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A STUDY ON THE EFFECT OF KUTAJYOGA WITH COMPARISON TO CIPROFLOXACIN ON OBJECTIVE PARAMETERS IN PATIENTS OF MOOTRAKRICHHRA WITH SPECIAL REFERENCE TO CYSTITIS

Suryawanshi Ravikumar Shyam [1]*, Kalmegh Manjusha Sushil [2], Gajare Kamlakar Vasant [3]

[1]Assistant professor, Department of Shalya, Vidarbha Ayurved Mahavidyalaya, Amravati, Maharashtra, India

[2]Associate Professor and HOD, Department of Shalya, Vidarbha Ayurved Mahavidyalaya, Amravati, Maharashtra, India

[3]Associate Professor, Department of Shalya, Maharashtra Arogya Mandals Sumatibai Shaha Ayurved Mahavidyalay, Hadpsar, Pune, Maharashtra, India

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***Corresponding author**
E-mail: ravisuryawanshi4601.ms@gmail.com

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ABSTRACT

Urinary tract infections (UTIs) are the second most common infections in community. Incidence of UTI is higher in women than men, 40% to 50% of whom will suffer at least one clinical episode during their lifetime. This was a randomized clinical trial in the patients of Cystitis at Surgical ward of I.P.D.& O.P.D. of tertiary health centre. Randomly 60 patients of Mootrakrichhra Vyadhi (Cystitis) was selected. 30 patients of study group were given pishtit Kutajtwak Churna in dose 2.5gm with 100 ml Godugdha in two time per day just before meal i.e. Apana kala for 7 days. Remaining 30 patients of control group was given Ciprofloxacin drug. In Statistical analysis; For parametric variables, paired samples T-test and for non-parametric variables, Wilcoxon's signed rank test was used. For Objective parameters: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients results in increase in WBC count over the period of treatment, decrease in Pus Cells count, decrease in USG count over the period of treatment more in Kutajyoga group as compared to Ciprofloxacin group. The *Kutajyoga* treatment was found more effective as compared to Ciprofloxacin standard regimen in the treatment of Cystitis in objective parameters of assessment like increase in WBC count, decrease in Pus Cells count, decrease in USG count.

Keywords: Kutajyoga, ciprofloxacin, mootrakrichhra, Cystitis.

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 suffer at least one clinical episode during their lifetime.[1] 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 flora.[2] Approximately 90% of pregnant women develop ureteral dilation, which will persist until delivery 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]

A urinary tract infection (UTI) is an infection that affects part of the urinary tract.[5] When it affects the lower urinary tract it is known as a bladder infection (cystitis) and when it affects the upper urinary tract it is known as kidney infection (pyelonephritis).[6,7] The most common cause of infection is *Escherichia coli*, though other bacteria or fungi may rarely be the cause. Risk factors include female anatomy, sexual intercourse, diabetes, obesity, and family history.[8] Although sexual intercourse is a risk factor, UTIs are not classified as sexually transmitted infections (STIs).[9] Kidney infection, if it occurs, usually follows a bladder infection but may also result from a blood-borne infection.[10] The bacteria that cause urinary tract infections typically enter the bladder via the urethra. However, infection may also occur via the blood or lymph. It is believed that the bacteria are usually transmitted to the urethra from the bowel, with females at greater risk due to their anatomy. After gaining entry to the bladder, *E. Coli* are able to attach to the bladder wall and form a biofilm that resists the body's immune response.[7]

In straightforward cases, a diagnosis may be made and treatment given based on symptoms alone without further laboratory confirmation.[11] In complicated or questionable cases, it may be useful to confirm the diagnosis via urinalysis, looking for the presence of urinary nitrites, white blood cells (leukocytes), or leukocyte esterase.[12] Another test, urine microscopy, looks for the presence of red blood cells, white blood cells, or bacteria.

MATERIALS AND METHODS

This study was approved by institutional ethics committee. This was a randomized Clinical trial in the patients of Cystitis at Surgical ward of I.P.D.& O.P.D. of tertiary health care center.

Randomly 60 patients of Mootrakrichhra Vyadhi (Cystitis) was selected irrespective of age, sex, religion, marital status, socioeconomic status & diet. 30 patients of study group were given pishtit Kutajtwak Churna in dose 2.5gm with 100 ml Godugdha in two time per day just before meal i.e. Apana kala for 7 days. Remaining 30 patients of control group was given Ciprofloxacin drug.Informed written consent of patient will be taken prior to commencement of trial. Information was collected in case record form. Follow up of the patients (Clinical Assessment of Objective Parameters) was done on 1st, 3rd, 5th,

7th day. For selection of Kutajtwak drug Raw materials taken from authentic source. Choorna form was prepared as mentioned in Sharangdhar Samhita.[13] Authentification and standardization of drugs done from authorized pharmacy. Kutajtwak choorna was prepared at pharmacy of our hospital. 2.5gms of Kutajtwak choorna was given, twice a day, before meal with Godugdha. In this patients Randomly divided into

Trial Group: 30 patients were treated with Kutajyoga (Table 1).

Control Group: 30 patients were treated with Ciprofloxacin drug for the 7 days. A newly diagnosed case of Mutrakrichhra (w.s.r. Cystitis) according to subjective and objective parameters (Table 2). The patient will be selected irrespective of age, sex, religion, occupations and marital status were included into the study while Disease causing bladder outlet obstruction i.e. Benign prostatic hypertrophy, Balanitis xerotica obliterance, Urethral stricture, Bladder neck stenosis, Cystocele, Phimosis. Carcinoma of prostate or urinary bladder, Bladder Diverticulum, Neurogenic bladder, Renal failure, Diabetes Mellitus, Hypertension, Tuberculosis, Metabolic disorder were excluded from the study. Rescue Therapy: In clinical trial if any adverse or untoward effect is seen that will be treated with proved ayurvedic or modern therapy.

If patient develops any adverse effect, if not responding to treatment and aggravation of symptoms, Patient refuses to continue treatment were withdrawn from the study

Kutaj Choorna was prepared by using principal of Choorna kalpana as described in Sharangadhara Samhita. Fine powder i.e. Choorna (Vastragalita choorna 60 mesh) of Kutaj was prepared in pulviliser. The prepared powder stored in sterilized pack kept at room temperature in dry place and used for clinical trials on the patients. Standardization of final product done.

Table 1: Drug Regimen for Trial Group

Drug	**Kutajtwak churna**
Dose	2.5gm twice a day
Route of administration	Oral
Kala	Apana (before meal)
Duration of treatment	7 days
Anupana	100 ml Godugdha

Follow up of the patients (Clinical Assessment) was done on1st, 3rd, 5th, 7th day in both groups. Concomitant treatment of patient was continued in both group.
Informed written consent of patient was taken prior to commencement of trial.
Case was taken in specifically prepared case record form.

Table 2: Drug Regimen for Control Group

Drug	Ciprofloxacin
Dose	500mg
Route of administration	Oral
Time	12 H
Duration of treatment	7Days

Clinical evaluation was done by the Objective parameters like Haemogram, Urine Routine, USG (Abdomen and pelvis) etc. for repeated measures for incomplete emptying, increased frequency, intermittency, urgency and burning micturition criteria. For testing effectiveness of the control versus trial treatment in variables for which before and after treatment values were calculated, the following comparison was made: In Statistical analysis [14]; For parametric variables, paired samples T-test was used to compare the efficacy of treatment of the control vs the trial group. The P-value of control group was compared with the trail group to conclude which treatment was better effective. For non-parametric variables, Wilcoxon's signed rank test was used to compare the efficacy of treatment of the control vs the trial group. The P-value of control group was compared with the trail group to conclude which treatment was better effective. P<0.05: P-values less than 0.05 was considered to be significant.

RESULTS

Haemogram – WBC count

(For Haemogram – WBC count, the before and after treatment values were compared for each control and trial group assuming the following hypothesis: Hypothesis: H_0: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients does not affect WBC count over the period of treatment. i.e. H_0: Null hypothesis: H_O: $M_{AT} = M_{BT}$, H_1: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients results in increase in WBC count over the period of treatment i.e. H_1: Alternative hypothesis: H_1: $M_{AT} > M_{BT}$
where: M_{AT} = Mean of WBC count after treatment, M_{BT} = Mean of WBC count before treatment) (Table 3 & 4).

Table 3: Control Group

Variable	Paired Differences					t	Df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Haemogram (WBC's /cumm) Before - Haemogram (WBC's /cumm) After	443.333	368.298	67.242	305.808	580.858	6.593	29	.041

Table 4: Trial Group

Variable	**Paired Differences**					t	df	P-value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
Haemogram (WBC's /cumm) Before - Haemogram (WBC's /cumm) After	353.333	636.658	116.237	115.601	591.065	3.040	29	.005

For both the groups, a significant value has been obtained indicating that the null hypothesis can be rejected and alternative hypothesis can be retained for both the control and trial group. But the P-values indicate that the trial group (P=0.05) is more effective than the control group (P=0.041).

Urine Routine (Pus Cells)

(For Urine Routine (Pus Cells), the before and after treatment values were compared for each control and trial group assuming the following hypothesis: **Hypothesis**: H_0: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients does not affect Urine Routine (Pus Cells) count over the period of treatment. i.e. H_0: Null hypothesis: H_O: $M_{AT} = M_{BT}$, H_1: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients results in decrease in Urine Routine (Pus Cells) count over the period of treatment.i.e. H_1: Alternative hypothesis: H_1: $M_{AT} < M_{BT,}$ where: M_{AT} = Mean of WBC count after treatment, M_{BT} = Mean of WBC count before treatment) (Table 5 & 6).

Table 5: Control Group

Test Statistics	
Wilcoxon's Signed Rank Test	Urine Routine (Pus Cells) After - Urine Routine (Pus Cells) Before
Z	-3.051
P-value	.02

Table 6: Trial Group

Test Statistics	
Wilcoxon's Signed Rank Test	Urine Routine (Pus Cells) After - Urine Routine (Pus Cells) Before
Z	-2.399
Asymp. Sig. (2-tailed)	.016

For both the groups, a significant value has been obtained indicating that the null hypothesis can be rejected and alternative hypothesis can be retained for both the control and trial group. But the P-values indicate that the trial group (P=0.016) is slightly more effective than the control group (P=0.02).

USG

(For USG, the before and after treatment values were compared for each control and trial group assuming the following hypothesis:
Hypothesis: H_0: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients does not affect USG count over the period of treatment.i.e. H_0: Null hypothesis: H_O: $M_{AT} = M_{BT}$, H_1: Kutajyoga treatment in Mutrakrichhra with special reference to cystitis in surgical ward patients results in decrease in USG count over the period of treatment. i.e. H_1: Alternative hypothesis: H_1: $M_{AT} < M_{BT,}$ where: M_{AT} = Mean of WBC count after treatment, M_{BT} = Mean of WBC count before treatment) (Table 7 & 8).

Table 7: Control Group

Test Statistics	
Wilcoxon's Signed Rank Test	USG (Abdo Pelvis) After - USG (Abdo. Pelvis) Before
Z	-3.162
Asymp. Sig. (2-tailed)	.002

Table 8: Trial Group

Test Statistics [a]	
Wilcoxon's Signed Rank Test	USG (Abdo, Pelvis) After - USG (Abdo, Pelvis) Before
Z	-2.828[b]
Asymp. Sig. (2-tailed)	.005

For both the groups, a significant value has been obtained indicating that the null hypothesis can be rejected and alternative hypothesis can be retained for both the control and trial group, but the P-values indicate that the trial group (P=0.005) is more effective than the control group (P=0.002).

DISCUSSION

Ayurveda is based on Vedas but with the main aim of eradication of the diseases and maintenance of health of healthy individuals (Su. Su. –1/4). Ayurveda is divided into eight branches in which Shalyatantra is one of the important branch. Shalyatantra was popular because this could give fast relief as compared to the slow process of recovery from medicines or herbs.

Charaka the best-known physician of ayurvedic medicine also recommended for Shalyatantra in treatment of certain diseases, which required immediate attention like hemorrhoids [15].

Sushrut Samhita is one of the most ancient and authoritative classical book of indian medicine on Shalyatantra. Aachrya Susruta discusses in detail about an exhaustive range of surgical methods including about how to deal with various types of tumors, internal and external injuries, fracture of bones, complications during pregnancy and delivery, and obstruction in intestinal loop.[15] Acharya Vagbhata has classically divided the Rogas of Mootra in to two categories viz. Mootra Atipravrittija and Mootra Apravrittija Rogas (A. S. Ni. 9/40). The disease Prameha comes under the first group where as Asmari, Mootrakricchra and Mootraghata fall under the second. Mootrakrichhra clinical entity predominated by the symptom of "**Krichhra Mootrapravritti"** due to the vitiated Vata has been extensively described all the Acharyas. Cystitis is a condition characterized by "Painful Urination" was therefore thought of to be managed by Vata-alleviating procedures especially incorporating a set of principles based on the Chikitsa Sutra of Mootrakrichhra. A specific Pathya regimen was also included in the study to provide nourishment to the aging body there by helping in alleviation of Vata and further enhancing the effect of the drugs administered.[16] All these considerations provided a firm launch pad to think on the therapeutic alternatives, which could be provided from the Ayurvedic samhitas. Therefore, a 'set' of therapeutic procedures was designed to assess its efficacy on the symptomatology of Cystitis and to give relief to the sufferers of Cystitis.

Mootrakrichhra is a Vyadhi where difficulty in micturation is pradhan lakshan, affecting physical and mental health of person.[17] In Cystitis, *E. coli*, *Staphylococcus aureus*, etc. bacteria are responsible for pathogenesis. The treatment of Cystitis is mainly by Antibiotics. There are many high grade antibacterial drugs available in present era but still there is high incidence of resistance and recurrence of cystitis. Although these 7 days' regimen is highly efficacious, it is associated with certain side effects. Considering above difficulties in Modern medicine, Ayurveda may offer better medicine to alleviate the symptoms of Mootrakrichhra. So Kutajyoga is selected.

In our study the for the Objectives parameters were as follows:

Haemogram-For both the groups, a significant value has been obtained indicating that the null hypothesis can be rejected and alternative hypothesis can be retained for both the control and trial group but the P-values indicate that the trial group (P=0.05) is more effective than the control group (P=0.041).

Urine Routine (Pus Cells): For both the groups, a significant value has been obtained indicating that the null hypothesis can be rejected and alternative hypothesis can be retained for both the control and trial group.But the P-values indicate that the trial group (P=0.016) is slightly more effective than the control group (P=0.02).

USG: For both the groups, a significant value has been obtained indicating that the null hypothesis can be rejected and alternative hypothesis can be retained for both the control and trial group.But the P-values indicate that the trial group (P=0.005) is more effective than the control group (P=0.002). After testing the effectiveness of Kutajyoga treatment against the Standard Ciprofloxacin Treatment, results showed that The Kutajyoga treatment has better results than the Standard Ciprofloxacin Patients.

Probable mode of action of drug (Kutajtwak): Kapha and Vata always play a major role in Cystitis. As Kutajtwak choorna is **Kaphghna, Pitta** in its Doshaghnata, it is helpful for Shaman of associated Doshas taking part in etiopathogenesis of Moortakrichhra. Ruksha, Laghu, Tikshna properties of Kutajtwak choorna reduces the chances of nidus formation as well as reduces the growth of infection by inhibiting the binding property of Kaphadosha.

Aqueous and methanol extract of Kurchicine showed high **antimicrobial** activity against the *E. Coli*, *Staphylococcus aureus* and many gram-positive bacilii which is responsible for Urinary tract infection which plays major role in pathogenesis of Cystitis.

Analgesic and anti **inflammatory** property of Kutajtwak helps to reduce pain in abdomen associated with Cystitis. Kashaya rasa of Kutajtwak helps in diminishing the 'Kleda' at Basti, ultimately preventing the growth of infection at Bastipradesh.Due to Ruksha guna of Kutajtwak, frequency of the Urine also get decreased.Thus, action of Kutajtwak choorna may ultimately result in reducing burning micturition, pain in abdomen associated with Cystitis due to their **anti-inflammatory** action. As described in Ashtanghridaya Samhita, Godugdha which is taken as Anupana also help in Mootrakrichhra naashana.

Mootrakrichhra is a disease of mootravaha strotas which is under influence of Apana-vayu. So Kutajtwak choorna is given in **apana-kala** i.e. before meal to enhance the action of drug.

Kutajtwak choorna is easily available and doesn't need special preparations. As the drug is given by oral route, there is no need of hospitalization. The drug can be given on O.P.D. basis.

Anti-microbial activity of Kutajtwak choorna (in pyorrhea) was studied. Study shows that Kutaj having significant activity against dysuria.

Kutaj due to alkaloids, exert potent anti-microbial activity against many micro-organisms viz. gram +ve, gram –ve bacteria. It is found to decrease the capillary permeability, thus checks excessive discharges from genital system. Thus the churna with its anupana acts on mucous membrane of urinary tract significantly showed in elimination of pathogenesis.

Blood sugar level (B.S.L.) is mentioned in Investigations to exclude the patients of Diabetes mellitus. As there is no significance of B.S.L. in before and after treatment of cystitis, it is excluded from Objective criteria for assessment.All the patients in Trial and Control group were having normal range of pus cells in their Urine microscopic examination, so investigation of the Urine Culture and sensitivity was not done.

In the investigations for Cystitis, Pus cells as well as Leukocyte count (W.B.C. count) are more significant, therefore, Pus cells and W.B.C. count are taken into consideration in **objective criteria** for assessment in Urine Routine Microscopic examination as well as in Haemogram respectively.

CONCLUSION

The Kutajyoga treatment was found more effective as compared to Ciprofloxacin standard regimen in the treatment of Cystitis in objective parameters of assessment like increase in WBC count, decrease in Urine Routine (Pus Cells) count, decrease in USG count over the period of treatment.

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