



## EVALUATION OF THE EFFECT OF ERANDAPATRA KASHARA CAPSULE IN STHULAPRAMEHI W.S.R. TO VATASTHEELA (BPH) - PILOT STUDY

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### ABSTRACT:

**Background:** *Sthulaprameha* with *Vatastheela* (BPH) both disease that causes voiding dysfunction in elderly male patients and impairs their quality of life. In present study *Erandapatra Kshara* was given to patients of *Sthulapramehi* with BPH. An attempt was made to evaluate the effect of *Erandapatra Kshara*. Total 20 Patients of *Sthulapramehi* with BPH were registered in this study. *Erandapatra Kshara* capsule was used of 1000 gm divided dose daily after meals for 45 days. The efficacy of treatment was assessed based on relief in cardinal signs and symptoms and Blood sugar, Lipid profile, BMI and ultrasound etc. The result showed that the *Erandapatra Kshara* given better relief in signs and symptoms as well as on FBS, PPBS and BMI. **Objective :** 1) To evaluate the effect of *Erandapatra Kshara* in *Sthulapramehi* and BPH. 2) To evaluate the effect of *Erandapatra kshara* in reducing blood Sugar level with reducing BMI, and reducing symptoms of BPH. **Material method:** In present study 20 patients were reported BMI was 33.9kg/m<sup>2</sup>, having clinical signs and symptoms like *Sthulaprameha* with BPH noticed in Rajiv Gandhi education Societies Ayurvedic medical college and Hospital Ron. and registered following written consent. Registered patients have been administered *Erandapatra Kshara Churna* of 1000mg in divided dose with hot water for 45 days. Follow up has been recorded after every 10 days. **Results:** *Erandapatra Kshara* capsules, diet control and exercise show a significant reduction blood glucose level, weight reduction and reduces the symptoms of BPH. Specially relief from *Prabhuta mutrata*, *Karapadadaha*, *Swedadhikyata*, Urinary obstruction, Urinary incontinency, **Conclusion:** *Erandapatra kshara* can be used in the regular treatment of *Sthulapramehi* with BPH free from side effects& it is effective management.

**KEY WORDS** - *Sthulaprameha*, *Vatastheela* *Erandapatra*, *Kshara*, *BPH*.

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## INTRODUCTION:

According to *shareera prakruti Sthulaprameha* is a type of *Santarpanajanya vyadhi* which has been included in *Prameharoga*<sup>[1]</sup>. Old age male are more prone towards *Sthulapramehi* and *Vatashteela*. After 55 years of age years more incidence are finding ie *Sthulaprameha* and *Vatasteela*. People having mixed diet, sedentary lifestyle, *Kapha pitta prakruti* and *teekshagni* have more chances of *Sthulaprameha*<sup>[2]</sup> and later this *prameha* and *sthoulya* leads to the *Vatasteela* (BPH).

Diabetes Mellitus is the most common metabolic disorder encountered in clinical practice. It is strongly linked to obesity and BPH<sup>[3]</sup>. Benign Prostate Hyperplasia is most common problem in one third of male population aged over fifty years.<sup>[4]</sup> Original studies of BPH pathogenesis identified androgen and aging as risk factors, and more recent studies have identified additional risk factors, such as genetics, diet, immune status, metabolism, and inflammation. Studies of BPH patients with metabolic disorders, such as diabetes and obesity, have found a positive correlation between fasting glucose level and the progression of BPH<sup>[5]</sup>.

*Vatasteela* is a disease one among the twelve types of *Mutraghata*. *Acharya Sushruta* described that vitiated apana vayu<sup>[6]</sup>, settled in between the rectum and urinary

bladder, produce distention of the bladder and occurs symptoms like Urine retention, incomplete voiding dribbling, hesitancy, straining during urination and can be co-related with BPH. *Ayurveda* mention many natural medication and procedures for, among which *Kshara*. is one of the potent preparations that helps to effectively breakdown the pathogenesis of *Sthoulya*, *madhumeha* and BPH due to its property and potency.

*Eranda Patra Kshara*, mentioned in *Bhaishyaja Ratnaval*<sup>[7]</sup> *Eranda Patra Kshara* where in the drug is easily available and easy mode of preparation of the formulation makes it worth testing for its efficacy, hence the present clinical study is under taken to evaluate the “*Effect of Eranda Patra Kshara in Sthula Pramehi w.s.r. to Vatasteela ( BPH)*”.

**Aims and Objectives:** 1) To evaluate the effect of *Eranda Patra Kshara* in *Sthulapramehi* and *Vatasheela*. 2) To evaluate the effect of *Eranda patra kshara* in reducing blood Sugar level, reducing BMI, and reducing symptoms of BPH.

## MATERIALS AND METHODS :

### 1) Source of data:

- Patient** - Patients diagnosed as *Sthulapramehi* with BPH randomly selected from OPD and IPD of Rajiv Gandhi Education Societies *Ayurvedic*

Medical College, Hospital, PG and PhD research center Ron.

b) **Literary** - Literary aspect of study will be collected from classical *Ayurvedic* and Modern texts and updated recent medical journals, research works.

c) **Eranda Patras** -The trial drugs required for the preparation of medicine are collected from local areas.

Weight machine, Height measuring stand, measuring tape and Herpendine's calipers are used for the measurement of Height, Weight, Body girth and Skin fold thickness respectively.

**Study design** – Single blind placebo controlled clinical trial.

**Sample size** – 20 patients excluding drop outs.

### Grading of Parameters

#### 1. *Prabhuta Mutrata*

- 3 to 6 times per day, Rarely at night - 0
- 6 to 9 times per day, 0 to 2 times per night- 1
- 9 to 12 times per day, 2 to 4 times per night - 2
- More than 12 times per day, more than 4 times per night- 3

#### 2. *Pipasadhikyata*

- Feeling of thirst 7 to 9 times per day - 0
- Feeling of thirst 9 to 11 times per day - 1
- Feeling of thirst 11 to 13 times per day - 2
- Feeling of thirst > 13 times per day - 3

#### 3. *Ksudhadhikyata*

- As usual - 0
- Slightly increase 1 to 2 meals - 1
- Moderately increased 3 to 4 meals - 2
- Markedly increased 5 to 6 meals - 3

#### 4. *Krapada daha*

- No daha - 0
- *Krapada daha* is not continuous - 1
- *Krapada daha* is continuous - 2
- *Krapada daha* is not continuous - 3

#### 5. *Atisweda*

- Absent / Normal sweat -0
- Present with normal physical activity -1
- Present even at rest -2

#### 6. BMI

- 25 to 28 kg /m<sup>2</sup> - 0
- 28 to 30 kg /m<sup>2</sup> - 1
- 30 to 35 kg /m<sup>2</sup> - 2
- 35 to 40 kg /m<sup>2</sup> - 3

#### 7. Prostate Size and volume

- 25 to 30 ml - 0
- 30 to 50 ml - 1
- 50 to 80 ml - 2
- >80ml - 3

#### 8. Urine Flow and initiation

- Clear and Easy - 0
- Clear and difficult initiation - 1
- Obstruction and easy initiation- 2
- Both Obstruction and difficulty - 3

#### 9. Residual Volume

- 50 to 80 ml - 0

- 80 to 90 ml - 1
- 90 to 100 ml - 2
- More than 100 ml - 3

#### 10. Fasting Blood Sugar

- 75 to 110 mg / dl - 0
- 111 to 125 mg / dl - 1
- 126 to 180 mg / dl - 2
- > 180 mg / dl - 3

#### 11. Postprandial blood sugar

- Up to 140 mg/dl - 0
- 141 to 160 mg/dl - 1
- 160 to 300 mg/dl - 2
- >300mg/dl - 3

#### Lipid Profile

##### 12. LDL

- <130 mg/dl - 0
- 130 to 159 mg/dl - 1
- 160 to 180 mg/dl - 2

##### 13. HDL

- >60 mg/dl - 0
- 40 to 60 mg/dl - 1
- 40 to 30 mg/dl - 2

##### 14. Serum Cholesterol

- >200 mg/dl - 0
- 200 to 239 mg/dl - 1
- 239 to 250 mg/dl - 2

##### 15. Serum Triglyceride

- <150 - 0
- 150 to 199 mg/dl - 1
- 199 to 220 - 2

#### Inclusion criteria :

- 1) Patients between the age group 55 to 75 years will be selected.
- 2) Patient with BMI between 28 kg /m<sup>2</sup> to 39.9 kg/m<sup>2</sup> will be included in this study.
- 3) Abdominal circumference over > 40 inches will be considering.
- 4) Patient with the history of DM less than 3 year will be included in the study.
- 5) Blood sugar with the range of FBS 110 - 170mg /dl
- 6) Patient with PSA between >4 µg/L to <8 µg/L will be included in this study.
- 7) Patients with Prostate volume (PV) >80 ml will be included
- 8) Prostate size >30 gms and <60 gms
- 9) Post residual urine volume [PRUV] >50 ml will be included

#### Exclusion criteria:

- 1) Patient associated with systemic disorders viz. CVD, Endocrine disorders affecting the clinical trial.
- 2) On long term medication that may interfere the study.
- 3) Obese patient suffering from Hemiplegia, associated with sever Hypertension and from other such diseases in which the patient cannot do his routine physical activities were excluded.

- 4) Any physical and systemic disability that may interfere the clinical trial.
- 5) BMI > 40 kg/m<sup>2</sup> Obesity Class –III
- 6) Blood sugar with the range of FBS more than 180 mg /dl were excluded
- 7) Patient with PSA >8 µg/L and Prostate Cancer will be excluded
- 8) Prostate size >60 gms

**Diagnostic criteria:**

**Subjective Parameter :** Diagnosis is made on the basis of Classical signs and symptoms of *Sthulaprameha* and *Vatastheela* or BPH with Laboratory investigations and USG report. Criteria's like :- *Prabhuta Mutrata Pipasadhikyata, Kshudadhikyata, Karapadadaha, Atisweda*, Night frequency, Urine incontinency, BMI >28kg/m<sup>2</sup> , Blood sugar with the range of FBS 110 - 170mg /dl and PPBS 180 TO 200 mg/dl, Prostate size and volume >30ml, Residual urine volume >80ml, Urine Flow and Initiation.

**Objective parameters:** Prostatic enlargement by digital and Ultrasonographic methods, BMI (kg/m<sup>2</sup>), FBS, PPBS, Lipid Profile, Urine Flow and Initiation.

**Posology and intervention:**

- Drug -*Eranda Patra Kshara* 1000mg + Hingu 500mg
- *Anupana- Sukoshna jala*
- Frequency - Twice daily in divided dose before meals ( EPK – 500mg + 250mg Hingu )

- Duration- 45 days
- Diet- As recommended (A low calorie, balanced diet chart will be prepared and provide to the patients)
- Exercise- Cardiovascular exercises (Brisk walk for 30 min once daily in early morning).

**Investigations<sup>[8]</sup> :**

- FBS, PPBS,
- Lipid Profile :-
- Cholesterol Total, HDL Cholesterol, Triglycerides (TGL),
- Abdominal Ultrasound

**Assessment of result:**

The Subjective and Objective parameters of base line data to pre medication and post medication were compared for assessment of result. All the result will be analyzed statistically in terms of mean score (X), Standard deviation (S.D.), Standard error (S.E.), and "P" value using unpaired and paired "t" test.

**RESULTS:**

Clinical study has been 20 registered cases of *Sthulaprameha* and *Vatastheela* each patient was analyzed on the basis of subjective and objective parameter during the course of treatment.

**Table 1: Distribution of the patients on the basis of age group**

Sl.No	Age group	No of Patients'	Percentage
1	50 to 55 years	3	30%
2	56 to 65 years	8	33.44%
3	66 to 75 years	9	36.66%
Total		20	100%

The observation shows that the maximum number of the patients were in the age group of 66 to 75 years, i.e. 36.66 %, followed by 33.44 % of the age group 56 to 65 years and 3 patients were in the age group of 50 to 55 years.

**Table – 2. Showing incidence of Symptoms of *Sthulapramehi* and *Vatastheela* om 20 cases**

Sl.No	Symptomes	Total	Percentage
1	<i>Prabhuta Mutrata</i>	16	80%
2	<i>Pipasadhikyata</i>	12	60%
3	<i>Ksudhadhikyata</i>	09	45%
4	<i>Karapadadaha</i>	15	75%
5	<i>Atisweda</i>	11	55%
6	Urine flow and initiation symptoms	18	90%

**Table – 3. Showing weight of *Sthulapramehi* in 20 registered case**

Sl.No	Weight in KG	Total	Percentage
1	70 to 80	01	5%
2	81 to 90	02	10%
3	90 to 100	13	65%
4	100 to 110	04	20%

**Table – 4. Showing incidence of BMI in 20 registered cases**

Sl.No	BMI Kg/m <sup>2</sup>	Total	Percentage
1	25 to 29.9 Over weight	01	5%
2	30 to 39.9 Obese	08	40%
3	> 40 Very Obese	11	55%

**Table – 5. Effect of therapy on Subjective Parameter**

Sl.No	Symptomes	Percentage of relief	SD	P-Value
1	<i>Prabhuta Mutrata</i>	68.96%	0.487	0.001
2	<i>Pipasadhikyata</i>	82.60%	0.593	0.001
3	<i>Ksudhadhikyata</i>	89.47%	0.743	0.001
4	<i>Karapadadaha</i>	66.66%	0.560	0.001
5	<i>Atisweda</i>	75%	0.534	0.001
6	Urine flow and initiation symptoms	83.33%	0.816	0.001

**Table – 6. Effect of therapy on Objective Parameter**

Sl.No	Symptomes	Percentage of relief	SD	P-Value
1.	Body Weight	6.05%	1.887	0.001
2.	BMI	5.55%	0.763	0.001
3.	Urine Residual Volume	2.10%	0.774	0.001
4.	Prostate Size	3.04%	1.207	0.001
5.	FBS	3.40%	1.373	0.001
6.	PPBS	6.31%	1.032	0.001
7.	HDL	9.61%	6.478	0.02
8.	LDL	18.89%	20.398	0.01
9.	Serum Cholesterol	17.73%	27.187	0.001
10.	Serum Triglyceride	23.68%	38.634	0.001
11.	VLDL	30.10%	9.445	0.01

**OVERALL EFFECT OF THERAPY :**

***Prabhuta Mutrata:***

Here before treatment *Prabhuta Mutrata* mean was 3.2 and after it was 0.75 and Among 20 patients 16 patients were

having symptom of *Prabhuta Mutrata*. The most important presenting sign of *Prabhuta Mutrata*. This Symptom is the most conclusive sign of the both the disease. Regarding the effect of therapy, very significant result was

Raghavendra P., Shettar, Sangeeta H. Toshikhane. Evaluation of the effect of Erandapatra Kashara capsule in *Sthulapramehi* w.s.r. to *Vatastheela* (BPH) - Pilot study. Jour. of Ayurveda & Holistic Medicine, Vol.-XI, Issue-II (Feb. 2023). seen in 68.98%. The results were found to be Highly significant in ( $p < 0.001$ ). The reason for good results in patients may be due to eradicated symptom of *Prabhuta mutrata*.

#### **Pipasadhikyata:**

Here before treatment *Pipasadhikyata* mean was 2.6 and after it was 0.47. Among 20 patients 12 patients were having *Pipasadhikyata*. Thus, it may also be concluded that this symptom is also most prominent symptom in *Sthulaprameha*. Regarding the effect of therapy results were highly significant in case of 82.60% relief was found with statistically P-value ( $P < 0.001$ ).

#### **Ksudhadhikyata :**

Here before treatment *Ksudhadhikyata* mean was 0.95 and after it was 0.18. About 9 patients (45%) had this symptom. 89.47% relief was observed this is statistically highly significant with the P-value ( $P < 0.001$ ).

#### **Karapadadaha:**

Here before treatment *Karapadadaha* mean was 0.95 and after it was 0.12, 15 (75%) patients were having this symptom. It is commonly present in *Sthulapramehi*. Highest relief was observed in patients which was insignificant ( $p < 0.001$ ).

#### **Atisweda :**

Here before treatment *Atisweda* mean was 0.95 and after it was 0.2. Here 11 (55%) were having *Aruchi* symptom and 75% relief

was observed this is statistically highly significant with the P-value ( $P < 0.001$ ).

#### **Urine flow and Initiation:**

Here before treatment Urine flow and initiation mean was 0.97 and after it was 0.15. It was found in 19 (90%) patients. The relief was good in 83.33%. which is statistically insignificant ( $p < 0.001$ ).

#### **Body weight**

Here before treatment Body weight - mean was 2.17 and after it was 0.17. More body weight was found all in 20 (100%) patients. The relief was good in 95%. which is statistically insignificant ( $p < 0.001$ ).

#### **BMI**

Here before treatment BMI was 2.05 and after it was 0.23. In all 20 (100%) patients BMI was more. The relief was good in 95%. which is statistically insignificant ( $p < 0.001$ ) The reason for good results may be given as the Erandapatra kshara which helps in reducing the Body weight.

#### **Urine Residual Volume:**

Here before treatment Urine residual volume mean was 0.95 and after it was 0.2. Here 11 (55%) were having this symptom and 75% relief was observed this is statistically highly significant with the P-value ( $P < 0.001$ ).

#### **Prostate size:**

Here before treatment Prostate size mean was 3.2 and after it was 0.75 and All 20 (100%) patients observed the increase size of

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#### **FBS :**

Here before treatment increased FBS mean was 2.17 and after it was 0.17. increase FBS level was found all in 20 (100%) patients. The relief was good in 98%. which is statistically insignificant( $p<0.001$ )

#### **PPBS :**

Here before treatment increased PPBS mean was 2.05 and after it was 0.23. In all 20 (100%) patients PPBS was more. The relief was good in 95%. which is statistically insignificant( $p<0.001$ )

#### **Lipid Profile:**

Here before treatment Lipid profile mean was 2.5 and after it was 1.2. Here 20 (100%) were finding the variation in Lipid profile and 65% relief was observed this is statistically highly significant with the P-value ( $P<0.01$ ).

Totally Maximum 63.33% observed good improvement, 30% patients showed marked improvement, while 6.66% patients showed marked improvement.

#### **DISCUSSION :**

Prevalence of *Sthulaprameha* with *Vatastheela* patients are more found in old age patients. Due to the *avarana* of the *vata*. Diabetes and Obesity have found a positive correlation between fasting glucose level and the progression of BPH. A positive correlation

has also been shown between hyperlipidemia and the progression of BPH.

*Eranda patra kshara* is described in *Bhaishyaja Ratnavali*. and it is specially indicated for the treatment of *sthulapramehi* with BPH, because *Eranda patra kshara* is having the properties like *Tikshna*, *Ushna*, *Katu rasa* and *tikta rasatmaka*. and also having the special properties like *Lekhana*, *Medhaghna* and *Kaphahara*. so whole combination acts to breakdown the vicious cycle of *samprapti* of *Sthulapramehi* and *vatastheela* (BPH) For *sroto shodhanartha Hingu* is added in *eranda patra kshara churna*. *Hingu* having special properties of *Vatashamana*, hence this *churna* was selected for the present study and administered to treat the *Sthulaprameha* with BPH.

Maximum patients belonged to the age of 55 years and above shows *Sthulaprameha* and BPH. maximum patients were in all the community who are in sedentary lifestyle, who do not concentrate on health and specially *Diwaswapna* which may lead to *Sthulapramehi* and in future days turns to *Vatastheela*. Maximum patients have the family history, it shows that the genetically it is an important etiological factor in the development of *Sthulapramehi*. Maximum patients were having *Vishamagni* and *teekshnagni* is the main cause for *Sthulaprameha*, its due to the

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*avarana of vayu in kostha by vitiation of Kapha and meda.*

#### **Effect of trial on Subjective Parameter :**

The effect of *Erandapatrakshara* symptomatically providing highly significant ( $p < 0.001$ ) result with marked relief in symptoms like *Prabhutamutrata*, *Avilamutrata* and Urine flow and initiation also, Moderate relief in *Ksudha Karapada daha* and *atisweda*.

#### **Effect of trial on Objective Parameter :**

In the *Erandapatrakshara* result were highly significant and reduction was observed in Weight, BMI, Urine residual volume, Prostate size, FBS, PPBS provided highly significant (0.001) and significant reduction in Lipid profile. Considering the effect of *Erandapatrakshara*.

#### **Overall effect of Therapy :**

*Erandapatra kshara* has the properties *Katu*, *Tikta*, *Kashaya rasa*, *Ushna virya*, *Ruksha*, *Ushna*, *Lekhana*, *Medoghna Guna*, *Katu vipaka* causes *Dipana*, *Pachana*, and digest *Ama* thus clears the *Margavarodha* of *Medovahasrotas*. By the all above character of *Kapha*, *Vata shamaka*. Thus brings these two *doshas* *Medoghna*, *Pramehaghna*, and inturn reduce the size of BPH by *Lekhana* property. Among 20 patients of *Sthulaprameha* with *Vatastheela* given a good results like marked improvement in 60% of patients, Moderate improvement in 33.33% patients and 6.66% patients were found mild improvement result.

#### **CONCLUSION :**

*Erandapatra kshara* showed maximum percentage relief in all the Subjective and Objective parameters. It can be said that *Erandapatra Kshara* more effective control all the parameter due to its highly *Tikshna*, *Ushna*, *Katu rasa* and *tikta rasatmaka Lekhana*, *Medhoghna* and *Kaphahara* properties. I conclude that the *Erandapatra kshara* can be used in the regular treatment of *Sthulapramehi* with BPH.

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