

International Ayurvedic Medical Journal, (ISSN: 2320 5091) (May, 2017) 5 (5)

A COMPARATIVE CLINICAL STUDY OF *MUTRAGRAHAHAR YOG* AND *GUD-AMALAKA YOG* IN *GARBHINI MUTRAGRAHA* W.S.R TO URINARY TRACT INFECTIONS DURING PREGNANCY

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ABSTRACT

Healthy mother and healthy baby are foremost aims of antenatal care. Progressive anatomical and physiological changes during pregnancy are not only confined to the genital organs however within other systems of the body too, some among them may be felt as discomfort by a pregnant woman. A pregnant woman having painful micturition or burning micturition, fever with chills, nausea, vomiting and cloudy urine having bad smell can be diagnosed as having Urinary Tract Infection (UTI). UTI is most common bacterial infection encountered during Pregnancy and troublesome to the woman suffering from it. Pyelonephritis, premature delivery and other risk such as PROM, IUGR etc can be the long term result of UTI, hence prompt attention is requisite. In the present study *MutragrahaharYog* and *Gud-amalaka Yog* has been tried in 30 patients for evaluation of its clinical efficacy and adverse / side effects if any. It was observed that *Mutragrahahar Yog* showed better results (87% patients markedly improved and 17% patients moderately improved) than *Gud-amalaka Yog* (25% patients were moderately improved, 75% patients were mildly improved). None of the patient reported any adverse effects during or after the treatment.

Keywords: Urinary Tract Infection, Premature Rupture of Membrane, MutragrahaharYog,

INTRODUCTION

Urinary tract infections (UTIs) are the second most common infections in community practice. Incidence of UTI is higher in women than men, 40% to 50% of whom will suffer at least one clinical episode during their lifetime¹.

The increase risk factor for UTI in women may be due to short urethra, absence of prostatic secretions, pregnancy and easy contamination of urinary tract with faecal flora². Approximately 90% of pregnant women develop ureteral dilation, which will persist until delivery³. And it may contribute to increased urinary stasis and ureterovesical reflux. Additionally, the physiological increase in plasma volume during pregnancy decreases urine concentration and up to 70% of pregnant women develop glycosuria, which is considered to encourage bacterial growth in the urine 3,4 .

Thus UTIs are the most common bacterial infections during pregnancy, with pyelonephritis being the most common severe bacterial infections complicating pregnancy⁵. Recurrent infection cause considerable morbidity, if complicated, it can cause severe renal disease⁶.

Modern medical management of UTI includes chiefly antibiotics. Use of antibiotics for long time in pregnancy may cause bad effects on growing fetus and presently chance of resistance is high. Due to development of resistance to present day antibiotics there is a need to evaluate new antibiotics which are equally effective. Although a lot of classical references of drugs on Mutrakrichhra^{7,8} are available in Ayurvedic texts. It is imperative for us the antimicrobial properties of the mentioned drug using scientific parameters. Acharya Sushruta⁹ and Acharya Charak¹⁰, has explained Mutrakrichhra under Mutravahastroto DusthiVikar. Symptoms of U.T.I. like Burning Micturition, Abdominal pain, and increased Frequency are same in Mutrakrichchra Vyadhi. The symptoms of

Urinary tract infections during pregnancy are nearer to those of Mutrakrichhra. In the Ayurvedic texts, Acharya Kashayap has described the treatment of Mutrasanga and Mutragraha respectively, among the Garbhini Vyadhi's. This depicts the importance to observe the symptoms carefully and timely treat the disease. In the routine antenatal check-up. the signs and symptoms of *Mutrakrichhra* are generally present which are similar to those of U.T.I. So the present study has been taken on Garbhini Mutragraha w.s.r. to Urinary tract infections during pregnancy using the Mutragrahahar Yog described by Acharya Kashyap in Khilasthana¹¹ and to see the effect of another formulation on Gudamalaka Yog mentioned in Chakradutta¹² and to compare the the efficacy of both the drugs in the light of objective as well as subjective criteria if found to be effective.

So the study has been taken on "A Comparative Clinical Study of *Mutragrahahar Yog* and *Gud-amalaka Yog* in *Garbhini Mutragraha* w.s.r. to Urinary Tract Infections during Pregnancy". This study was undertaken with following aims and objectives.

Aims and Objectives

- To review the Ayurvedic and modern literature related to Mutrakrichhra w.s.r. to UTI in Garbhini.
- To compare the efficacy of Mutragrahahar Yog and Gud-amalaka Yog w.s.r. to UTI in Garbhini.
- To study the other associated effects of the trial drugs.

To establish the safe and cost effective medicine for the treatment of *Mutrakrichhra* in *Grabhini*.

Methodology:

✤ The present study was conducted in the department of Prasuti Tantra & Stri Roga OPD / IPD of hospital affiliated to R.G.G.P.G. Ayuvedic College & Hospital, Paprola, Dist. Kangra (HP) during 2015. The study consisted of 30 pregnant females, age group of 20-35yrs, having pregnancy of 24-36 weeks of G.A. with complaint of urinary tract infection. The detailed history regarding the age, complaint and its associated symptoms was interrogated and recorded. The collected data was analyzed statistically.

Protocol During Trial

- Fulfillment of inclusion criteria.
- Consent of patient after making them aware of the merits/demerits of the trial.
- Registration of the patient.
- Investigations & management of patients before inclusion into the trial.
- Follow up of the patients for assessment and clinical evaluation.
- Statistically analysis & presentation of data.

Inclusion Criteria

- ✤ Patients willing for the trial.
- Pregnant female patient's age group of 20-35yrs having pregnancy of 24-36 weeks of G.A.
- Patients fulfilling diagnostic criteria

Exclusion Criteria

- ✤ Patients not willing for trial.
- Patients suffering from medical illness like Polycystic kidneys, Hydronephrosis, Impaired renal functions, Malignancy of urinary tract, Immune-compromised patient, Pregnancy induced hypertension, Gestational Diabetes, K/c/o Thyroid dysfunction with pregnancy.
- Patients with Complications of pregnancy like placental abnormalities, Polyhydramnios.

Diagnostic criteria

- Pregnant females presenting symptoms of Mutrakricchra w.s.r. UTI.
- Lab Investigations of urine suggestive of UTI.

Drugs

Group1: Mutragrahahar Yog- Shatavari (Asparagus Racemosa), Darbhamoola (Imperata Cylindrical), Madhuk (Glycyrrhiza Glabra), Kshiramorat (peeluparni) (Maerua Arenaria), Pashanbheda (Bergenia Ligulata) Ushira (Vetiveria Zizanioidis) Katak (Strychnos Potatorum).

Group 2: *Gud-amalaka Yog- Gud* (jaggary), *Amalaki* (Emblica officinalis)

Investigation

All the selected patients were subjected to routine investigation, which included the following

• Biochemical examination Hbgm %, TLC, DLC. ESR, Glucose tolerance tests (GTT), Renal function tests (RFT), HIV (Human immunodeficiency virus).

- Urine routine and microscopic examination
- Radiological Investigation:-USG for whole abdomen including urinary system (KUB) was done to rule out any pathology in urinary tract.

Consent of the Patients

All patients selected for trial were explained the nature of the study and their written consent was, obtained on the consent form attached with the Performa, before the commencement of the clinical trial.

Random division of the patients:- 30

patients fulfilling the inclusion criteria were selected for the study. Selected patients were divided randomly into two groups on alternate basis.

Treatment protocol:-

Group I

In this group patients were treated with *Mutragrahahar Yog*. This *Yog* was given in the decoction form in the dose of 100 ml BD for the duration of 15 days.

Group II

In this group patients were treated with *Gud-amalaka Yog*. This yog was given in the candy form as one candy (5gm) thrice in a day for the duration of 15 days.

Follow-up

- Two follow-up at weekly interval during treatment.
- One follow-up after 15 days of drug free period after the completion of treatment.

Instructions to the Patients:-

The *Do's and Don't's* were advised to every patient.

Do's:

The dietary and behavioral schedule advised to patients:-

- a. High liquid intake, at least 3 liters a day.
- b. Fruits containing high water content e.g. coconut.
- c. Use of *Takra* and curd.
- d. Maintenance of good perineal hygiene.
- e. Complete and frequent emptying of the bladder.
- f. Voiding before and after coitus.

Don't's:

The dietary & behavioral schedule prohibited to the patients.

- a. Low intake of water.
- b. Poor personal hygiene.
- c. Over indulgence in sexual activity.
- d. Suppression of the urge of micturition.

Assessment of the Patients: Assessment of the effects of therapy was done on the basis, of various subjective and objective criteria. Patients were assessed after one week of the commencement of clinical trial and after completion of trial i.e. after 15 days. In first follow up, the patients were assessed on clinical grounds only. The patients who did not come for follow up were considered drop out. At the end of 15th days, final detailed examination of the patients was, carried out including all investigations.

Assessment Criteria: Assessment of clinical features on subjective criteria (*sadahmutrata* (burning micturition), *sarujamutrata* (painful

micturition), *krachhra- mutrata* (difficulty in micturition), *muhur- muhurmutrata* (increased frequency of micturition) urgency, suprapubic pain) and objective criteria (presence of Albumin, Epithelial Cells, Pus Cells, RBC in urine) was assessed by evaluating already mentioned laboratory findings, which were carried out at the time of commencement of clinical trial. Some of these were assessed by simply evaluating the results obtained from them as follows.

1. Statistical Analysis of Results:-

The information regarding gathered demographic data was given in percentage. The data related to clinical features and laboratory investigations was collected and then statistically analyzed. The scoring of criteria of assessment was analyzed statistically in terms of mean values of B.T. (Before Treatment), A.T. (After treatment), S.D. (Standard Deviation) and S.E.(Standard Error). The effect of therapy in both the groups was assessed by applying students paired t' test for comparing before treatment & after treatment scores of assessment criteria. For intergroup comparison unpaired t test was applied. Their significance was estimated by means of 't' table on (n-1) degrees of freedom. 't' test was carried out at p <0.05, p <0.01, p <0.001. The obtained results were interpreted as:

*	Insignificant	-	p <0.05
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- Significant p < 0.01
- Highly significant p < 0.001

Total Effect of Therapy:-Steps for calculating overall percentage of improvement of individual patient; All the BT score of

every symptoms of a patient were added. All the AT score of every symptom of that patient were added. Overall percentage of improvement of each patient was calculated by the formula:

(Total BT – Total AT) / Total BT X 100.

The obtained results were measured according to the grades given below:

- ✤ Complete Remission: 100% relief
- ✤ Marked Improvement: 75% relief
- ✤ Moderate Improvement: 50 % to 75 % relief
- ✤ Mild Improvement: <50 % relief</p>
- Unchanged :<25 % or No relief

OBSERVATION & RESULTS

Total 30 patients were registered for the clinical study. The demographic data of 30 patients were presented. Maximum number of patients 36% were observed in age group of 26-30 yrs, 60% were observed to be affected at fetal gestational age of 24 -28 wks,67% patients were of primigavida, 100% patients of both the groups were of Hindu religion, 87% belonged to rural habitat, 73% were house wives, 40% were educated up to Primary level, 66.67% were of lower middle class, 60% were vegetarian, 40% had normal appetite, 50% were following medium hygiene,70% were of Vata-pittajaprakriti. Clinical Features wise Distribution of both group showed that 100% had increased micturition 11-20 frequency of times/day,87% had burning micturition,70% patients had suprapubic pain.60% patients had urgency of micturition,50% patients had difficult micturition and 40% had painful micturition. Urine analysis showed that all patients i.e.100% having yellow colored and acidic urine, pus cells and epithelial cells. Albumin was observed in 33% and R.B.C. was observed in 30%.

Effects of the therapy

A total of 30 patients were registered for present clinical study. Out of them 3 patients could not complete the trial, therefore they were considered drop out and remaining 27 patients completed the study.

Variables	N	Mean Score		D	%age Relief	<u>+</u> S.D.	<u>+</u> S.E.	ʻť'	ʻp'
	11	BT	AT		Relief				
Burning Micturition	15	2.66	0.40	2.26	85.00	1.03	0.267	8.50	< 0.001
Painful Micturition	8	1.60	0.533	1.06	70.83	1.03	0.267	4.00	0.001
Difficult Micturition	7	1.40	0.33	1.06	76.19	1.28	0.33	3.22	0.006
Frequency of Micturition	13	1.66	0.40	1.26	77.77	1.03	0.267	4.75	< 0.001
Urgency	9	1.80	0.53	1.26	70.37	1.10	0.284	4.46	< 0.001
Suprapubic Pain	12	2.26	0.46	1.80	79.41	1.01	0,262	6.87	< 0.001

Table 1: Effect of therapy on clinical Profile of patients:- group I

Table 2: Effect of therapy on microscopic findings of urine:- group I

Variables	N	Mean Score		D	%age	<u>+</u> S.D.	<u>+</u> S.E.	ʻt'	ʻp'
variables		BT	AT		Relief				
Albumin	7	1.60	0.467	1.13	70.83	1.54	0.291	3.90	0.002
Pus cells	15	2.26	0.200	2.06	90.32	.96	0.248	8.32	< 0.001
Epithelial cells.	15	3.00	0.40	2.60	86.00	.737	0.190	13.66	< 0.001
R.B.C	06	1.40	0.33	1.06	76.19	1.22	0.316	3.37	0.005

Table 3: Effect of therapy on clinical Profile of patients:- group II

Variables	N	Mean Score		D	%age	<u>+</u> S.D.	<u>+</u> S.E.	ʻt'	ʻp'
variables		BT	AT		Relief				
Burning Micturition	12	3.00	1.75	1.250	41.66	0.866	0.250	5.00	< 0.050
Painful Micturition	9	2.25	1.25	1.00	44.44	0.953	0.275	3.63	< 0.050
Difficult Micturition	8	2.00	1.25	.75	37.50	0.622	0.179	10.58	< 0.050
Frequency of Micturition	12	3.00	1.91	1.08	30.55	0.900	0.260	4.16	< 0.050
Urgency	9	2.25	1.33	0.91	40.74	0.99	0.288	3.18	<0.050
Suprapubic Pain	12	3.00	1.83	1.16	38.88	0.577	0.167	7.0	< 0.050

Table 4: Effect of therapy on microscopic findings of urine

Variables	N	Mean Score		D	%age	<u>+</u> S.D.	<u>+</u> S.E.	't'	ʻp'
variables	IN	BT	AT	-	relief				
Albumin	6	1.417	1.167	0.250	17.64	1.505	0.434	1.915	< 0.050
Pus cells	12	3.00	1.91	1.08	36.11	.90	0.26	4.16	< 0.50
Epithelial cells.	12	3.00	1.67	1.33	44.44	1.07	0.310	4.304	< 0.001
R.B.C	08	1.25	0.125	1.12	29.60	0.83	0.30	3.81	< 0.01

Table 5: Overall effect of therapy in both groups

Through Grade Score system

Results	Group-I	Group-I		
	No. of patients	% age	No. of patients	%age
Completely remission (100% relief)	-	-	-	-
Marked improvement (75 to 99% relief)	13	86.66	-	-
Moderate improvement (50 to 74% relief)	2	13.33	3	25
Mild improvement (< 50% relief)	-	-	9	75
unchanged (0% relief)	-	-	-	-

Through grade score system in Group-I, 86.66% patients were markedly improved and 13.33% patients were observed moderately improved. In group-II, 25% patients were moderately improved, 75% patients were mildly improved.

In comparison to *Gud-amalaka Yog*, *Mutragrahahar Yog has shown* better results.

Probable mode of *Mutragrahahar* Yog: kwath *Mutragrahahar* Yog is a Mutravirechaneeya drug. The Mutravirechaneeya drugs perform their action by decreasing the Agneyatatva and increasing the Jaliyatatva in the urine. They act by their Vatanulomana Pittashamana, and Srotodahahara Karma.¹³

Probable mode of action of *Gud-amalakaYog*

- *Guda* –By increasing volume of urine, it increases frequency of micturition. So there is less chance of bacterial colonization.
- Amalaki Due to Tridoshashamaka and Sheetaveerya properties of Amalaki may have shamaka effect on the disease UTI. It enhances all the thirteen Agnis and supports Apana Vata and helps to eliminate waste products from the body but does not over stimulate the urinary system.¹⁴ Bhattacharya et al in a study on

the hydroalcoholic extracts of three components of *Triphala* powder have reported varying degrees of strain specific anti bacterial activity against multi drug resistant uropathogenic bacteria and quoted that drug resistant does not interfere with the anti bacterial potential of *Triphala* components.¹⁵

DISCUSSION

- On comparing the effect of two Yog it is concluded that Mutragrahahar Yog provided better relief than Gud-amalaka Yog.
- In group I therapy showed statistically highly significant results while group II showed statistically significant results.
- *Gud-amalaka Yog* also showed statistically significant results. Hence in further study to reestablish its role or to get better results, preparation methodology of the dry drug can be modified or the dose can be increased.
- Mutragrahahar Yog and Gud-amalaka Yog can be used effectively in infections and delaying the recurrence.
- The dose and duration of *Mutragrahahar Yog* and *Gud-amalaka Yog* can be increased to see the results in chronicity.

CONCLUSION

- This study is carried out in a small sample. For better exploration of the study in Large sample is necessary.
- Urinary tract infections are a common cause of serious maternal and perinatal morbidity. All pregnant women should be screened for bacteriuria.

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Source of Support: Nil Conflict Of Interest: None Declared

How to cite this URL: Sandeep Kumar Rajan Et Al: A Comparative Clinical Study Of Mutragrahahar Yog And Gud-Amalaka Yog In Garbhini Mutragraha W.S.R To Urinary Tract Infections During Pregnancy. International Ayurvedic Medical Journal {online} 2017 {cited May, 2017} Available from:

http://www.iamj.in/posts/images/upload/1383_1390.pdf