

Clinical Trial on the Efficacy of Root Powder of *Asparagus racemosus* Willd. (*Shatavari*) in Urinary Tract Infection

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Abstract—Urinary tract infection is the second most common infection after respiratory tract for bacterial infection. The cause of the infection is a wide range of microorganism, and the toxicities producing the difficulties during the act of micturition which results in pain and burning sensation along with passage of urine with obstruction. Thus the treatment aims at creating an environment where the growth of microorganism is prevented (*prakruti vighatam*) along with subsidence of the symptoms produced. The main objective of the study was to find the efficacy of *Shatavari moola choorna* (tuberous root powder of *Asparagus racemosus* Willd.) in Urinary tract infection. In the study, thirty patients were administered 6 g of *Shatavari moola choorna* (3 g each in morning and evening) before food along with cold water as adjuvant. Responses of the patients to the drug intervention were assessed before and after the treatment and follow up after one month. The results of clinical study was statistically analysed using paired t test for objective criteria and Wilcoxon signed rank test for subjective criteria. It revealed the drug is effective in reducing the pus cell count, epithelial cell count and other symptoms considerably. The inventions of antibiotics have been a boon to the infectious diseases but its irrational and indiscriminate use resulted in newer challenges posed by the changes that occurred at chromosomal levels of these microorganism. The knowledge regarding the herbal medicinal are yet to be explored in terms of their antimicrobial, anti-inflammatory, analgesic, antipyretic activity etc. *Shatavari moola choorna* not only reduces the urinary tract infection significantly but also boost the immune mechanism of the body, thereby improving the general health and preventing the recurrence of infection can be suggested as a promising drug for the future revolution of herbal medication.

Keywords— Urinary tract infection, *Mutrakrchra*, *Shatavari*, antimicrobial resistance.

I. INTRODUCTION

Urinary tract infection is the second most common infection after respiratory tract for bacterial infection. Each year, approximately 10% of women report having UTI, and more than 50% of all women have at least one such infection in their lifetime^[1]. Urinary tract infection is defined as the presence of bacteria undergoing multiplication in urine within the urinary drainage system^[2]. or It is an infection that affects part of the urinary tract. An infectious disease is any change from a state of health in a part or all of the host body and is not capable of carrying on its normal functions due to the presence of an organism or its products.^[3]

Predisposing factors are - women are more prone to the infection because of the close approximation of urethral opening to the anus and its shorter length of about 4 cm, the reproductive age where the sexual activities are more is the vulnerable age group. Sexual intercourse leads to ascending of infection, urinary calculi, prostatic hypertrophy are a major cause of UTI particularly in males, and pregnancy is a vulnerable period, because of the alkaline p^H of tract throughout the period of pregnancy, systemic diseases such as Diabetes mellitus are predisposing to the condition^[4].

The causative organisms in the predominance of their chances of producing infection are:

A. Gram – negative bacteria

1. *Escherichia coli* causes 80% of acute infections in patients without catheters.
2. *Proteus mirabilis*

3. *Klebsiella pneumoniae* (11%)
4. *Enterobacter*
5. *Serratia*
6. *Pseudomonas aeruginosa*.(11%)

B. Gram – positive bacteria

1. *Staphylococcus saprophyticus* (10-15%)
2. *Staphylococcus epidermis* (1-5%)
3. *Staphylococcus aureas* (1-5 %)
4. *Enterococcus sp.*(7%)

C. Fungus

Candida albicans.(9%)

D. Other organisms

Chlamydia trachomatis
Neisseria gonorrhoeae
Trichomonas
Herpes simplex virus.

Clinical symptoms:

The symptoms of urinary infection based on the site of occurrence is classified to two- lower urinary infection (below the urinary bladder) known as cystitis and upper urinary tract infection (above the level of bladder) known as pyelonephritis. Clinical symptoms of cystitis: Though the term specifies the infection of urinary bladder, it also includes the infection of urethra broadly known as lower urinary tract infection. It includes a syndrome of –Dysuria, Increased Frequency, Urgency, Voiding small volumes of urine, Urine may be foul smelling or blood stained, Occasional suprapubic pain.

Clinical symptoms of pyelonephritis; Acute pyelonephritis is a clinical syndrome including irritating bladder syndrome along with an association of systemic illness such as gastric irritations and fever, High grade Fever with chills, Flank pain, Irritating voiding symptoms, Nausea and vomiting, Epigastric or abdominal discomforts.

Patients with indwelling catheters have asymptomatic bacteriuria, but fever may occur rapidly associated with bacteraemia^[5,6].

II. MATERIALS AND METHODS

Preparation of Medicine:

The individual tubers were separated from the root stalk and then washed thoroughly in running water for many times until the mud and soil particles were completely washed off. Each tuber was cut longitudinally to remove the central cork portion, and chopped to small pieces. This was then subjected to drying in sun until free from moisture completely. Finally these were powdered finely and then packed, weighing 3 g each, in self-sealing packets.

Selection Method:

a) Inclusion criteria

- i) Sex- both male and female were included.
- ii) Age- between 16 – 60 years of age.
- iii) Patients with symptoms of Urinary tract infection and with supporting lab reports.
- iv) Patients willing for the study.

b) Exclusion criteria

- i) Patients undergoing antibiotic treatments or any other medication for Urinary tract infection.
- ii) Patients diagnosed with fibroid, malignancy, fibro adenoma etc.
- iii) Patients undergoing infertility treatments or any other hormonal treatments.
- iv) Patients undergoing dialysis or with renal damage or failure.

Sampling method

a) Sample frame:

- i) Sample size- 30
- ii) Sampling technique- purposive sampling
- iii) Study design – Interventional pre & post-test without control group
- iv) Selection of patients- As per inclusion & exclusion criteria

Methods of assessment criteria: Both pre and post assessment of the patient was done on the basis of clinical symptoms and necessary investigations.

Subjective Criteria:

Assessment of therapy was done based on the relief observed in the sign and symptoms with the help of following scoring pattern, extracted from the international scoring technique for BPH.

The scoring pattern was as follows-

- 1. Pain (supra pubic pain)
 - Grade 0 – no pain
 - Grade 1 – mild, occasional pain

- Grade 2 – irregular, bearable pain
- Grade 3 – regular, unbearable pain
- 2. Burning sensation while micturition
 - Grade 0 – no burning sensation
 - Grade 1 – mild occasional burning sensation
 - Grade 2 - irregular, burning sensation
 - Grade 3 – regular, unbearable burning sensation
- 3. Supra pubic discomforts
 - Grade 0 – no discomforts
 - Grade 1 – occasional mild discomforts
 - Grade 2 – moderate discomforts
 - Grade 3 – severe discomforts
- 4. Frequency of micturition
 - Grade 0 – no increase in frequency
 - Grade 1 – mild increase in frequency
 - Grade 2- moderate increase in frequency
 - Grade 3- severe increase in frequency
- 5. Colour of urine
 - Grade 0 – no discolouration
 - Grade 1 – smoky
 - Grade 2 – cloudy, turbid
- 6. Hematuria
 - Grade 0 – no haematuria
 - Grade 1 – microscopic presence of RBC
 - Grade 2 – dusty brown or light tinged red
 - Grade 3 – bright red
- 7. Urgency
 - Present/ absent
- 8. Chill fever
 - Present/absent

Objective Criteria

Urine examination – Routine & Microscopic.

All the above mentioned investigations were carried out before and after treatment. Changes in the values and in sign and symptoms were recorded in the case preforma in each visit, every 7 days for one month for the assessment.

III. RESULTS

The data obtained was analysed and the suitable statistical method was adopted to ascertain the clinical and statistical significance of the work. The Wilcoxon signed-rank test was applied to the statistical data for evaluating the difference in grading scores of subjective parameters before and after treatment. Paired t test was applies for the objective parameter. Graphs were plotted based on the findings to make the interpretations better.

Effectiveness of intervention on Supra pubic discomforts

Stage	Transition	Frequency	P
Pre-post	3→ 0	9 (45%)	0.000*
	3→ 1	3(15%)	
	3→ 2	7(35%)	
	2→ 0	7(77.8%)	
	2→ 1	2(22.2%)	
Post-follow up	2→ 1	1 (14.3 %)	0.660 ^{NS}
	2→ 0	1 (14.3 %)	
	1→ 0	3 (60%)	
	0→ 0	16 (94.1%)	
	0→ 1	1 (5.9%)	

*: significant, (P<0.05), NS: Not significant (P> 0.05)

From table, Wilcoxon Sign Rank test revealed that the treatment has significant effect on supra pubic discomforts ($P < 0.05$). During the follow up period also the efficacy of the treatment is maintained as 60% of the patients reported a transition of severe suprapubic discomforts to either mild or no discomforts due to the treatment in the follow up period. And 77 % of the patients recovered from moderate discomforts.

Effectiveness of intervention on Supra pubic discomforts



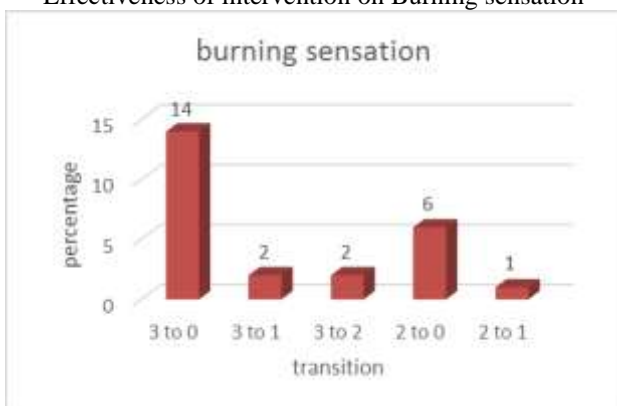
Effectiveness of intervention on Burning sensation

Stage	Transition	Frequency	P
Pre-post	3→0	14 (77.8%)	0.000*
	3→1	2 (11.1%)	
	3→2	2 (11.1%)	
	2→0	6 (85.6%)	
	2→1	1 (14.3%)	
Post-follow up	2→1	1 (50%)	1.000 ^{NS}
	1→0	3 (100%)	
	0→1	2 (8%)	
	0→2	1 (4%)	

*: significant, ($P < 0.05$), NS: Not significant ($P > 0.05$)

From table, Wilcoxon Sign Rank test revealed that the treatment has significant effect on burning sensation ($P < 0.05$). During the follow up period also the efficacy of the treatment is maintained ($P < 0.05$). Due to the treatment, 77.8% of the patients reported complete cure from severe burning sensation. And 85.6% of the patients recovered from moderate burning sensation.

Effectiveness of intervention on Burning sensation



Effectiveness of intervention on supra pubic pain

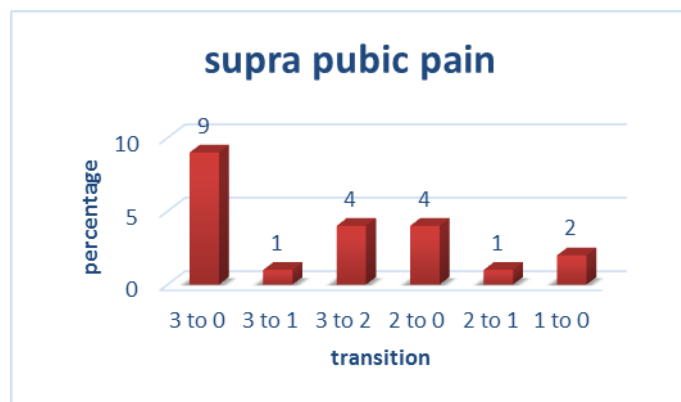
Effectiveness of intervention on supra pubic pain

Stage	Transition	Frequency	P
Pre-post	3→0	9 (64.3%)	0.000*
	3→1	1 (7.1%)	
	3→2	4 (28.6%)	
	2→0	4 (66.7%)	
	2→1	1 (16.7%)	
Post-follow up	1→0	2 (100%)	1.000 ^{NS}
	2→1	1 (50%)	
	1→0	3 (100%)	
	0→1	2 (8%)	
	0→2	1 (4%)	

*: significant, ($P < 0.05$), NS: Not significant ($P > 0.05$)

From table, Wilcoxon Sign Rank test revealed that the treatment has significant effect on Supra pubic pain ($P < 0.05$). During the follow up period also the efficacy of the treatment is maintained ($P > 0.05$) Due to the treatment, 64.3% of the patients reported complete cure from severe Supra pubic pain. And 100% of the patients recovered from mild Supra pubic pain.

Effectiveness of intervention on supra pubic pain



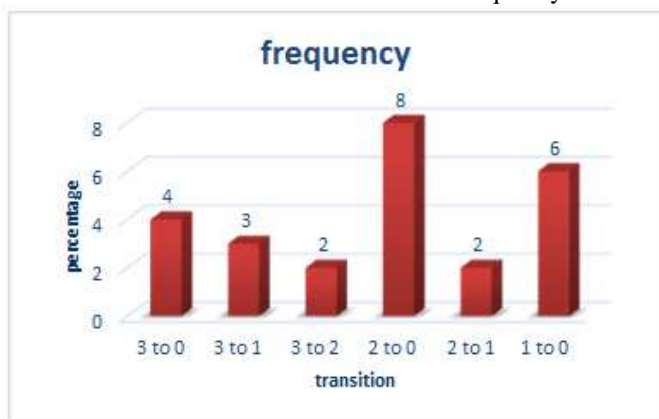
Effectiveness of intervention on frequency

Stage	Transition	Frequency	P
Pre-post	3→0	4 (40%)	0.000*
	3→1	3 (30%)	
	3→2	2 (20%)	
	2→0	8 (80%)	
	2→1	2 (20%)	
	1→0	6 (100%)	
Post-follow up	2→1	1 (50%)	0.058 ^{NS}
	2→0	1 (50%)	
	1→0	3 (100%)	
	0→1	2 (8%)	
	0→2	1 (4%)	

*: significant, ($P < 0.05$), NS: Not significant ($P > 0.05$)

From table, Wilcoxon Sign Rank test revealed that the treatment has significant effect on frequency of micturition ($P < 0.05$). During the follow up period also the efficacy of the treatment is maintained ($P > 0.05$). Due to the treatment, 70% of the patients reported transition from severe frequency of micturition to either mild increase or no increase in the frequency. And 100% of the patients recovered from mild increase in the frequency.

Effectiveness of intervention on frequency



Effectiveness of intervention on haematuria

Effectiveness of intervention on haematuria

Stage	Transition	Frequency	P
Pre-post	3→2	1 (100%)	0.010*
	2→0	4 (80%)	
	2→1	1 (20%)	
Post-follow up	1→0	2(100%)	0.414 ^{NS}
	2→0	1 (100 %)	
	0→1	1 (100 %)	

*: significant, (P<0.05), NS: Not significant (P> 0.05)

From table; Wilcoxon Sign Rank test revealed that the treatment has significant effect on haematuria (P< 0.05). During the follow up period also the efficacy of the treatment is maintained (P> 0.05) Due to the treatment, 100% of the patients reported transition from severe frequency of micturition or mild increase to no increase in the frequency.

Effectiveness of intervention on cloudy urine

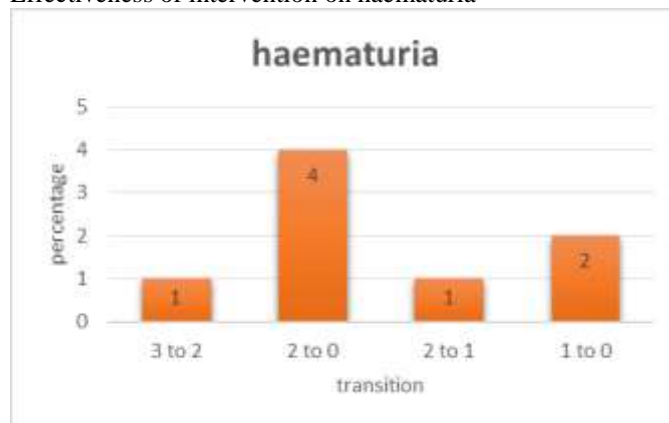
Effectiveness of intervention on cloudy urine

Stage	Transition	Frequency	P
Pre-post	3→0	4 (40%)	0.001*
	3→1	3 (30%)	
	3→2	2 (20%)	
	2→0	8 (80%)	
	2→1	2 (20%)	
Post-follow up	1→0	6 (100%)	0.317 ^{NS}
	2→1	1 (50 %)	
	2→0	1 (50 %)	
	0→1	3 (100%)	
	0→1	2 (8%)	
	0→2	1 (4%)	

*: significant, (P<0.05), NS: Not significant (P> 0.05)

From table; Wilcoxon Sign Rank test revealed that the treatment has significant effect on cloudy urine (P< 0.05). During the follow up period also the efficacy of the treatment is maintained (P> 0.05) Due to the treatment, 70% of the patients reported transition from severe frequency of micturition to either mild increase or no increase in the frequency. And 100% of the patients recovered from mild increase in the frequency.

Effectiveness of intervention on haematuria



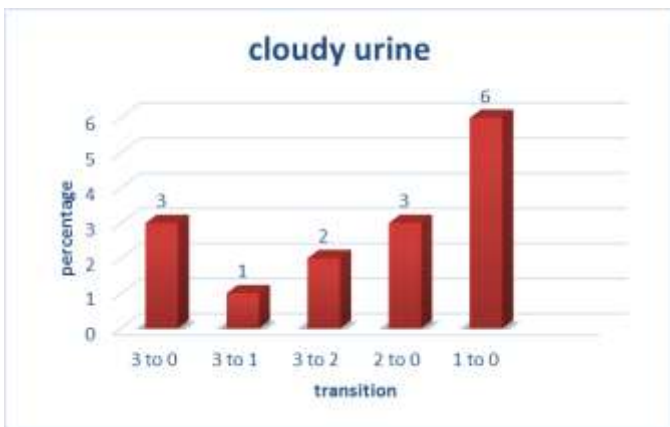
Effectiveness of intervention on pus cell count

Pus cells	Mean	SD	p – value
Pre test	14.70	11.338	<.0001
Post test	4.350	6.458	
Follow up	3.450	5.595	<.0013

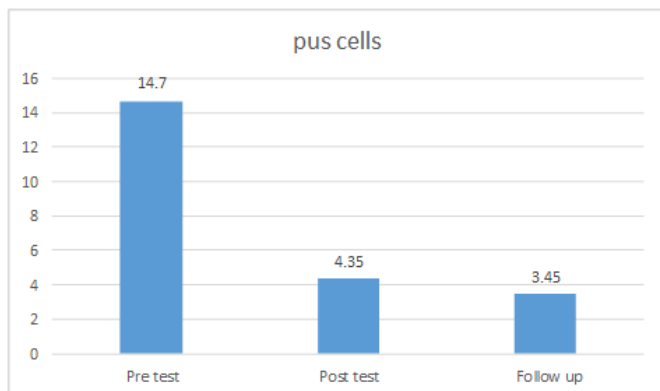
*significant (P< 0.05)

From table, Here the p-value after the treatment is less than .0001 that shows the change in the presence of pus cells is extremely significant and the p-value after follow up is 0.04 that means the change in presence of pus cells considered as very significant. The diagrammatic representation of presence of pus cells before and after treatment is shown in figure.

The diagrammatic representation of average pus cell count in before and after treatment is shown in figure.



Effectiveness of intervention on pus cell count

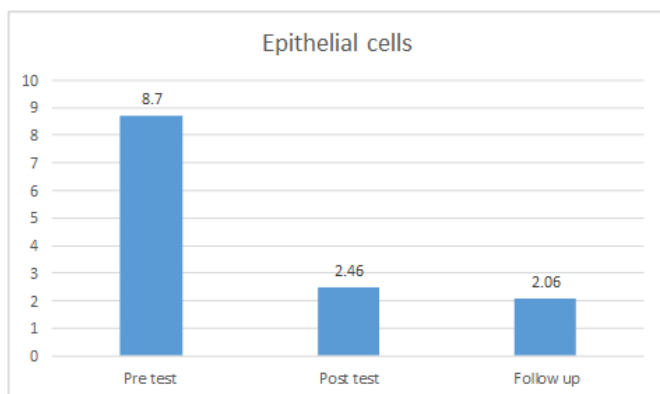


Effectiveness of intervention on epithelial cells

Epithelial cells	Mean	SD	p-value
Pre test	8.70	7.04	0.0001
Post test	2.46	3.40	
Follow up	2.06	2.65	0.0251

*significant (P < 0.05)

Here the p-value after the treatment is less than .0001 that shows the change in the presence of epithelial cells is extremely significant and the p-value after follow up is 0.0251 that means the change in presence of epithelial cells considered as significant. The diagrammatic representation of presence of epithelial cells before and after treatment is shown in figure.



IV. DISCUSSION

The microorganism which gain entry into the body establish itself by producing colonies. The exotoxins and endotoxins released in the system results in symptoms of infection such as fever, chills. The Shatavari choorna helped

in producing the antimicrobial effect, reducing the symptoms considerably as well as reducing the recurrence considerably. Flavonoids are metabolite which possess the antibacterial activity. The mechanism of antibacterial effect of flavonoids is proposed as inhibition of nucleic acid synthesis, inhibition of cytoplasmic membrane function, inhibition of energy metabolism, inhibition of attachment and biofilm formation, alteration of cell membrane permeability and attenuation of pathogenicity.

The antibacterial mechanism of Tannins are proposed as inducing complexation with enzymes and substrates, membrane toxicity to microorganism by complexation of metal ions by tannins^[7]. Saponins may be attributed for enhancing the immune mechanism and phagocytosis prevention of recurrence.^[8].

V. CONCLUSION

Tannins and Flavonoid are expected to be the major metabolites for the expression of antimicrobial activity and saponins plays the major role in prevention of recurrence, stimulation of immune system and thereby promoting the general health. Thus the drug Shatavari moola choornam can be suggested as a promising drug for the future revolution of herbal medication.

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