



A CLINICAL STUDY TO EVALUATE THE EFFICIENCY OF *ASHWABALADI TAILA UTTAR BASTI* ALONG WITH *BRAHATIYADI KASHAYAM* ORALLY IN *MUTRATITA* (URINE INCONTINENCE)

(1) Dr. Om Prakash nain (2) Prof.(Dr.) Rajesh Gupta

(1) PG Scholar, PG Department of *Shalya Tantra* ,PGIA DSRRAU Jodhpur Rajasthan

(2) Professor & HoD, PG Department of *Shalya Tantra* ,PGIA DSRRAU Jodhpur Rajasthan

Abstract:- According to ancient research methodology before establishing any theory, *Upanaya* (Discussion) is the prior step to *Nigamana* (conclusion). *Upanaya* is processes of re-examine own self. It forms a base for *Nigamana*. In spite of detailed classical study and experimentation in various ways, a theory is accepted only after the proper reasoning of observation. Hence, discussion is very much crucial part of any scientific research. Beginning with the formation of hypothesis based on *Aptopadesa*, to observations made and ultimately the results obtained, through *Pratyaksha*, each of these should be supported by the proper logic with *Anumana*. It can either support by the hypothetic at concepts and observations or it can help in the amendment of the same or it may revolutionize the concept totally. This helps in achieving the main objective of *Ayurvedic* research, which is to elaborate the Basic principles of *Ayurveda* in context to present era. The present study entitled. **A clinical study to evaluate the efficacy of ashwabaladi taila uttar basti along with brahatiyadi kashayam orally in mutratita (urine incontinence).** It is single study group, open labeled Trial. The proposed trial is an interventional study, which attempts to test the trial drugs on selected group of participants. The effects of intervention was measured by comparing the outcomes in the trial groups.

Key words:- ashwabaladi taila uttar basti, brahatiyadi kashayam, mutratita, urine incontinence.

Introduction:-

Urinary Incontinence is defined as the involuntary leakage of urine. This condition is more common in women than in men. Urinary incontinence can significantly impair quality of life, restricting social activity in women and usually accompanied by medical complications. Though urinary incontinence is not life-threatening, it is a very debilitating condition. "Incontinence is a condition that will not kill me, but it took my life away," is an emotional quote that aptly describes the impact of urinary incontinence on the patient.

Basti is one of the three vital organs in the body, the other two being *Hridaya* and *Nabhi*. It is the most important organ maintaining the homeostasis by regulating the excretion of the metabolites and waste products, i.e. *Dosha*, *Dhatu* and *Mala*. *Vegavarodha*, i.e. suppression of natural urges is an important cause of various diseases. Ayurveda states that suppression of micturition is one of the most important causes of the disease of urinary tract. With progressive urbanization and inadequate toilet facilities, this cause has assumed greater importance. In present and attempt to made a sincere effort to acquaint the reader with the wealth of knowledge available in Ayurvedic literature on the important subject of *Mutraghata*. The literal meaning of the texts has been adhered to as far as possible and the basic concepts are presented in the original form. According to Ayurveda body physiology is maintained by *Tridosha* Theory i.e. *Vata*, *Pitta* and *Kapha*. Likewise the functions of *Mutravahasrotas* (urinary system) is also regulated by *Apanavayu* one among the five types of *Vayu*. Obviously any derangement of *Apana Vayu* leads to the pathology of the urinary system. So, the treatment principle is to correct the vitiated *Apana Vayu*, thereby attaining the normal physiology of the urinary system. This controls the symptoms of the *Mutravaha Shrotas* (urinary system). *Basti* therapy is one of modality of *Pancharma* which is specially used for pacification of *Vayu*. Still the time these no work is done to compile *Mutraghata* disorders, so its need to compile them to remain update.

NEED OF STUDY: -

- Urine Incontinence is now a very common as realated problem. It is mainly seen in old age person and in women. Modern science also searched for several treatments but success rate is very less along with this recurrence rate of disease is also a major problem till the present era. So, to overcome all these problems, the future study is required.
- In ayurvedic classical several type of studies have been done. Regarding *mutratita* which can be co-related with urine incontinence various type of ayurvedic management are describes.
- As the Recurrence rate is less after the ayurvedic management the side effect are also less with less complication. So an approach should be made to get rid of these problems with ayurvedic management.

AIMS AND OBJECTIVES:-

- Contemporary and comprehensive study of the related urine incontinence problem.
- The present study is aimed to establish the clinical effect of Ayurveda. multimodal treatment which consists of oral medicines *Brahatyadikashay* and *Uttar basti* as well as specific in the aged patients of urinary incontinence.
- Effect of this treatment on daily lifestyle with the help of improvement notice in.
- To improve quality patient's life.
- To reduce side effects of modern medicine and drug dependency.
- To prevent the recurrence of the disease with a non-invasive approach.

Material and Methods:-

- Patients with classical sign and symptoms of urinary incontinence and registered from OPD, IPD and camps of university college of Ayurveda hospital Dr. Sarvepalli Radhakrishnan Rajasthan Ayurved University Jodhpur.
- Sri kaniram salagram tak satellite Hospital of Ayurveda Mangra Punjla.
- Irrespective of age, sex, religion, occupation etc. full filling the criteria of selection and eligible for the study.
- Patient may be hospitalized as per the requirement and condition of patients

Sample size –

- 30 patient were randomly selected for the study.

Informed consent –

- Written informed consent was taken from each patient before starting the study.

Criteria for selection of patients: -Inclusion criteria: -

- Patients who will give written consent.
- Patients should be in 40-to-60-year age group.
- Patients with classical sign and symptoms of urinary incontinence will be included in the trial.
- Neurogenic bladder :- it is the altered bladder function due to defect anywhere in the pathway of micturition reflex.

Exclusion Criteria: -

- Patients suffering from disease like UTI,prostate enlargement, cystocele, vaginal prolapse.
- Patients having associated disease like cerebral vascular stroke are to be exclude.
- Patients related with any malignancy.

Withdrawal Criteria: -

- All the patients which may be found hypersensitive with the selected management will be discarded from the study even after registration.
- At the same time the patients show any allergic reaction with *bastidravaya* or non-cooperative patient will be withdrawal during treatment.

Criteria of diagnosis:-

- Each patient is to be selected with the pattern of micturition that is defining the incontinence of the urine with the help of criteria's given by ICI(international consultation on incontinence).
- The criteria for diagnosis of urine incontinence as per the ICI (international consultation on incontinence).criteria are to done on the basis of :-
 - Lower urinary tracts symptoms (LUTS)
 - Urodynamic diagnosis
 - Bladder pain syndrome
 - Pelvic organ prolapsed
- General neurological assessment will be done to exclude the patients from disorder like multiplesclerosis and the lumber spine should be inspected for feature of spinal bifida.
- Rectal examination should be done for prostate enlargement in men.
 - Genital examination be done for cystocele or rectocele or mucosal atrophy of vagina.Urine routine and microscopic examination should be for UTI and other disorder.

Method of collection of data:-**Criteria for diagnosis:**

All the patients confirming the above said inclusion criteria were included in the study and subjected to thorough interrogation, physical examinations. Patients were selected on the basis of their clinical presentation particularly related to Urinary incontinence (*Mutrghat*)

Method of research:

The method adopted in present study was open randomized control clinical trial. Ethical clearance was obtained for the study from the Institutional ethics committee. Total 30 patients were registered for trial and drug intervention completed in single g

Informed consent:

The purpose of the study, nature of the study drugs, the procedures to be carried out and the potential risks and benefits were explained to the patients in detail in non-technical terms. Thereafter their written consent was taken before starting the procedure

Criteria of Assessment –

- All the patients registered for the study will be assessed on various subjective and objective parameters before treatment, during treatment and after treatment.
- Assessment criteria for urine Incontinence will be in grading. Based on the level of incontinence of urine at the time and time of urgency (Ability to hold the urine) in minutes as mentioned in the table below.
- Assessment plan:- participate will be assessed before the treatment and 15 days later to the 3rd dose of uttar basti.

A. Subjective assessment:-

- Frequency of leakages.
- Psychological status and feeling of discomfort.
- Disturbance of normal routine life.

B. Objective assessment:-

- Tenderness.
- Irregular urine leakage.

ASSESSMENT CRITERIA

GIVEN BY THE ICI (INTERNATIONAL CONSULTATION ON INCONTINENCE)

SIGNS AND SYMPTOMS	0	1	2	3
Incontinence of urine	No incontinence	Incontinence during maximum stressful condition like coughing etc.	Incontinence during medium stressful condition like walking etc.	Incontinence without any stress like sleeping or rest.
Assessment of urgency (ability to hold the urine)	3 minutes or more	2 minutes or more but less than 3 minutes	1 minute or more but less than 2 minutes	Less than 1 minute

Discussion on drug Selection-

Selection of a relevant drug for a disease means that the half of the work or treatment is done. Drug that reverses or breaks the *Samprapti* without producing any side effect is ideal.¹ In Mutratita chikitsa many drugs have been explained by various acharyas in Brihatrayee, Laghutrayee and different Nighantus.

Keeping in view the above facts for present study a formulation is selected from the *Ayurvedic* texts namely the trial drugs *ashwabaladi tail* uttar basti and the Brahtyadi kashayam orally to evaluate their efficacy and effect in the management of *Mutratita (urine incontinence)*.

Selection of *Ashwabaladi Taila* in treatment of *Mutratita (urine incontinence)* .:

Bastidana procedure from the reference *shushruta samhita* will be followed under complete aseptic condition for the proposed study as patient will be made to sit on the stool up to height of knee and female patient will be in lithotomy posture. Head of the urinary bladder of patient will be washed thoroughly and *ghritayukta shalaka* will be introduced gently in the penis and urethra in order to check the presence of any obstruction . then *bastinetra (pusphanetra)* smeared with *ghrita* introduced slowly (6 *angula* in male and 2 *angula* in female) gently in the penis and urethra respectively acc. To the direction of perineal suture.

Bastiputaka (filled with *Ashwabaladi Tailaⁱⁱ*) will be attached with the another opening of the *basti netra*. By applying gentle pressure over the *basti putaka*, administration of the *uttarbasti* medicine will be done.

1. ***Ashwabaladi Taila Action on Dosha:*** From the *Samprapti* of *Mutradhata bheda mutratita*, it is clear that the main *Dosha* involved is *Tridosha*. *Ashwabaladi Tailaⁱⁱⁱ* is *Tridoshshamaka*.

Vatashamaka & Vatanulomana Property: Due to *Snigdha* and *guru Guna*, acts as a *Vatashamaka*.

Pitta shamaka Property: Due to *Tikta Rasa*, *Snigdha Guna*, *Sheeta Veerya* and *Madhura Vipaka*, it balances the *Pitta*.

Kaphashamaka Property: Due to presence of dominant *Tikta Rasa*. It is effective for *Kaphashamana*.

Srotosodhana^{iv}: *Tikta Rasa* is helpful for *Srotovishodhan*.

2. ***Action on Dushya:*** From the *Samprapti* of *mutraghata bheda mutratita* it is clear that the main *Dushya* involved is *Rasa Dhatu*. The combination shows, dominance of *Tikta Rasa*. *Tikta* helps in improving the digestion thereby causing formation of healthy *Rasa Dhatu*.

3. ***Action on Srotasa:*** *Tikta Rasa* is helpful for *Srotovishodhana*

Mode of action of *Ashwabaladi Taila:*

Ashwabaladi taila acts as a *Rasayana* which nourishes and rejuvenates. Its *uttara basti* used to enhance all aspects of *mutravaha strotasa* performance. It is comprehensive cure of both *mutratita* and uro-genital diseases. It establishes health and immunity in the body a part from nourishing the tissues and providing longevity. *Ashwabaladi taila* have *Tridoshashamaka* and *Rasayana* property. *Ashwabaladi taila uttar basti* decreases *mutramarga* distress and maintain proper health of *mutra marga* and corrects *mutratita* also.

Procedure

Uttar Basti Yantra consists of two parts- *Bastiputaka* and *Bastinetra (Pushpanetra)*. As the quantity of drug to be used in *Uttar Basti* is less in comparison to *Basti*, *Bastiputaka* should be *Mridu* and *Laghu*.

Pushpanetra should be of 10 *Angula* in *Pramana*, *Mutrastrotasa Parinaha* (circumference like urethra) and *Mudga Chidra Sadrushya*. In married women *Basti Netra* should be inserted up to 4 fingers in length. Now a day a 5 ml

disposable syringe without needle and a uterine canula of a steel material is used.

Sneha or *Kwatha* may be used for the *Uttar Basti*. *Sneha* is considered more useful in most of the diseases of *Garbhashaya*. The quantity of *Sneha* substance to be used for cleaning the uterus should be two *Prasruta*, this quantity is also same in case of decoction. *Uttar Basti* should be given consecutive 3 days in increasing dose of *Sneha*. As per *Vagabhatta* it should be stopped for 3 days and then again should be repeated for 3 days continuously.

TREATMENT PROTOCOL

- *Bastidana* procedure from the reference *shushruta samhita* will be followed under complete aseptic condition for the proposed study as patient will be made to sit on the stool up to height of knee and female patient will be in lithotomy posture.
- Head of the urinary bladder of patient will be washed thoroughly and *ghritayukta shalaka* will be introduced gently in the penis and urethra in order to check the presence of any obstruction. then *bastinetra (pusphanetra)* smeared with *ghrita* introduced slowly (6 *angula* in male and 2 *angula* in female) gently in the penis and urethra respectively according to the direction of perineal suture.
- *Bastiputaka* (filled with *Ashwabaladi Taila*^v) will be attached with the another opening of the *basti netra*. By applying gentle pressure over the *basti putaka*, administration of the *uttarbasti* medicine will be done.
- *Brahatiyadi Kashayam*^{vi} 5-10ml prepared as per the reference of *yogaratanakar* will be given twice a day orally (before food or on empty stomach).
- *Uttar basti* of *Ashwabaladi Taila* designed by male and female *bastiyantra* on the line of classical guidelines and given by the following guideline of *Sushrut Samhita* and will be strictly followed for proposed study and for oral medicine use *brahatiyadi kwath*.

Dose Of Taila For Uttar Basti :-

The ideal quantity of taila to be given as enema liquid for persons above forty five years of age in one *prakunca* (40 ml) and above that age, the quantity should be decided by the intelligence of the physician.

DISCUSSION ON OBSERVATION

In this study 32 patients were registered and the results obtained during clinical study in the signs and symptoms of the registered Patient were assessed statically before and after treatment.

- Age profile of the registered patient shows that the maximum number of patients i.e. 47.67% (14 patient) were in age group 51-60 years followed by 26.67% (8 patient) in 41-50 years age group, 23.34% (7 patient) in 30-40 years age group and only 3.3% (1 patient) in >60 years age group.
- In sex wise distribution of the registered patient there were 28 male and 2 female in the study.
- In Habitat wise distribution of the registered patient there were 18 patient from rural area and 12 patient from urban area in the study.
- In religion wise distribution of the registered patient there were 29 hindu patient and only 1 muslim patient in the study.
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- In socio-economic status wise distribution of the registered patient there were 17 middle class patient and 3 poor patient in the study.
- In educational status wise distribution of the registered patient there were 8-8 patients had primary and secondary education respectively, 7 patients completed higher secondary, 5 patient were graduated and 2 patients were illiterate in the study.
- In food habit wise distribution of the registered patient there were 23 vegetarian patient and 7 mix diet patient in the study.
- In bowel habit wise distribution of the registered patient there were 19 irregular bowel habit patient and 11 regular bowel habit patient in the study.
- In Appetite wise distribution of the registered patient there were 18 patient with poor appetite and 12 normal appetite patient in the study.
- In sleep wise distribution of the registered patient there were 20 patient with sound sleep and 10 disturbed sleep patient in the study.
- In Addiction wise distribution of the registered patient there were 10-10 patient with no addiction and opium addiction, 9 patient with tobacco addiction and 1 patient with alcohol addiction in the study.
- In koshtha wise distribution of the registered patient there were 20 patient with krura koshtha and 10 Madhayama koshtha patient in the study.
- In prakrati wise distribution of the registered patient there were 12 patient with vatta kapha dominance, 10 patient with vatta pitta dominance and 8 patient with pitta kapha dominance patient in the study.
- In sara wise distribution of the registered patient there were 18 patient with avara dominance, 10 patient with madhyama dominance and 2 patient with pravara dominance patient in the study.
- In samhanana wise distribution of the registered patient there were 14 patient with avara dominance, 12 patient with madhyama dominance and 4 patient with pravara dominance patient in the study.
- In praman wise distribution of the registered patient there were 10 patient with avara dominance, 15 patient with madhyama dominance and 5 patient with pravara dominance patient in the study.
- In satmya wise distribution of the registered patient there were 12 patient with avara dominance, 11 patient with madhyama dominance and 7 patient with pravara dominance patient in the study.
- In satva wise distribution of the registered patient there were 17 patient with avara dominance, 9 patient with madhyama dominance and 4 patient with pravara dominance patient in the study.
- In abhyaharana shakti wise distribution of the registered patient there were 12 patient with avara dominance, 13 patient with madhyama dominance and 5 patient with pravara dominance patient in the study.
- In jarana shakti wise distribution of the registered patient there were 18 patient with avara dominance, 12 patient with madhyama dominance and no patient with pravara dominance patient in the study.
- In vyayam shakti wise distribution of the registered patient there were 11 patient with avara dominance, 11 patient with madhyama dominance and 8 patient with pravara dominance patient in the study.
- In tenderness wise distribution of the registered patient there were 9 patient with tenderness and 21 patient with no tenderness in the study.
- In frequency wise distribution of the registered patient there were 18 patient with urination frequency 10-20 times/ day, 10 patient with urination frequency 21-30 times/ day and 2 patient with urination frequency >30 times/ day patient in the study.

DISCUSSION ON RESULT-

For the evaluating the effect of therapy within group before treatment and after treatment for the subjective parameters **Wilcoxon matched-pairs signed-ranks test** has used.

Effect of therapy on ICI Score study Group

Incontinence of urine - In study group the percentage of relief was 93.4% and the effect of the therapy was extremely significant at $P < 0.0001$.

Assessment of urgency- In study group the percentage of relief was 90.90% and the effect of the therapy was extremely significant at $P < 0.0001$

Distribution of patient according to Relief in urine incontinence Symptoms

In study group there was 10% of patient has showed **excellent relief**. 50% patient has showed **moderate relief** in study group. 30% patient in study group showed **marked relief**. 10% patient in study group showed **mild relief** and the percentage of **no relief** patient was zero in study groups.

COMPARATIVE VALUES:

- Test was carried out on the basis of P value.
- $P < 0.05$, $P < 0.01$, $P < 0.001$, $P < 0.0001$.
- Non-significant : $P > 0.05$
- Significant : $P < 0.05$
- Highly significant : $P < 0.01$, $P < 0.001$, $P < 0.0001$.

Effect of therapy on ICI Score study Group

Variable	Mean		Mean diff.	% Relief	SD±	SE±	P	Result
	BT	AT						
Incontinence of urine	5.067	0.3333	4.733	93.40%	0.7988	0.2063	<0.0001	ES
Assessment of urgency	4.400	0.4000	4.000	90.90%	0.7559	0.1952	<0.0001	ES

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Distribution of patient according to Relief in urine incontinence Symptoms

S. No.	Relief	Patient	%
1.	No relief	0	0
2.	Mild relief	3	10%
3.	Moderate relief	9	30%

4.	Marked relief	15	50%
5.	Excellent relief	3	10%

In study group there was 10% of patient has showed **excellent relief**. 50% patient has showed **moderate relief** in study group. 30% patient in study group showed **marked relief**. 10% patient in study group showed **mild relief** and the percentage of **no relief** patient was zero in study groups.



❖ **Pathya Ahara:** All the patients were advised to take *Laghu, Ushna* and *Snigdha Ahara*

- To have more cow's milk and cow ghee.
- Goat milk
- Regular intake of butter
- Sesame oil
- Take old rice
- Easy to digest food
- Warm water
- Fiber rich diet
- *Karela*, garlic, onion, *Krishna Jeeraka (Nigella sativa)*, *Amalaki*, *Draksha*, *Dadima*, *Kapittha* etc. add in food.
- Medicated wines

❖ **Apathya Ahara**

- *Paryushita Ahara*
- *Atisheeta Udaka* and *Ahara*
- *Ruksha Ahara* → *Besana* etc.
- *Vatala Ahara* → Potato, Chana, ladies finger, cabbage, cauliflower etc.
- Artificially preserved or coloured food, fermented food.
- Avoid oily & spicy food,.
- To avoid over eating, fried food, bakery items, fermented items, cold drinks, Junk food, Icecreams, Chocolates

- Alcohol, Sukta (acidic beverages)

❖ *Pathya Vihara*

- Manage stress levels
- Proper sleep
- Share the burden and get good support from your family and friends.
- Regular exercise, *Pranayama, suryanamaskara*.

❖ *Apathya Vihar*

- *Divaswapna*
- *Atichankramana*
- *Ratrijagarana etc*
- *Vegadharana*(with holding of urge)
- To avoid Mental Stress.
- Exposure to cold weather or air.
- Exposure to sun and heat
- Less Physical activity

❖ Notification of complications:

- No any complications were identified during study.

CONCLUSION-

- Acharya sushruta gives more descriptive explanation as far as the Anatomy & Physiology of the Mutravaha srotas is concerned. The Pratilomavayu is considered as the responsible factor for the diseases of Basti viz. Mutraghata, Ashmari, Prameha, & Mutradosha.
- Acharya charaka gives comprises sufficient but scattered matter related to anatomy, physiology and pathology of Mutravaha srotas as well as the diagnosis and treatment of its disorders. In Siddhithana, thirteen types of Bastiogas have been described under the caption of “Mutradosha”, which are similar to that of Mutraghata as explained by Sushruta.
- In any text of ayurveda mutratita is not described as a separate disease but mutratita is a type of mutraghata and as a type of mutraghata its nidana, lakshana and chikitsa is describe in texts of ayurveda.
- In this study 30 patient from OPD and IPD level registered in study on the basis of ICI criteria with assessment of the continence of urine and assessment of urgency (ability to hold the urine).
- For the calculation of data collected INSTATE 3 software was used. Statically the effect of Ashwabaladi taila basti and Brahatiyadi Kashayam twice a day orally is highly significant and patient showed overall improvement in his condition.
- According to clinical Performa maximum patient shows moderate to marked relief (80%) and then 10% of patient shows excellent relief in symptoms of mutratita (urine incontinence).

- In course of the present study ashwabaladi taila uttar basti shows very promising result in mutratita (urine incontinence) symptoms, stabilizing the uttar basti's ayurvedic text mentioned effects on mutra marga, basti and mutravaha nadis. Stabilizing effect of basti on mtravaha strotasa.

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