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A clinical study in the management of *Garbhini Mutrakricchra* with *Shatavari Ksheerapaka* w.s.r. to UTI in Pregnancy

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ABSTRACT

Background: Pregnancy is the state of carrying a developing embryo or fetus within the female body. Profound biochemical, anatomical and physiological changes occur during the course of pregnancy. Urinary tract infections are the second most common infections worldwide. Pregnant women have 4 times higher rate of developing UTI as compared to non-pregnant women. Pregnant women develop ureteral dilation resulting in increased urinary stasis and ureterovesical reflux due to increased progesterone level and the pressure of gravid uterus on the bladder. The classical *Lakshanas* of *Mutrakricchra* like frequent micturition, difficulty during micturition, burning sensation during micturition are similar to the signs and symptoms of Urinary tract infection. *Shatavari Ksheerapaka* has been mentioned in *Sahasrayogam* for the management of *Mutrakricchra*. *Shatavari* is *Sheeta* in *Virya*, acts as a diuretic and helps in the reduction of *Mutrakricchra* symptoms. According to *Bhavprakash Nighantu*, *Sita* is *Ruchikara* and *Ksheera* is *Rasayana*. **Aim:** To evaluate the efficacy of *Shatavari Ksheerapaka* in *Garbhini Mutrakricchra* w.s.r UTI in Pregnancy. **Method:** It is a controlled clinical study of two groups consisting 15 patient each in control and trial group. **Conclusion:** *Shatavari Ksheerapaka* and *Trinapanchmoola Ksheerapaka* both are equally effective in treating the *Garbhini Mutrakricchra* w.s.r. UTI in Pregnancy.

Key words: *Garbhini Mutrakricchra*, *UTI in pregnancy*, *Shatavari Ksheerapaka*, *Pregnancy*

INTRODUCTION

Pregnancy is the state of carrying a developing embryo or foetus within the female body. Profound biochemical, anatomical and physiological changes occur during the course of pregnancy. Women may suffer with minor or major disorders during pregnancy and Urinary Tract Infection is one among them.

UTI is an infection of the urinary tract including kidneys, ureters, bladder and urethra. Urinary tract

infections are the second most common infections worldwide. Incidence of UTI is higher in women than men. The increase risk factor for UTI in women may be due to short urethra, close proximity of external urethral meatus to the areas, catheterization or sexual intercourse.^[1] Pregnant women have 4 times higher rate of developing UTI as compared to non-pregnant women.^[2] Pregnant women develop ureteral dilation resulting in increased urinary stasis and ureterovesical reflux due to increased progesterone level and the pressure of gravid uterus on the bladder. The physiological increase in plasma volume during pregnancy decreases urine concentration and upto 70% of pregnant women develop glycosuria, which encourages bacterial growth in the urine.

Prevalence of pyelonephritis in pregnancy is 1 to 3%. A pregnant woman who develops UTI should be treated promptly to avoid pyelonephritis and other risks such as Premature delivery of baby, Premature rupture of membrane and Intra uterine growth retardation.^[3]

The classical *Lakshanas* of *Mutrakricchra* like frequent micturition, difficulty during micturition, burning

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sensation during micturition are similar to the signs and symptoms of Urinary tract infection.

Though there is not direct reference of *Garbhini Mutrakricchra* in our classics but *Acharya Kashyapa* has said that there is no difference in disorders of *Garbhini* from any other individual i.e., *Dosha* and *Dushya* are same in every individual from the childhood to the old age.

Ayurvedic classics mention a variety of preparations for the treatment of *Mutrakricchra*. *Shatavari Ksheerapaka* has been mentioned in *Sahasrayogam* for the management of *Mutrakricchra*.^[4] *Shatavari* is *Sheeta* in *Virya*, acts as a diuretic and helps in the reduction of *Mutrakricchra* symptoms. According to *Bhavprakash Nighantu*, *Sita* is *Ruchikara* and *Ksheera* is *Rasayana*.

OBJECTIVES OF THE STUDY

1. To evaluate the efficacy of *Shatavari Ksheerapaka* in *Garbhini Mutrakricchra*.
2. To re-evaluate the efficacy of *Trinapanchmoola Ksheerapaka* in *Garbhini Mutrakricchra*.
3. To compare the efficacy of *Shatavari Ksheerapaka* and *Trinapanchmoola Ksheerapaka* in *Garbhini Mutrakricchra*.
4. To study about *Mutrakricchra* in pregnancy as per Ayurvedic and modern literature.

MATERIALS AND METHODS

Since the present study was a controlled study, two drugs *Shatavari Ksheerapaka* (trial drug) and *Trinapanchmoola Ksheerapaka* (control drug) are selected.

Preparation of the drug

Shatavari Churna was prepared at the pharmacy of Department of *Rasa Shastra* and *Bhaishajya Kalpana* department of SSCASRH, Bengaluru.

Procedure of preparation of *Shatavari Ksheerapaka* was explained to the patient.

Shatavari Churna and *Trinapanchmoola Churna* was provided to the patient and patient was asked to

prepare the *Shatavari Ksheerapaka* and *Trinapanchmoola Ksheerapaka* by themselves.

Sampling method and research design

Source of data

A series of 30 subjects with classical signs and symptoms of *Garbhini Mutrakricchra* were selected randomly from OP and IP department of Prasuti Tantra and Stree Roga, Sri Sri College of Ayurvedic Science and Research Hospital, Bengaluru. A detailed proforma was prepared considering all points pertaining to the study. The parameters considered for the study was scored on the basis of Standard methods and were analysed statistically.

Research Design

It is a controlled clinical study with pre and post-test design, where 30 subjects with Classical signs and symptoms of *Garbhini Mutrakricchra* were selected.

Diagnostic Criteria

1. Pregnant women with difficulty in micturition
2. Pregnant women with burning micturition

Inclusion Criteria

1. Subjects presenting with primi and multi gravida aged 20-40 years.
2. Subjects presenting with gestational age of all three trimesters.
3. Subjects having classical signs and symptoms of *Mutrakricchra*.
4. Subjects presenting with Investigation showing pus cells > 5cell/HPF in urine.

Exclusion Criteria

1. Subjects associated with systemic disorders like Diabetes, Hypertension etc.
2. Subjects suffering from sexually transmitted diseases.
3. Subjects with Chronic Kidney Disorders.
4. Subjects with Recurrent Urinary tract infection
5. Subjects with Asymptomatic bacteriuria.

6. Subjects suffering from COVID-19.

Table 1: Showing Intervention in both the groups

SN	Group	Medication	Dose	No. of Patients	Days
1.	Group A Trial Group	<i>Shatavari</i> <i>Ksheerapaka</i>	15 ml BD After Food	15	15 Days
2.	Group B Control Group	<i>Trinapanchmoola</i> <i>Ksheerapaka</i>	15 ml BD After Food	15	15 Days

ASSESSMENT CRITERIA

Subjective Criteria

Burning micturition

Grading

No burning sensation - 0

Occasional mild burning - 1

Moderate troublesome burning - 2

Severe burning - 3

Frequency of micturition

Grading

Less than 5 times/day - 0

5-8 times/day - 1

8-12 times/day - 2

More than 12times/day - 3

Pain during micturition

Grading

No pain - 0

Occasional bearable pain - 1

Often/Moderate pain - 2

Severe Pain - 3

Suprapubic pain during and at the end of micturition

Grading

No - 0

Mild - 1

Moderate - 2

Severe - 3

Mild fever

Grading

Absent - 0

Present - 1

Objective criteria

Number of pus cell before and after the treatment

Grading

<5 cell/HPF - 0

5-10 cell/HPF - 1

>10 cell/HPF - 2

Urine culture and sensitivity positive or negative before and after the treatment

Grading

Absent - 0

Present - 1

Assessment/Follow Up

Table 2: showing assessment and follow-up

Assessment / Follow up	Day
Pre – Study Assessment	0 day
1 st Assessment	7 th day
2 nd Assessment	15 th day

OBSERVATION AND RESULTS

In the present study, 30 subjects were screened, out of which 30 subjects were selected, enrolled and completed the study. The study was completed in 15 subjects each in Group A and Group B. Group A (trial

group) received intervention *Shatavari Ksheerapaka* and Group B (control group) received intervention *Trinapanchmoola Ksheerapaka*. Among 30 patients, it was observed that 53.33% of subjects were in the age group 20 to 25, as it is common in reproductive age group. 66.67% subjects were graduates, this could be because of more health awareness in educated people. 53.33% were married for 0-3 years, as primigravida are more prone for UTI as compared to multiparous women. In the study, it is observed that 46.67% subjects reported in 1st trimester, 50% reported in 3rd trimester, as in 1st trimester there are changes in maternal osmoregulation and in 3rd trimester, there is increased pressure of gravid uterus on the bladder. 60.00% subjects were primigravida as primigravida are more prone for UTI. 76.66% were having mixed diet, this might be because *Nidana Sevana* like *Anupa Mamsa, Matsya Sevana* leads to *Mutrakricchra*. There was less intake of water in 40% of subjects, which encourages bacterial growth as more water intake helps in flushing out bacteria from the bladder. It is observed that, 50% of subjects were of *Vata Pitta Prakriti, Vata Pitta Dosha* are predominant in *Mutrakricchra Vyadhi*.

As the assessment parameters include both qualitative and quantitative data, two groups are compared for pre and post values using Friedman’s test, Mann whitney test, Repeated Measure ANOVA test and Unpaired t sample test.

Mann-Whitney U test between the groups

Table 3: Showing changes in burning micturition during and after treatment

	Group	N	Mean Rank	P Value	Remark
DT	Group A	15	15.97	0.775	NS
	Group B	15	15.03		
AT	Group A	15	15.50	1.00	NS
	Group B	15	15.50		

Table 4: Showing changes in frequency of micturition during and after treatment

	Group	N	Mean Rank	P Value	Remark
DT	Group A	15	12.47	0.061	NS
	Group B	15	18.53		
AT	Group A	15	12.90	0.106	NS
	Group B	15	18.10		

Table 5: Showing changes in pain during micturition during and after treatment

	Group	N	Mean Rank	P Value	Remark
DT	Group A	15	18.40	0.74	NS
	Group B	15	12.60		
AT	Group A	15	18	0.126	NS
	Group B	15	13		

Table 6: Showing changes in suprapubic pain during and at end of micturition during and after treatment

	Group	N	Mean Rank	P Value	Remark
DT	Group A	15	13.23	0.16	NS
	Group B	15	17.77		
AT	Group A	15	16	0.775	NS
	Group B	15	15		

Table 7: Showing changes in number of pus cell during and after treatment

	Group	N	Mean Rank	P Value	Remark
DT	Group A	15	18	0.126	NS
	Group B	15	13		
AT	Group A	15	14	0.36	NS
	Group B	15	17		

Table 8: Showing changes in mild fever during and after treatment

	Group	N	Mean Rank	P Value	Remark
DT	Group A	15	15.50	1	NS
	Group B	15	15.50		
AT	Group A	15	15.50	1	NS
	Group B	15	15.50		

Friedman’s test for within the group

Table 8: Showing changes in burning micturition Group A

	Mean	S.D.	P Value	Significance
BT	1.27	0.884	<0.001	HS
DT	0.47	0.640		
AT	0.13	0.352		

Table 9: Showing changes in burning micturition Group B

	Mean	S.D.	P Value	Significance
BT	1.20	0.775	<0.001	HS

DT	0.40	0.632		
AT	0.13	0.352		

Table 10: Showing changes in frequency of micturition Group A

	Mean	S.D.	P Value	Significance
BT	1.80	0.561	<0.001	HS
DT	1.07	0.594		
AT	0.87	0.516		

Table 11: Showing changes in frequency of micturition Group B

	Mean	S.D.	P Value	Significance
BT	2.33	0.617	<0.001	HS
DT	1.47	0.516		
AT	1.27	0.458		

Table 12: Showing changes in pain during micturition Group A

	Mean	S.D.	P Value	Significance
BT	2.13	0.834	<0.001	HS
DT	1.20	0.775		
AT	0.53	0.516		

Table 13: Showing changes in pain during micturition Group B

	Mean	S.D.	P Value	Significance
BT	1.87	0.516	<0.001	HS
DT	0.67	0.617		
AT	0.20	0.414		

Table 14: Showing changes in suprapubic pain during and at end of micturition Group A

	Mean	S.D.	P Value	Significance
BT	0.93	0.704	<0.001	HS
DT	0.27	0.458		
AT	0.13	0.352		

Table 15: Showing changes in suprapubic pain during and at end of micturition Group B

	Mean	S.D.	P Value	Significance
BT	1.47	0.834	<0.001	HS
DT	0.67	0.724		
AT	0.07	0.258		

Table 16: Showing changes in number of pus cells Group A

	Mean	S.D.	P Value	Significance
BT	1.53	0.516	<0.001	HS
DT	0.60	0.507		
AT	0.00	0.00		

Table 17: Showing changes in number of pus cells Group B

	Mean	S.D.	P Value	Significance
BT	1.33	0.488	<0.001	HS
DT	0.27	0.458		
AT	0.20	0.414		

Table 18: Showing changes in mild fever Group A

	Mean	S.D.	P Value	Significance
BT	0.07	0.258	0.368	NS

DT	0.00	0.00		
AT	0.00	0.00		

Table 19: Showing changes in mild fever Group B

	Mean	S.D.	P Value	Significance
BT	0.13	0.352	0.135	HS
DT	0.00	0.00		
AT	0.00	0.00		

Repeated measure Anova test within the group

Table 20: Showing changes in urine culture and sensitivity within Group A

	Mean	S.D.	S.E.M	P Value	Significance
BT	0.87	0.352	0.091	<0.001	HS
DT	0.87	0.352	0.091		
AT	0.00	0.00	0.00		

Table 21: Showing changes in urine culture and sensitivity within Group B

	Mean	S.D.	S.E.M	P Value	Significance
BT	0.93	0.258	0.067	<0.001	HS
DT	0.93	0.258	0.067		
AT	0.07	0.258	0.067		

Unpaired sample test between the group

Table 22: Showing changes in urine culture and sensitivity at between groups

	Group	Mean	S.D.	S.E.M	T Value	P Value	Significance
AT	Group A	0.00	.000	.000	-1.000	.326	NS

Group B	0.07	.258	.067	-1.000		
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DISCUSSION

Ksheerapaka is *Upakalpna* of *Kwatha Kalpana* which is advisable in *Pittaja Vyadhi* and patient with low digestive fire. *Shatavari* is having *Madhura, Tikta Rasa, Ksheera* and *Sita* is having *Madhura Rasa*. *Madhura Rasa* is *Vatapitta Shamaka, Mutrala, Dahashamaka, Garbhasthapaka*

Tikta Rasa is having *Deepana, Pachana, Krimighana, Pittashamaka* property. *Sheeta Virya* pacifies *Vata Pitta* vitiation.^[5] *Vedanasthapaka* property helps in relieving the pain during micturition. *Mutrala* property helps in production of good amount of urine, flushing out the bacteria and thus reducing sensitivity of bladder, thus helps in voiding of urine.

Pittashamaka property helps in reduction of *Pitta Dosh*a which causes *Daha*.

Rasayana being immunomodulator, boosts immunity. *Ruchikara* property increases palatability.

Shatavari contains phytochemicals^[6] like *Shatavarin I-VI, Diosgenin, Kaempferol, Alkaloids, Asparagamine A, Copper, Zinc, Manganese, Cobalt, Potassium, Calcium and Selenium* which are potent antioxidant, have antifungal and anti-inflammatory properties, *Diosgenin* which is analgesic and antimicrobial, *Alkaloids* has antibacterial and antiviral properties, *Asparagamine A* is potent antioxidative, which helps in reduction of oxidative stress. Anti-inflammatory and diuretic properties of these phyto-chemicals aids in reduction of inflammation and maintain the pH of urine. *Copper, Zinc, Manganese, Cobalt, Potassium, Calcium and Selenium* helps to boost immune system.

Burning Micturition

In group A, among 15 subjects included in this study 13.33% were having Grade 0 symptoms, 60.00% were having Grade 1, 13.33% were having Grade 2 and rest 13.33% were having Grade 3 symptoms before treatment. After treatment, 86.67% patients reduced to Grade 0 and 13.33% to Grade 1 symptoms.

In Group B, among 15 subjects included in this study 13.33% were having Grade 0 symptoms, 60.00% were having Grade 1, 20% were having Grade 2 and rest 6.67% were having Grade 3 symptoms before treatment. After treatment, 86.67% patients reduced to Grade 0 and 13.33% to Grade 1 symptoms.

Group A and B has shown highly significant improvement in burning micturition with p-value <0.001, Clinical effect size is calculated, both the group had fallen under trivial size, which shows there is no clinical difference in both the interventions.

Mode of action

Anti-inflammatory and diuretic properties of *Shatavari Ksheerapaka* might have reduced the inflammation and maintain the pH of urine. *Madhura Rasa, Madhura Vipaka* and *Sheeta Virya* might help in reduction of *Pitta Dosh*a which causes *Daha*.

Mutravirechaniya property of *Trinapanchmoola Ksheerapaka*^[7] might help to maintain the pH of urine.

Frequency of micturition

In Group A, among 15 subjects included in this study, 0% were having Grade 0 symptoms, 26.67% were having Grade 1, 66.67% were having Grade 2 and rest 6.67% were having Grade 3 symptoms before treatment. After treatment, 20% patients reduced to Grade 0, 73.33% had Grade 1 and 6.67% reduced to Grade 2 symptoms.

In Group B, among 15 subjects included in this study, 0% were having Grade 0 symptoms, 6.67% were having Grade 1, 53.30% were having Grade 2 and rest 40% were having Grade 3 symptoms before treatment. After treatment, 20% patients reduced to Grade 0, 73.33% had Grade 1 and 6.67% reduced to Grade 2 symptoms.

Group A and B has shown highly significant improvement in frequency of micturition with p-value <0.001, Clinical effect size is calculated, which shows both the groups had fallen under medium and larger size band and when D value is compared, it shows Group A is slightly more effective in treating frequency of micturition than Group B

Mode of action

Diuretic activity of the drug may help in flushing out the bacteria and thus reducing sensitivity of bladder, helps in production of good amount of urine thus helps in voiding of urine *Madhura Rasa, Guru-Snigdha Guna* pacify the vitiated *Vata*.

Madhura, Kashaya Rasa of *Trinapanchmoola Ksheerapaka* may alleviates vitiated *Vata*. *Mutravirechaniya* property may help to decrease stasis of urine, and helps in reducing the incontinence of urine.

Pain during micturition

In Group A, among 15 subjects included in this study, 0% were having Grade 0 symptoms, 26.67% were having Grade 1, 33.33% were having Grade 2 and rest 40% were having Grade 3 symptoms before treatment. After treatment, 43.67% patients reduced to Grade 0 and 53.33% reduced to Grade 1 symptoms.

In Group B, among 15 subjects included in this study, 0% were having Grade 0 symptoms, 20% were having Grade 1, 73.33% were having Grade 2 and rest 6.67% were having Grade 3 symptoms before treatment. After treatment, 80% patients reduced to Grade 0 and 20% reduced to Grade 1 symptoms.

Group A and B has shown highly significant improvement in pain during micturition with p-value <0.001, Clinical effect size is calculated, which shows both the groups had fallen under medium size band and when D value is compared it shows Group B is slightly more effective in treating pain during micturition

Mode of action

Shatavari is *Vedanasthapaka*, anti-inflammatory and analgesic property of phytochemicals like diosgenin and kaemeferon might help in reduction of pain during micturition.

Anti-inflammatory and analgesic property of phytochemicals like chlorogenic acid and caffeic acid present in *Trinapanchmoola* might have helped to relieve pain.

Suprapubic pain during and at the end of micturition

In Group A, 15 subjects included in this study, 26.67% were having Grade 0 symptoms, 53.33% were having Grade 1, 20% were having Grade 2 symptoms before treatment. After treatment, 86.67% patients reduced to Grade 0 and 13.33% reduced to Grade 1 symptoms.

In Group B, among 15 subjects included in this study, 6.67% were having Grade 0 symptoms, 53.33% were having Grade 1, 26.67% were having Grade 2 symptoms and 13.33% were having Grade 3 symptoms before treatment. After treatment, 93.33% patients reduced to Grade 0 and 6.67% reduced to Grade 1 symptoms.

Group A and B has shown highly significant improvement in burning micturition with p-value <0.001, Clinical effect size is calculated, both the group had fallen under trivial size band, which shows there is no clinical difference in both the interventions.

Mild fever

In Group A, among 15 subjects included in this study, 93.33% were falling under Grade 0 and 6.67% were under Grade 1 category before treatment. After treatment, 100% patients reduced to Grade 0.

In Group B, among 15 subjects included in this study, 86.67% were falling under Grade 0 and 13.33% were under Grade 1 category before treatment. After treatment, 100% patients fallen under Grade 0.

Group A and B has shown non-significant improvement in mild fever with p-value <0.368, Clinical effect size is calculated, both the group had fallen under trivial size band, which shows there is no clinical difference in both the interventions.

Mode of action

Madhura, Tikta Rasa and anti-inflammatory properties of *Shatavari* may help in reduction of fever. Zinc, Cobalt act as immunomodulator which might have reduced the fever.

Pus cells

In Group A, among 15 subjects included in this study, 0% were falling under Grade 0 category, 46.67% were

under Grade 1 and 53.33% were under Grade 2 category before treatment. After treatment, 100% patients reduced to Grade 0.

In Group B, among 15 subjects included in this study, 0% were falling under Grade 0 category, 66.67% were under Grade 1 and 33.33% were under Grade 2 category before treatment. After treatment, 80% patients reduced to Grade 0 and 20% reduced to Grade 1.

Group A and B has shown highly significant improvement in pus cell reduction with p-value <0.001, Clinical effect size is calculated, both the group had fallen under medium size band, when D value is compared, it shows Group B is slightly more effective in treating pus cells.

Mode of action

Antibacterial, antimicrobial properties of chemical components diosgenin and alkaloids, present in *Shatavari* might have reduced the pus cell.

Antibacterial, antimicrobial properties of lignin present in *Trinapanchmoola* might have acted against bacteria.

Urine culture and sensitivity

In Group A, among 15 subjects included in this study, 13.33% were falling under Grade 0 and 86.67% were under Grade 1 category before treatment. After treatment, 100% patients reduced to Grade 0.

In Group B, among 15 subjects included in this study, 6.67% were falling under Grade 0 and 93.33% were under Grade 1 category before treatment. After treatment, 93.33% patients reduced to Grade 0 and 6.67% had Grade 1.

Group A and B has shown highly significant improvement in Urine culture and sensitivity with p-value <0.001, Clinical effect size is calculated, both the group had fallen under trivial size, which shows there is no clinical difference in both the interventions.

Mode of action

Antibacterial, antimicrobial properties of chemical components diosgenin and alkaloids, present in *Shatavari* might have reduced the bacterial infection.

Antibacterial, antimicrobial properties of lignin present in *Trinapanchmoola* might have act against the bacteria.

CONCLUSION

The present study was completed with 30 subjects randomized into 2 groups comprising of 15 subjects in each group. Subjects in trial group (Group A) were treated with *Shatavari Ksheerapaka* and Subjects in control group (Group B) were treated with *Trinapanchmoola Ksheerapaka*. The intervention was administered for a span of 15 days and both objective and subjective parameters of *Garbhini mutrakricchra* w.s.r. to UTI in pregnancy were assessed on 0th day, 7th day, 15th day and observations were noted. Statistical analysis for parametric data was done using Repeated Measure ANOVA within the group and Unpaired 't' Test between the groups. Statistical analysis for non-parametric data was done using Friedman's Test within the group and Mann Whitney U test between the groups and result were obtained. Demographic data i.e., age, education, occupation, marital status, parity, water intake has significance in occurrence of *Garbhini Mutrakricchra*. Group A and B has showed highly significant improvement in burning micturition, frequency of micturition, pain during micturition, suprapubic pain during and after micturition, pus cell and urine culture and sensitivity and non-significant improvement in mild fever. Group A is slightly more effective in treating frequency of micturition than Group B. Group B is slightly more effective in treating pain during micturition and pus cells reduction. All the parameters showed statistically non-significant difference when compared between the groups, hence Null Hypothesis (H₀) is accepted i.e., both the drugs under the study are equally effective.

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