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A STUDY OF CLINICAL EFFECT OF HARITAKYADIKWATH AND BASTI IN BENIGN ENLARGEMENT OF PROSTATE

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ABSTRACT

Benign Prostatic Hyperplasia (BPH) is the most common condition in aging men associated with lower urinary tract symptoms as irrigative or obstructive pathology. BPH is the non-malignant enlargement of the prostatic gland caused by excess growth of prostatic nodules. BPH is age dependent and initiate usually at the age of 40 yrs. and BPH is a progressive disease. BPH can disturb the day to day life activity in male. In modern medicine the management of BPH is either by conservative treatment using chemotherapy, Harmonal therapy or surgical approach as TURP. But while taking of medical treatment there are more side effect of modern medicine and operative in aged male can be risky. So, there is a need for Herbal and least side effect Ayurvedic treatment for the BPH. So we decided to use HaritakyadiKwath as oral and for Basti in BPH patients for the relief of symptoms. We asses the patients on irritative symptoms, IPSS score, uro flow metric, measurement and USG findings.

KEYWORDS: Benign Enlargement of Prostate, Haritakyadikwat, Ayurved, Basti.

1) INTRODUCTION

In Ayurved classical texts two broad categories Mutrakriccha and Mutraghat have been used to list all urinary symptoms.

Mutrakriccha means urine is formed but there is difficulty in passing urine Vataj, Pittaj, Kaphaj, Sannipataj, Ahhighataj, Purishaj, Ashmarij and Sukraj are 8 types.

Mutraghat means when there is more obstruction to pass urine i.e. retention of urine. There are 12 types of Mutraghat i.e. Vatakundalik, Vatabasti, Mutratit, Mutrajathar Mutrotsanga, mutrakshay. Mutrashukra, UshnvatMutragranthi, Pittajmutrautsad, Kaphajmutraoutsad and ashtheela.

In BPH irritative and obstructive symptoms can be observed as per the severity of condition.

Irritative symptoms- Frequency of urine urgency of urine, nocturia, dysuria, & hesitancy.

Obstructive symptoms- Dribbling micturation, weak flow of urine, sensation of incomplete evacuation and retension of urine.

The irritative symptoms and some partial obstructive symptoms can be treated with Ayurvedic drugs.

So we choose Haritakyadikwath from Bhavprakashmadhyamkhand(भा. प्र. म. खंड) हरितकीगोक्षुरराषाणभेदधन्वयासकानाम।

क्वाथिबन्माक्षिकसम्प्रयुक्तकृच्छ्रेसदोह, सरूजे, विबधेच।।

भा. प्र. म्र खंड^{३५/२०}

Thus this kwath may act on कृच्छता i.e. Dysuria सदाहे i.e. burning mictarat, सरुजे i.e. painful micturat and विवंधेi.e. dribbling micturat. Retention, Hesitancy weak flow and incomplete evacuation.

As the disease is occurred in old age and there is vitiation of aapanvayu we used Haritakyadi kwath in our patient.

2) AIMS AND OBJECTIVES

- 1. To see the effect of Haritakyadi kwath and Basti in Beningn Prostahc Hyperplasia.
- 2. To reduce frequency of urine and Nocturia.
- 3. To reduce dysuria and dribbling micturation.
- 4. To increase the poor flow of urine and urgency time.
- 5. To see the difference in wt of prostate gland pre and post medication with USG.

3) MATERIALS AND METHODS

a) Study design

The study was a randomised open clinical trial conducted at Govt. Auyurved Hospital,

Dharashiv (Osmanabad) from 2004 to 2006 as per ethical guidelines with informed consent.

The study was conducted in three groups of 50 patient each.

Ist**group-** Pt was given Haritakyadi kwath orally for 1 month.

IInd **group-** Pt was given Haritakyadi kwath as Nirun Basti c alternative Anuvasan Basti c til tail for 15 days.

IIIrd group-Pt was given Haritakyadi kwathNiruh basti c tiltailAnuvasan basti for 15 days and Haritakyadi kwath orally for next 15 days.

b) Inclusive criteria

Pt's of BPH with following symptoms i.e. one or more are taken for study. Frequency of micturation, Urgency of micturation, Nocturia.

Dribbling mictuation, Dysuria, Urge incontinence Hesitacy, sensation of incomplete bladder emptying. Postive Digital Rectal examination finding of BPH. USG finding suggestive of mild to moderate BPH.

IPSS (International Prostate Symptom Score) <18 i.e. mild to moderate BPH. Pt agreed for t/t and with written conscent.

c) Exclusive criteria

Grossly dibilited, pt's with renal failure and major cardiovascular and respiratory disorders.

Prostatic carcinoma, urethral stricture Bladder instability, Neurogeni Lbladder Acute or chronic prostatitis.

Severe BPH evaluate by USG residual urine > 200 ml with hydronephrosis and hydroureter.

Acute retension of urine with bleeding on catheterisation.

d) Study procedure

50 pts diagnosed with mild to moderate BPH, for each group was taken for study Pt of age group 45 to 95 yrs. were taken.

Total 150 pts studied during 2 yrs. of clinical trial.

At the initial randamized visit a detailed medical history with special emphasis of the historyof urinary symptoms (urgency, frequency, Nocturia, Dysuria, terminal dribbling) was obtained from all pts.

Digital Rectal Examination done for every pt, for prostate size, Presence of nodule asymmetry and tenderness in left lat position.

Proctoscopy done for any rectal growth /piles or fissure.

Routine blood examination (HB%, TLC, BSL-R) urine Routine, sr. creatinine, blood urea were taken.

Ptcheck on Ist day, 15th day and 30th day for urinary symptoms, IPSS score anduroflow measurement.

Haritakyadi kwath was prepared as per samhita and add honey and taken 30 min. before meal two times a day.

Basti- Niruh basti was prepared c Haritakyadi kwath and anuvasan of till tail given.

e) Study drug

This selected trial drug Haritakyadi kwath contains Haritaki, Gokshur, Argvadh, Pashanbhed, Damasa and Honey.

The detailed literary review of constitunts of drugs denotes its action on urinary system as well as rasayan and vatashamak properties perfectly suits to the pathogenesis of BPH that is a geriatric dsrequri trasayan vtashamanand diuratre properties.

4. OBSERVATION AND RESULT

In the present study "A study of clinical effect of Haritakyadi Kwath and Basti in Benign enlargement of Prostate" total number of patients taken for study were 50 in each group. The study contains three groups as oral group, Basti group and oral+Basti group.

I) Distribution of patient according to frequency of urine Before and After treatment Grading for frequency of urine.

1) 0 Grade - Normal - 3-4 times/day
2) 1 Grade - Mild - 5-6 times/day
3) 2 Grade - Moderate - 7-8 times/day
4) 3 Grade - Severe - > 8 times/day

A] Distribution of frequency of urine in oral kwath group.

Gradation of	No. Patients	Percentage	No. of	
Frequency of	before	(%)	patents after	Percentage (%)
Urine	treatment	(70)	treatment	
3	11	22	0	0
2	3	6	3	6
1	24	48	22	44
0	12	24	25	50
Total	50	100	50	100

B] Distribution of frequency of urine in Basti group.

Gradation of Frequency of Urine	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	7	14	1	2
2	6	12	4	8
1	22	44	19	38
0	15	30	26	52
Total	50	100	50	100

C] Distribution of frequency of urine in oral +Basti group.

Gradation of Frequency of Urine	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	6	12	1	2
2	11	22	1	2
1	15	30	22	44
0	18	36	26	52
Total	50	100	50	100

II) Distribution of patents according to Nocturia before and after treatment. Grading for Nocturia

1) 0 Grade - Normal - 0-1 times/day
2) 1 Grade - Mild - 2-3 times/day
3) 2 Grade - Moderate - 4-5 times/day
4) 3 Grade - Severe - > 5 times/day

A] Distribution of Nocturia in oral group.

Gradation of Nocturia	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	13	26	4	8
2	10	20	3	6
1	27	54	17	34
0	0	0	26	52
Total	50	100	50	100

B] Distribution of nocturia in basti group.

Gradation of Nocturia	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	13	26	3	6
2	16	32	3	6
1	20	40	23	46
0	1	2	21	42
Total	50	100	50	100

C] Distribution of Nocturia in oral + Basti group.

Gradation of Nocturia	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	15	30	2	4
2	19	38	8	16
1	15	30	21	42
0	1	2	19	38
Total	50	100	50	100

III)Distribution of patents according to Urgency time in minute before and after treatment.

Grading for urgency of urine

1) 0 Grade - Normal - 30-60 Min. 2) 1 Grade - Mild - 15-29 Min. 3) 3) 2 Grade - Moderate - 5-14 Min. 4) 4) 3 Grade - Severe - <5 Min.

A] Distribution of Urgency in oral group.

Gradation of Urgency time	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	16	32	3	6
2	29	58	18	36
1	4	8	13	26
0	1	2	16	32
Total	50	100	50	100

B] Distribution of urgency time in Basti group.

Gradation of Urgency time	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	17	34	2	4
2	28	56	20	40
1	4	8	15	30
0	1	2	13	26
Total	50	100	50	100

C] Distribution of urgency in oral + Basti group.

Gradation of Urgency time	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	14	28	5	10
2	34	68	15	30
1	2	4	20	40
0	0	0	10	20
Total	50	100	50	100

IV) Distribution of patents according to IPSS (International prostate symptom score) in BPH before and after treatment

Grading for frequency of Urine

1) 0 Grade - Normal - 0. 2) 1 Grade - Mild - 0-7. 3) 2 Grade - Moderate - 8-19. 4) 3 Grade - Severe - 20-35.

A] Distribution of IPSS in oral group.

Gradation of IPSS	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	2	4	1	2
2	47	94	15	30
1	1	2	34	68
0	0	0	0	0
Total	50	100	50	100

B] Distribution of IPSS in Basti group.

Gradation of IPSS	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	2	4	0	0
2	47	94	10	20
1	1	2	40	80
0	0	0	0	0
Total	50	100	50	100

C] Distribution of IPSS in oral + Basti group.

Gradation of IPSS	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	5	10	0	0
2	44	88	22	44
1	1	2	28	56
0	0	0	0	0
Total	50	100	50	100

V) Distribution of patents according to voiding time per second before and after treatment

Grading for frequency of urine

1) 0 Grade - Normal - 10-15 Sec. 2) 1 Grade - Mild - 16-24 Sec. 3) 2 Grade - Moderate - 26-35 Sec. 4) 3 Grade - Severe - >35 Sec.

A] Distribution of voiding in oral group.

Gradation of voiding time	No. Patients before treatment	Percentage (%)	- natente atter	
3	3	6 1		2
2	17	34 3		6
1	30	60 23		46
1	0	0 23		46
Total	50	100	50	100

B] Distribution of voiding time in Basti group.

Gradation of voiding time	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	1	2	1	2
2	20	40	5	10
1	29	58	21	42
0	0	0	23	46
Total	50	100	50	100

C] Distribution of voiding in oral + Basti group.

Gradation of voiding time	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	5	10	0	0
2	25	50	8	16
1	20	40	26	52
0	0	0	16	32
Total	50	100	50	100

VI)Distribution of 30 patents according to weight of prostate with the help of USG finding before and after treatment in each group.

Grading for weight of prostate in-group:

1) 0 Grade - Normal - < 20 gm. 2) 1 Grade - Mild - 21-35 gm. 3) 2 Grade - Moderate - 36-50 gm. 4) 3 Grade - Severe - > 50 gm.

A] Distribution of weight of prostate in oral group.

Gradation of weight of prostate	No. Patients before treatment	Percentage (%) No. of Patents after treatment		Percentage (%)
3	9	30	3	10
2	1	3.3	2	6.7
1	20	66.7	17	56.7
0	0	0 0 8		26.6
Total	30	100	30	100

B] Distribution of weight of prostate in Basti group.

Gradation of weight of prostate	No. Patients before treatment	Percentage (%)	No. of patents after treatment	Percentage (%)
3	5	16.7	1	3.3
2	7	23.3	1	3.3
1	18	60	20	66.7
0	0	0	8	26.7
Total	30	100	30	100

C] Distribution of weight of prostate in oral + Basti group.

Gradation of weight of prostate		Percentage (%)	No. of patents after treatment	Percentage (%)
3	14	46.7	3	10
2	5	16.7	5	16.7
1	11	36.6	18	60
0	0	0	4	13.3
Total	30	100	30	100

Results after treatment of oral group

Sr. No.	Symptom or Parameter	Percentage (%) of Improvement
1	Frequency of Urine	94
2	Nocturia	86
3	Urgency time	58
4	IPSS	68
5	Voiding time	92
6	Prostate weight by USG	84

Above table shows that frequency of urine in oral group is improved in 94% patients.

Nocturia improved in 86% of patients. Urgency time improved in 58% of patients. IPSS improved in 68% of patients.

Voiding time improved in 92% of patients.

Prostate weight by USG improved in 84% of patient.

Results after treatment of basti group

Sr. No.	Symptom or parameter	Percentage (%) of Improvement
1	Frequencyof Urine	90
2	Nocturia	88
3	Urgency time	56
4	IPSS	80
5	Voiding time	88
6	Prostate weight by USG	93

Above table shows that frequency of urine is improved in 90% of patients. Nocturia improved in 88% of patients. Urgency time improved in 56% patients.

IPSS improved in 80% of patients. Voiding time improved in 88% of patients.

Prostate weight by USG improved in 93% of patients.

Results after treatment of Oral + Basti Group

Sr. No.	Symptom or Parameter	Percentage (%) of Improvement
1	Frequencyof Urine	96
2	Nocturia	80
3	Urgency time	58
4	IPSS	56
5	Voiding time	84
6	Prostate weight by USG	74

Above table shows that frequency of urine is improved in 96% of patients.

Nocturia improved in 80% of patients. Urgency time improved in 58% patients. IPSS improved in 56% of patients.

Voiding time improved in 84% of patients.

Prostate weight by USG improved in 74% of patients.

5. Statistical analysis of Symptom and Parameters

A) Statistical analysis of frequency of urine per day in BPH in Oral, Basti and Oral + Basti group.

	Oral group		Basti group		Oral+Basti group	
Follow up	Mean (X)	SD	Mean (S)	SD	Mean (X)	SD
BT	6.32	2.483	5.94	2.17	5.88	2.344
AT	4.76	1.256	4.8	1.227	4.66	1.394

This table shows means of frequency of urine in all groups before and after treatment with standered deviation (SD) of each mean.

Group	X	SD	SE	T	P
Oral	1.56	1.58	0.223	6.996	P < 0.05
Basti	1.14	1.355	0.192	5.938	P < 0.05
Oral + Basti	1.22	1.389	0.196	6.224	P < 0.05

This table shows that oral, basti and oral + basti groups are significantly acts on frequency of urine in BPH as the values of P < 0.05 that the difference of means is greater in oral group than other two groups indicates that oral Haritakyadikwath acts better on frequency of urine in BPH than other groups.

B) Stastistical analysis of nocturia in BPH in Oral, Basti and Oral + Basti group.

	Oral group		Basti g	roup	Oral+Basti group	
Follow up	Mean (X)	SD	Mean (S)	SD	Mean (X)	SD
BT	4.04	2.196	4.28	2.157	4.66	2.318
AT	1.9	1.681	2.06	2.104	2.08	1.589

Table II

Group	X	SD	SE	T	P
Oral	2.14	1.443	0.204	10.49	P < 0.05
Basti	2.22	1.632	0.231	9.61	P < 0.05
Oral + Basti	2.58	1.691	0.239	10.795	P < 0.05

This table shows that oral, basti and oral + basti groups are significantly acts on nocturia in BPH as the value of P < 0.05 which is significant.

Above observation shows that the difference of means is greater in oral + basti group. This shows that oral + basti group better acts on nocturia in BPH than other groups.

C) Stastistical analysis of urgency time in BPH in all three groups.

Table I

Oral group		Basti	group	Oral+Basti group		
Follow up	Mean (X)	SD	Mean (S)	SD	Mean (X)	SD
BT	6.11	5.421	6.42	5.462	5.46	3.5
AT	17.1	10.039	18.36	13.759	15.14	9.792

Table II

Group	X	SD	SE	T	P
Oral	10.99	7.943	1.123	9.786	P < 0.05
Basti	11.94	10.182	1.44	8.292	P < 0.05
Oral + Basti	9.68	8.267	1.169	8.281	P < 0.05

This table shows that oral, basti and oral + basti groups are significantly acts on urgency time in BPH as the value of P < 0.05 which is significant.

Above observation shows that the difference of means is greater in basti group than other two groups. This indicates that Haritakyadi swath as basti route acts more on urgency time in BPH.

D) Stastistical analyasis of IPSS in BPH in Oral, Basti and Oral + Basti group.

Table I

	Oral group		Basti g	roup	Oral+Basti group	
Follow up	Mean (X)	SD	Mean (S)	SD	Mean (X)	SD
BT	12.26	3.319	11.96	3.207	13.04	3.796
AT	5.82	4.374	5.5	4.132	6.8	4.111

Table II

Group	I	SD	SE	t	P
Oral	6.44	3.308	0.468	13.761	P < 0.05
Basti	6.46	3.125	0.442	14.615	P < 0.05
Oral + Basti	6.24	3.55	0.503	12.406	P < 0.05

This table shows that all three groups significantly acts on IPSS, as the value of 'P' is <0.05.

Above observation shows that the differences of means is greater in basti group than other two groups. This indicates that Haritkyadi swath as basti route acts more on IPSS in BPH.

E) Statistical analysis of uroflow measurement taking voiding time in BPH in Oral, Basti and Oral + Basti group.

Table I

	Oral	Oral group		group	Oral+Basti group	
Follow up	Mean (X)	SD	Mean (S)	SD	Mean (X)	SD
BT	24.74	6.461	25.66	5.659	27.6	6.679
AT	17.36	6.515	18.2	6.887	19.58	6.021

Table II

Group	X	SD	SE	T	P
Oral	7.38	4.44	0.628	11.752	P < 0.05
Basti	7.46	5.273	0.746	10.00	P < 0.05
Oral + Basti	8.02	5.355	0.757	10.594	P < 0.05

This table shows that all three groups significantly acts on voiding time as the value of 'P' is < 0.05.

Above observation shows that the difference of means is greater in oral + basti group than other two groups. This indicates that Haritakyadi swath as oral + basti route acts more on voiding time in BPH.

F) Statistical analysis of weight of prostate in BPH in Oral, Basti and Oral + Basti group.

Table I

Follow up	Oral group		Basti gı	coup	Oral+Basti group	
Follow up	Mean (X)	SD	Mean (S)	SD	Mean (X)	SD
BT	42.7	23.349	39.767	17.13	48.223	15.841
AT	31.335	18.996	22.067	13.141	32.80	11.637

Table II

Group	X	SD	SE	T	P
Oral	11.367	12.642	2.308	4.925	P < 0.05
Basti	12.20	9.617	1.756	7.232	P < 0.05
Oral + Basti	15.433	11.116	2.029	7.606	P < 0.05

This table shows that all three groups significantly acts on weight of prostate, as the value of 'P' is <0.05 this table gives that Haritakyadi swath acts on weight of prostate. From above observation we may conclude that oral+basti group is better acts on weight of prostate.

6. DISCUSSION

Benign prostatic enlargement is the ds of old age. Its incidence increases with age.

The irritative and obstructive symptoms of BPH disturb the daily routine of pt. In modern medicine the medical management of BPH have fewer effect of daily life so most of the surgeons may prefer surgery as total prostatactorny or TURP.

But cost of the surgery and co-morbidity may cause more problem to patients.

So we want to search for more non-invasive and safe tlt option for the tlt of the BPH and Ayurveda is the solution.

The drug we have studied is safe and had very much effective on symptomatic relief of BPH and reduction of prostate size.

In presence study the Haritkyadikwath/ churna is composed of Haritaki, Goksur, Pashanbed, Dhamasa, Aaragvadh and Honey.

1) Haritaki- acts as rasayan,. Ayusha, Vayasthapak, Tridoshaghna, Yogavahi, Vibandhar, mutrakrychahanVatanuloman, Pathya, mutraghatnashak and shukrashodhakproperhes.

Haritaki- acts as antibacterial, anti-inflammatory diuretic, immunomodulator, antiviral analgesic, antioxidant laxative and antiagine. It inhibits rate of cell proliferation and acts as apoptosis on cancer cells so thus acts anticancer.

2) Gokshur- acts as vrisyia, bastishodhak, ashmarihar, mutrakruchahar, rasayanmutravirechaniya and tridoshahar. It also acts as diuretic, aphrodiasiac, anti-infertility, cooling, anti-inflammatory, anti urolithetiz, anti-oxidant and anti-aging.

As Gokharu contains B-sitosterol-a sterol which prostate the protect gland from swelling and cancer. Gokshur also increased level of testosterone increases libido, erection of penis and decreases impotency.

3) Aaragvadha- Acts as a rasayan, mruduvirechan, mutravirechaniya, tridoshahar and kosthashodhan. It also acts as laxative antiviral, cooling, anti-oxidant, anti- bacterial, analgesic, anti-inflammatory, anti tumour. It also contains B sitosterol.

- **4) Pashanbhed-** Acts as rasayana, Basti sudhikarashmaribhedak, shulhar, mutrakruechahar, mutravirechaniya and pathya. It also acts as diuretic, astringent and best anti urolithetic.
- 5) **Dhamasa-** Acts as rasayanamutrajanan, Dahvinashak and Lekhana. It also acts as Diuretic, astringent, colling, anti-septic and antitymour.
- **6) Anuphana** (**Madh**) **Honey)-** Acts as yogvahi, lekhaviy, shrotovishodhan, Vrushya, rochan and rasayana. It also acts as Diuretic, anti-bacterial, anti- inflammatory, mild laxative and antiaging.

Above drugs acts synergistically on the symptom of BPH and redieues the irritative & obstructive symptoms along with control of prostate tissue growth.

Basti of Haritakyadi kwath was used in our study. As the kwath itself acts on the Aapanavayu to reli urinary symptoms. So Haritkydi kwath basti has good action on irritative & obstructive syptoms to BPH.

In our study we check pts on following parameters in all three groups.

- 1) Frequency of urine- Frequency of urine is very much improved in oral Haritakyadi kwath group.
- 2) Nocturia is improved in oral+Basti group.
- 3) Urgency time is improved in Basti group.
- 4) IPSS score is much improved in Basti group.
- 5) Voiding time is improved in oral + Basti group.
- 6) Wt of prostate is much better after oral+ Basti group.

7) CONCLUSION

From above discussion we conclude that Haritakyadi kwath is well tolerated by all pts and is a best option in treating mild to mod symptoms of BPH. We can use Haritakyadikwath in all types of pts without any side effects.

This study higlightine that Haritakyadi kwath orally and or basti is simple and effective modality in symptomatic BPH.

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