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"A RANDOMIZED CONTROLLED CLINICAL TRIAL ON DASHAMOOLADI VATI IN THE MANAGEMENT OF ASTEELA W. S. R. TO BPH"

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ABSTRACT:

Introduction: Asteela is apravritti mutravikara caused by vitiation of Vata in basti and guda Pradesh leading to Asteela formation (Cobbler Stone). By the description of Asteela it can be compared with BPH. It is benign enlargement of prostate which occurs after 50 years, the frequency of benign changes in the prostate increase with age. The high prevalence of this disease in elderly population with competing cause of morbidity and mortality mandates a risk adapted approach to diagnosis and treatment. **Aim:** To evaluate the effect of Dashamooladi Vati in the management of Asteela (BPH). **Material and methods:** Dashamooladi Vati as a study drug and Dashamoola Kashaya, Shudda Shilajithu as control drugs are taken for the present study. It is a randomized controlled comparative clinical study and it is carried over 3 months. A total 60 cases of BPH are included for the study. 60 cases will be equally allocated into three groups namely Group-A (Study), Group-B (Control) & Group C (Control). Subjective Criteria for the study is IPSS scale and objective parameters for the study are prostate volume (PV), post void residual urine (PVRU). Paired and unpaired't' test is done for statistical analysis.**Result:** Group A showing statistically better result in both subjective and objective parameters. Statistically there is no significant difference between the effect of Group A and B, Group A and C. This suggests that change occurred with the treatment was not enough to exclude the possibility that the difference was due to chance. **Conclusion:** Group A has shown better result in both subjective and objective parameters with mild to moderate overall improvement, whereas in Group B & C has only shown statistically significant result in subjective parameters with no to mild overall improvement.

Key word: Asteela, BPH, Dashamoola, Shilajithu, IPSS, PVRU, PV

INTRODUCTION

In Astang Hridaya total 40 diseases are explained in the context of Mutravikar. Among them 20 Mutra Atipravritta Vyadhis i.e., 20 types of Prameha and 20 Mutra Apravritti Vyadhis i.e, 13 types of Mutraghat and 7 types of Mutrakrichra. Mutraghata is made up of two words i.e., Mutra – urine, Aghata or Vighata– complete obstruction/vitiation of urine.[1]

Asteela is one among thirteen types of Mutraghata (obstructive uropathy). Vata Prakop Ahara, Vihar and Mala, Mutraadi Vega Dharana are said to be the causes of Asteela. Vitiatiated Vata gets located in gets Basti and Guda Pradesh, which form Asteelavata Ghana Granthi, and leads severe pain and obstruction of urine feces.[2] By the description Asteela can be compared with BPH.

BPH is benign enlargement of prostate[3]. BPH is clinical diagnosis describing urinary symptoms attributable to obstruction by the prostate[4]. Overtime, incomplete emptying may lead to chronic bladder over distension that can result in a defunctionalized bladder and kidney.

The frequency of benign changes in the prostate increase with age[5]. Autopsies of men in the eighth decade of life show hyperplasia changes in more than 90 per. It is involuntary due to disturbance of the ratio and quantity of circulating androgen and estrogen. BPH is a benign neoplasm, also called as fibromyoadenoma. BPH usually involve median and lateral lobes or one of them[3]. The high prevalence of this disease in elderly population with competing cause of morbidity and mortality mandates a risk adapted approach to diagnosis and treatment[5].

AIM

To evaluate the effect of Dashamooladi Vati in the management of Asteela (BPH).

OBJECTIVES

- To evaluate the efficacy of Dashamoolaadi Vati in the management of Asteela w.s.r to BPH
- To evaluate the efficacy of Dashamoola Kashaya and in comparision with Dashamoolaadi Vati in the management of Asteela w.s.r to BPH
- To evaluate the efficacy of Shudda Shilajithu and in comparision with Dashamoolaadi Vati in the management of Asteela w.s.r to BPH

MATERIALS

Following material were selected for the present study.

1) Dashamooladi Vati[6]

2) Dashamoola Kwath Churna
3) Shudda Shilajithu

This formulation was procured and manufactured, supplied by NKCA Pharmacy, Mysuru.

METHODS

Source of Data

- Subject selected incidentally from the OPD of BVVS AMC&H, Bagalkot.
- Specific pro forma was prepared for the documentation of the data. Subjects were registered for the study after taking written informed consent.

Inclusion Criteria:

1. The cases with features mentioned in International prostate symptoms scoring namely Frequency, Intermittency, Urgency, Straining of urination, Weak stream of urine, Nocturia, Incomplete emptying of bladder will be included.
2. Cases of Asteela (BPH) confirmed by USG with Post void urine < 200ml.
3. Cases of Asteela (BPH) with age > 50 years and < 80 years will be selected.

Exclusion Criteria:

1. Cases of Asteela (BPH) in which surgery is indicated (Post Voidal Urine >200ml).
2. Ca Prostate other metastatic conditions of urinary system.
3. Neurological disease of urinary system.
4. Stricture of urethra.
5. Infective conditions of either urinary tract or prostate.
6. Patients having any systemic diseases, which interfere with the course of treatment.

Investigations:

- USG Abdomen & Pelvis
- Serum PSA

Study Design

- It is a randomized controlled comparative clinical study.
- A total **60** cases of B.P.H. are included for the study. 60 cases will be allocated into three groups namely **Group-A (Study), Group-B (Control) & Group C** (**Control**) with **20** patients in each group.
- Pre (0^{th} day) and post test (90^{th} day) design.

Intervention

Group	Drug	Dosage	Duration	Route of administration
Group A	DashamooladiVati-600 mg	2 BD,BF.	3 months	Oral administration
Group B	Dashamoola Kashaya-30ml	TID,BF.	3 months	Oral administration
Group C	Shudda Shilajithu (3gm)	1BD, BF.	3 months	Oral administration

Table 1: Showing Groups, Drugs, Dosage, Duration, and Route of administration.

Subjective Criteria Assessment

Following scoring and grading methods were adopted to assess the effect of the treatment in subjective parameters.

IPSS Scale

In the past month:	Not at All	Less than 1 in 5 Times	Less than Half the Time	About Half The Time	More than Half the Time	Almost Always
Incomplete Emptying	0	1	2	3	4	5
Frequency	0	1	2	3	4	5
Intermittency	0	1	2	3	4	5
Urgency	0	1	2	3	4	5
Weak Stream	0	1	2	3	4	5
Straining	0	1	2	3	4	5
Nocturia	0	1	2	3	4	5
Total	0-35					

Table 2: Showing IPSS Scale.

IPSS Grade

Grade	Severity	Score
i1	Mild	1 - 7
i2	Moderate	8 - 19
i3	Sever	20 -35

Table 3: Showing IPSS grading.

Objective Criteria Assessment

Following scoring and grading methods were adopted to assess the effect of the treatment in objective parameters.

PV Grade

Grade	Severity	Volume
v0	None	‹ 30cc
v1	Mild	› 30 to ‹ 60cc
v2	Moderate	› 60 to ‹ 90cc
v3	Severe	‹ 90cc

Table 4: Showing Prostate Volume grading.

PVRU Grade

Grade	Severity	Quantity
u0	Mild	› 50 to ‹ 100 ml
u1	Moderate	› 100 to ‹ 150 ml
u2	Severe	› 150 to ‹ 200 ml

Table 5: Showing PVRU grading.

Overall assessment of clinical response

Complete Remission	**100**%
Marked improvement	75 - 99%
Moderate improvement	50%-74%
Mild improvement	25 -49%
No improvement	< 25%.

Table 6: Showing Overall assessment of clinical response.

OBSERVATION

- The total 63 subjects were registered for the study. Among them 60 cases completed the treatment, 3 cases discontinued the intervention at various stages of clinical study.
- In this clinical study, out of 60 patients, 17 (28.3%) of patients belongs to 50 - 60 year age group, 24 (40%) of patients belong to 60 -70 year age group, 19 (31.6%) of patients belong to 70 - 80 year age group.
- In this clinical study, 24 (40%) of patients belong to 60 -70 year age group.
- Observation on education status of the patients revealed that, 47 (76%) patients were literates.
- Observation on occupation of patients revealed, 6 (10%) patients were businessmen's, 19 (33%) patients were retired.
- Observation on the distribution of socio-economic status of patients revealed that, maximum patients belong to middle class i.e., 24 (47%).
- Observation on the distribution of habitat in patients of Asteela (BPH) revealed that, 33 (57%) patient were from urban region.
- Observation on familial history revealed that, 51 (86%) patients had no family history.
- Observation on previous history revealed that, 37 (62%) patients were treated.

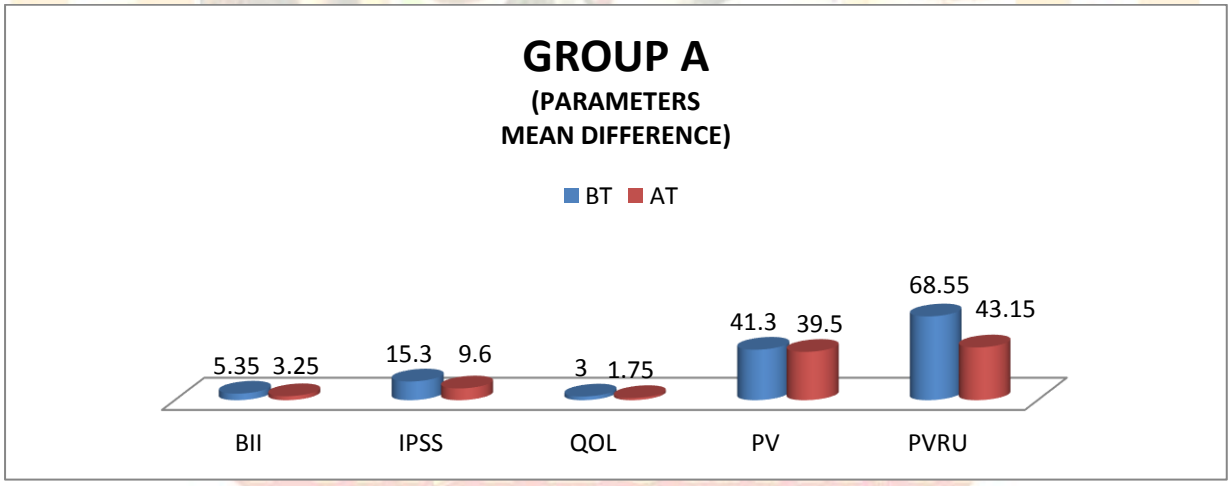
- Observation on previous history revealed that, 37 (73%) patients had chronicity of › 0 to ‹ 2yrs.
- Observation on addictions revealed that, 14 (23%) patients were addicted to Smoking, Tea, and Coffee.
- Observation on sleep revealed that, 46 (77%) patients had disturbed sleep.

RESULTS

EFFECT OF THERAPY ON PARAMETERS-GROUP A

Subjective Parameters	n	Mean Difference		Percentile Relief	SE	df	t	p
		BT	AT					
BII	20	5.35	3.25	39%	0.355	19	5.921	< 0.0001
IPSS	20	15.30	9.60	37%	0.751	19	7.592	< 0.0001
QOL	20	3	1.75	42%	0.143	19	8.752	< 0.0001
PV	20	41.30	39.5	4.35%	0.835	19	2.335	0.0305
PVRU	20	68.55	43.15	37%	3.556	19	7.143	0.0001

Table No 7: Showing the statistical analysis of Group A (Subjective Parameters).



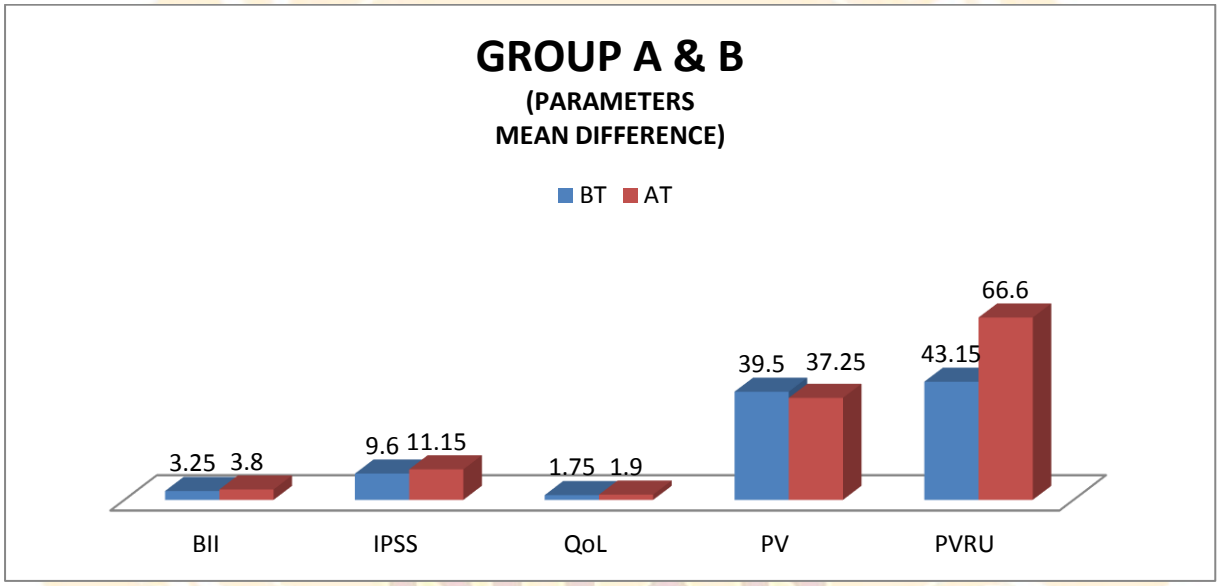
Graph No 1: Showing the mean difference of parameters in Group A BT & AT.

Group A (Dashamooladi Vati) has shown extremely significant result (P value < 0.0001) on BII, IPSS and QOL. Group A (Dashamooladi Vati) has shown significant result (P value < 0.0305) on PV and extremely significant result (P value < 0.0001) on PVRU. Percentage wise effect of Dashamooladi Vati in the patient of Asteela (BPH) is 39%, 37% and 42% of mild improvement in BII, IPSS and QoL respectively. It has shown 4.35% of improvement in PV and 37% of mild improvement in PVRU.Group A showing statistically better result in both subjective and objective parameters.

COMPARISION OF EFFECT ON GROUP A & B ON PARAMETERS

Subjective Parameters	n	Mean Difference		SE	df	t	p
		BT	AT				
BII	20	3.25	3.80	0.462	38	1.191	0.240
IPSS	20	9.60	11.15	1.436	38	1.079	0.287
QOL	20	1.75	1.90	0.269	38	0.557	0.580
PV	20	39.5	37.25	4.289	38	0.4896	0.627
PVRU	20	43.15	66.60	12.914	38	1.8158	0.077

Table No 8: Showing the result of unpaired't' test in Group A & B (Subjective Parameters).



Graph No 2: Showing the mean difference of Parameters in Group A (AT) & Group B (AT).

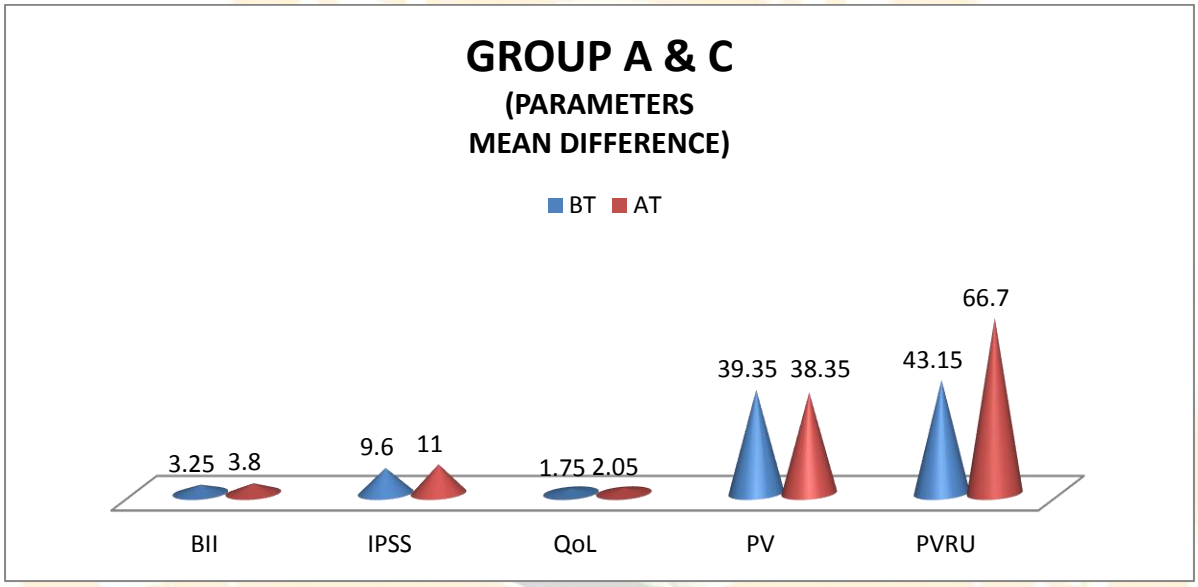
The result is not significant on BII, IPSS and QoL with p value 0.240, 0.287 and 0.580 respectively. The result is not significant on PV and PVRU with p value 0.627 and 0.077 respectively.

Statistically there is no significant difference in effect of Group A and Group B. This suggests that change occurred with the treatment was not enough to exclude the possibility that the difference was due to chance. Group A has shown better result in both subjective and objective parameters whereas Group B has only shown statistically significant result in subjective parameters.

COMPARISION OF EFFECT OF GROUP A & C ON

Subjective Parameters	n	Mean Difference		SE	df	t	p
		AT	AT				
BII	20	3.25	3.80	0.531	38	1.0367	0.3064
IPSS	20	9.60	11.00	1.391	38	1.0068	0.3204
QOL	20	1.75	2.05	0.275	38	1.0916	0.2819
PV	20	39.35	38.35	5.049	38	0.198	0.844
PVRU	20	43.15	66.70	11.63	38	2.024	0.050

Table No 9: Showing the result of unpaired 't' test in Group A & C.



Graph No 3: Showing the mean difference of subjective parameters in Group A (AT) & Group C (AT).

The result is not significant on BII, IPSS and QoL with p value 0.306, 0.320 and 0.28 respectively. The result is not significant on PV and PVRU with p value 0.844 and 0.050.

Statistically there is no significant difference in effect of Group A and Group C. This suggests that change occurred with the treatment was not enough to exclude the possibility that the difference was due to chance. Group A has shown better result in both subjective and objective parameters whereas Group C has only shown statistically significant result in subjective parameters.

DISCUSSION ON RESULTS

Dashamooladi Vati is multi herbo-mineral drug containing Dashamoola, Shudda Shilajitju and Sharkar. Tatra Vatabastyadayo Nava

Vatolbana **-** Obstruction of Apana Vata is a main cause for Asteela. Dashamoola is found to be indicated in the group of diseases where Vata is obstructed or deviated by other Doshas. Dashamoola is having properties like Vatakapha hara, Ushna virya, Shotha hara, Mutrala[7]. Shudda Shilajithu posseses properties like Mutrala, Shothahara, Basti Shodhaka, Shoshana, Chedana, and Yogavahi8. And Sharkar is having mutral property. Hence, it is helpful in samprapti vighatan of Asteela.

Dashamoola contains β-sitosterol and lupeol[9]. β-sitosterol possesses antioxidant, antimicrobial, antioxidant, immunomodulatory, anti-inflammatory and anticancer activities without major toxicity[10]. β-sitosterol, Pygeum africannum and Cernilton were reviewed in one study each, and significant improvement in BPH was observed for all three[11]. Dashamoola is having Smooth Muscle relaxation property acts on smooth muscle of prostate and decreases its tone. Shudda shilajithu posseses anti inflammatory activity, anti tumor effect. Shudda Shilajithu acts as 5@ reductase inhibitor which inhibits conversion of testosterone to dihydrotestosterone.

SUMMARY

1. Asteela is a type of Mutraghata and it is compared with benign prostatic hyperplasia.
2. It is randomized controlled comparative clinician study. A total 60 cases of BPH will be included for the study. 60 patients allocated into 3 groups, 20 patients in each group.
3. As per Yoga Ratnakar, Dashamooladi yoga (Dashamoola, Shudda Shilajithu and Sharkar) is indicated in Asteela. Vati is prepared with same Yoga and it is taken as a study drug (Group A). Dashamoola Kashaya (Group B) and Shudda Shilajithu (Group C) are taken as control drugs.
4. Subjective parameters for the study are IPSS Scale, BII and QoL. Objective parameters for the study are PV and PVRU. Observation was done on various parameters. Paired and unpaired t test is done evaluate the results.
5. Group A has shown statistically better result in both subjective and objective parameters.Statistically there is no significant difference in effect of Group A and Group B. Statistically there is no significant difference in effect of Group A and Group C.

CONCLUSION

Dashamooladi Vati has shown better result in both subjective parameters and objective parameters compared to other groups.

SCOPE FOR FUTURE WORK

1. Sample size need to be increased for further analysis.
2. Analysis of the drugs should be done in proper chemical laboratory setup, to analyze chemical composition and to know active principles.
3. For qualitatively assessing or quantitatively measuring the presence, amount, or functional activity of Dashamooladi Vati and other drugs, biochemical assay is necessary.
4. Bioavailability must be considered when calculating dosages for non-intravenous routes of administration of drugs.
5. To evaluate the effect of drug in hormones for that hormonal level test is necessary

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