was observed that in the present study, highest number of patients around 50% (15) had marked mild improvement in their subjective complaints and 23% (7) had good improvement, around 20% (6) of patients showed moderate improvement and 7% showed no/ poor relief.

Discussion The formulations utilized in this study have components high in *madhura*, *tikta-ras*, *sita-virya*, *laghu*, *snigdha-guna*, and *madhura-vipaka*, which aided to reduce *pitta dosha* and *daha*. *Vatashaman*, *shothaharan*, and *bastishodhan* are made easier by the antibacterial and antimicrobial components.

Keywords: *Mutrakricchra*, Urinary tract infection, *Chikitsa*

INTRODUCTION

Good urination practices are a must for a healthy lifestyle. People with a healthy urinary tract are more resistant to infections. UTI is more common in women than in males, with 40 percent to 50 percent of women experiencing at

least one clinical episode over their lives. A urinary tract infection (UTI) is a frequent annoyance that can be life-threatening. It affects females more than males, with an 8:1 ratio. Female sex, obstructive uropathy, severe vesico-ureteric reflux, constipation, and repeated catheterization,



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as well as unclean living situations and environments, poverty, and illiteracy, are major risk factor for recurrent urinary tract infections.¹ The finest *pranaayatana* is *Basti*, which is the seat of pee and faeces (where life resides). Because *Hridaya* (Heart), *Shira* (Head), and *Basti* (Urinary Bladder) represent the living essence of a person, we should endeavor to save them by treating ailments and adhering to *swastha vritta* (Daily Healthy Routines). *Mutrakricchra*² is a condition that affects the *mutra marga and basti* (urinary passage). *Mutrakricchra*, *Mutraghata*, *Prameha*, and *Ashmari* are diseases of the *mutravaha srotas* (urinary channels). When a *mutravaha srotas*³ is injured, the treatment is explained as a *Mutrakricchra chikitsa*⁴. Ayurveda is an ancient system of medicine that treats the body, mind, and soul. *Trimarma* (vital component) is named after *Hirdaya* (heart), *Shira* (head), and *Basti* (bladder) in Ayurveda texts. One of them is *Basti* (bladder).⁵

Mutra is a byproduct of food digestion and metabolism in the body that is passed by the urethra. *Krichhrata* (dysuria) and *Mutra-vibandhta* are both present in *Mutraghata* and *Mutrakricchra* at the same time, but *krichhrata* (dysuria) has the upper hand in *Mutrakricchra*. It may be concluded that *vata prakopa* is caused by *Vyayama*, *adhyashan*, *ruksha sevana*, and *yana gamana*. *Pitta prakopais* caused by *Tikshna aushadha*, *amla sevana*, and *kapha prakopa* is caused by *Anupa mamsa sevana*, *vyayama*, *adhyashan*. These *Nidanas* eventually contribute to *Mutrvaha strota stroto-dushti* and *Dosha* vitiation. *Kha-vaigunya* will result from *stroto-dusti* in *Mutravaha srotas*.⁶

The aim of the present study was to determine the value of oral administration of a simple, cost-effective herbal combination in alleviating *Mutrakricchra* symptoms. Shubhdeep kidney care pill being used in this regard, has mostly herbomineral elements that are expected to be useful in the treatment of *Mutrakricchra* (UTI) and other kidney problems.

MATERIALS AND METHODS

Preparation of shubhdeep kidney care pill:

The shubhdeep kidney care pill of 500 mg weight of each was prepared according to *vati kalpana*.

Table 1 Shows Ingredients

The drug was prepared in the pharmacy of Shubhdeep Ayurvedic Medical College & Hospital (P.G. Institute), Indore.

Ethical Clearance:- Ref no-EC/2020/04 (Date -13/01/20)

CTRI number-CTRI/2021/10/037643

Informed consent:

The current study involved 30 patients who attend Shubhdeep Ayurved Medical College & Hospital (P.G. Institute), Indore's O.P.D. and I.P.D. (M.P.). Everyone was informed about the study, and their informed consent was obtained. They were only included in the study after receiving informed consent.

Study Design: It is an Open labelled single arm clinical trial.

SHUBHDEEP KIDNEY CARE PILL 500mg 1 bd
Anupana –Luke warm water before meal.

Duration- 30 days.

Follow up of patients 15 days.

Source of data: Patients attending O.P.D & I.P.D of Shubhdeep Ayurved Medical College & Hospital (P.G. Institute), Indore (M.P.).

Method of data collection: Study was carried out on the patients fulfilling the criteria of *mutrakricchra* (UTI) and those who were willing to participate in this study.

Grouping And Sampling:

This study was carried out in one group, which was done on 30 subjects without masking.

Inclusion Criteria:

- Patients presenting with clinical features of *Mutrakricchra* (UTI).
- Patients between the age group of 20-50 years will be selected with irrespective of gender.
- Both new and old patient of *Mutrakricchra* (UTI) are included in this study.
- Patient is having painful micturition; burning sensation in urine should be taken for study.
- Patient willing to participate in this study and after given their consent.

Exclusive Criteria:

- Patient age below 20 years and above 50 years.
- Renal failure, severe hydro nephrosis, pyonephrosis, renal tumours, renal calculi and renal abscess, septicaemia.
- Co morbidity of obstructive disease like urethral stricture, post urethral, CA prostate, bladder neck Constricture, BPH.
- Vesico-uretric reflux (in childhood).
- AIDS, STD (sexually transmitted diseases).
- Neurogenic bladder, granulocytopenia, solid organ transplant
- Pregnant and lactating women.
- T.B., Carcinoma, diabetes mellitus, CCF will be excluded.

Sample Size: Total 30 Patients.

Dropped Out: ADR and have any other illness during study.

Procedure Planned:

After selection of patients, drug was given to every patient for 30 days and patient will be followed every 15 days to see the effect of drug.

Investigations:

- Urine routine and microscopic examination.
- Serum creatinine (if required).
- Urine culture (if required).

Data Collection And Method:

Depending upon subjective & objective parameters, assessment of response was made based on Gradation Index mentioned below, before & after treatment.

Subjective Criteria: Table 2

- 1) Difficulty in micturition (*kricchra*)

Objective Criteria: Table 3

Final Assessment Of Results: Table 4

Statistical Analysis Plan:

The information collected on the basis of observation made during the treatment are analyzed on a statistical criterion in terms of mean score (B.T. & A.T.), Standard Deviation (S.D), Standard Error (S.E.), Anova and *Paired T Test* was carried at the significance level of 0.05, 0.01, 0.001, thus the obtained results were interpreted as:

- $P > 0.05$ Unimproved
- $P < 0.05$ Improved
- $P < 0.01$ Significantly improved
- $P < 0.001$ Highly significantly improved

RESULTS

Effect of Therapy on Subjective Criteria:

Table no. 01: Effect of Therapy on the Urine Pus cell before & after treatment

Urine Pus cells before and after treatment was clinically reduced by 34.85% which was statistically highly significant. “P” value is 0.0002 which is statistically significant and indicated that after treatment condition is significantly improved.

Table no. 02: Effect of Therapy on the Urine Epithelial Cell routine before & after treatment

Epithelial Cell routine before and after treatment was clinically reduced by 21.43%. “P” value is 0.08 which is statistically insignificant.

Table no. 03: Effect of Therapy on the improvement on difficulty in urination before & after treatment

Effect of treatment on the improvement in symptom “difficulty in urination” before & after treatment was clinically reduced in 62.07% patients. “P” value is 0.0001 which is indicated after treatment condition is statistically significant.

Table no. 04: Effect of Therapy on the improvement on dysuria before & after treatment

Effect of treatment on the improvement in symptom “dysuria” before & after treatment was clinically reduced by 68.75%. “P” value is 0.0003 which is statistically significant.

Table no. 05: Effect of Therapy on the improvement on urgency before & after treatment

Effect of treatment on the improvement in symptom “urgency” before & after treatment was clinically reduced by 55.56%. “P” value is 0.0067 which is statistically significant.

Table no. 06: Effect of Therapy on the improvement on Pain in supra pubic region before & after treatment

Effect of treatment on the improvement in symptom “Pain in supra pubic region” before & after treatment was clinically reduced by 50.00%. “P” value is 0.3256 which is statistically insignificant.

Table no. 07: Effect of Therapy on the improvement on Burning micturition before & after treatment

Effect of treatment on the improvement in symptom “Burning micturitions” before & after treatment was clinically reduced by 54.9% which was clinically significant; “P” value is 0.00001 which is statistically significant.

Table no. 08: Effect of Therapy on the improvement on Urine colour before & after treatment

Effect of treatment on the improvement in symptom “Urine colour” before & after treatment was clinically reduced by 36.7% which was clinically significant. “P” value is 0.0091 which is statistically significant.

Overall Improvement

The overall assessment considering the improvement was assessed as follows:

Table no. 09: – OVERALL IMPROVEMENT

DISCUSSION

The *Mutrakricchra's chikitsa*⁷, which needs *vata & pitta shaman*, is its most challenging thing. It was observed that the formulations used in this study had properties that decreased a number of *Mutrakricchra* metrics. The

formulations utilized in this study have components high in *madhura*, *tikta-ras*, *sita-virya*, *laghu*, *snigdha-guna*, and *madhura -vipaka*, which aided to reduce *pitta dosha* and *daha*. *Vatashaman*, *shothaharan*, and *bastishodhan* are made easier by the antibacterial and antimicrobial components. Analgesic and anti-inflammatory effect against bacteria has been proven for the flavonoid and tannin in *nimb twak*, which was found in the study. The vitiated *vata* and *pitta doshas* were fixed owing to *shweta parpati's* alkalizing properties. We discovered that two of the elements, *suryakshara* and *sphatika*, are *ksharas* had the *karma* of *shodhana* and *ropana* when we carefully examined their qualities. There is no doubt that *Mutrakricchra* is a *pitta pradhana tridoshajavyadhi* based on the *samprapthivighatana*. *Pitta* is lessened by *shatika's* *madhura rasa* and *vipaka*. Being *teekshna* and *ushna*, *Suryakshara* could affect *kapha* and *vata*. Additionally, salts' alkaline pH and presence would further lessen the possibility of bacterial survival in the urinary system.

The drug compound consists of *Chandan*, *Usheera*, *Neem*, *Pashaanbhedha*, *Chopchini*, *Lavan* (*Saindhav*) and *Sweta Parpati* which was considered as good remedy for the disease *Mutrakricchra*. An observation into the properties of individual drugs and in combination in the *Vati* form, reveals that the combination which is named here as a shubhdeep kidney care pill is very effective in Controlling and treating Urinary disorders. Hence this formulation proved its efficacy clinically in *Mutrakricchra*.

CONCLUSION

Mutrakricchra is a common condition in adult population because of multiple factors. shubhdeep kidney care pill was found effective in relieving all the symptoms of *Mutrakricchra* in adults within the duration of 1 month. Adults having *Vatapitta* (50%) – *Vatakapha* (33%) *Prakruti* dominated in the study. By virtue of *Vatapitta*, *Vatakapha Prakruti*, properties of the ingredients used in shubhdeep kidney care pill have helped in curing the disease *Mutrakricchra* without any side effects. 50% of patient shows improvement in their symptoms. 50% of patients show mild improvement i.e. 20-40% improvements in the complaints. 23% of patients have good improvement in their symptoms i.e. 60-80% of improvements. 20% of Patients show moderate improvement i.e. 40-60% of improvements and 7% show no improvement after taking the treatment. Improvement

was calculated after 1 month of taking shubhdeep kidney care pill and it was concluded that Shubdeep Kidney care pill is effective in *Mutrakricchra*. It is further suggested that, for the confirmation of the efficacy the study is needed in large number of samples in different geographical areas.

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Conflicts Of Interest- Nil

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Table 1 Shows Ingredients

Ingredient	Latin name	Part used	Quantity(500mg)
<i>Chandan</i>	<i>Santalum album</i>	<i>Bark</i>	50mg
<i>Usheera</i>	<i>Vitivera zizanoidis</i>	<i>Root</i>	50mg
<i>Neem</i>	<i>Azadirechta indica</i>	<i>Twak</i>	50mg
<i>Pashaanbheda</i>	<i>Bergenia ligulata</i>	<i>Twak</i>	50mg
<i>Chopchini</i>	<i>Smilax china</i>	<i>Root</i>	50mg
<i>Lavan(saindhav)</i>	<i>Rock salt</i>	---	50mg
<i>Shweta parpati</i>	---	----	200mg

Table 2 SUBJECTIVE CRITERIA:

Difficulty in micturition (*kricchra*)

CRITERIA	GRADING
None	0
Mild difficulty in forcible urination (rarely)	1
Moderate difficulty in urination (often)	2
Severe difficulty in urine	3

Painful urination (*dysuria*)

None (no pain)	0
Mild rare pain in morning or at starting of micturition (occasionally bearable pain)	1
Moderate ,tolerable pain at starting and during micuration (often)	2
Severe not tolerable at starting ,during micturition and prolonged	3

Frequency of urine (*urgency*)

Normal urination (6-8 times)	0
Mild ,rarely frequent micturition (9-10 times)	1
Moderate ,often frequent not able to control (11-12 times)	2
Severe ,persistent many times (more than 12 times)	3

Burning micturition

No burning	0
Mild, rare , burning in morning or at starting of micturition	1
Moderate ,tolerable burning at starting and during micturition	2
Severe ,not tolerable at starting ,during micturition and prolonged micturition	3

Urine colour

Normal /colourless	0
Mild yellow colour, <i>Alpa peetata</i> (light yellow/pale)	1
Moderate , <i>Peeta</i> (yellow)	2
Severe or deep yellow colour (<i>haridra varna</i>)	3

Suprapubic pain

No pain	0
Mild (ocassionaly / bearable pain)	1
Moderate (often/pain may awake at night)	2
Severe (daily/long time,unbearable pain)	3

Table 2 OBJECTIVE CRITERIA:

s.no.	investigation	before treatment	after treatment
1	urine routine and microscopy		
2	serum creatinine (if required).		
3	urine culture (if required).		

FINAL ASSESSMENT OF RESULTS: Table 3

Percentage of decrease in symptoms	Result
0% to 20% improvement	No relief / Poor
20% to 40% improvement	Mild
40% to 60% improvement	Moderate
60% to 80% improvement	Good
80% to 100% improvement	Excellent

Table no. 04: Effect of Therapy on the Urine Pus cell before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	2.2	1.43	34.85	0.72	0.13	4.32	<0.0002

Table no. 05: Effect of Therapy on the Urine Epithelial Cell routine before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	1.87	1.47	21.43	0.75	0.14	1.80	>0.08

Table no. 06: Effect of Therapy on the improvement on difficulty in urination before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	0.97	0.37	62.07	0.73	0.13	4.54	<0.0001

Table no. 07: Effect of Therapy on the improvement on dysuria before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	0.53	0.17	68.75	0.63	0.12	4.10	<0.0003

Table no. 08: Effect of Therapy on the improvement on urgency before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	0.90	0.40	55.56	0.84	0.15	2.92	<0.0067

Table no. 09: Effect of Therapy on the improvement on Pain in supra pubic region before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	0.07	0.03	50.0	0.22	0.04	1.00	>0.3256

Table no. 10: Effect of Therapy on the improvement on Burning micturition before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	1.70	0.77	54.9	0.72	0.13	7.99	<0.00001

Table no. 11: Effect of Therapy on the improvement on Urine colour before & after treatment

n	Means Score		% OF RELIEF	S.D.	S.E.	t	p
	B.T.	A.T.					
30	1.00	0.63	36.7	0.65	0.12	2.80	<0.0091

Table no. 12: – OVERALL IMPROVEMENT

RESULT	PERCENTAGE OF DECREASE IN SYMPTOMS	NO OF PATIENTS	PERCENTAGE
NO RELIEF / POOR	0% TO 20% IMPROVEMENT	2	7%
MILD	20% TO 40% IMPROVEMENT	15	50%
MODERATE	40% TO 60% IMPROVEMENT	6	20%
GOOD	60% TO 80% IMPROVEMENT	7	23%
EXCELLENT	80% TO 100% IMPROVEMENT	0	0%