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EFFICACY OF SABAL SERRULATA IN HOMOEOPATHIC MANAGEMENT OF BENIGN HYPERTROPHY OF PROSTATE: A RANDOMIZED SINGLE BLIND PLACEBO CONTROL STUDY

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ABSTRACT:-

Background: The aim of this study was to explore the efficacy of Sabal Serrulata along with diet & yoga in the homoeopathic management of benign hypertrophy of prostate. It was a randomized single blind placebo controlled trial. Total 30 patients in the age group of 50 to 75 years of age suffering from BPH confirmed on the basis of clinical features along with the positive ultrasound sonography were randomly selected. Prior to the administration of medicine, appropriate dietary and yogic methods were put into effect. International Prostate Symptom Score (IPSS) was used to evaluate treatment efficacy in the form of pre-test and post-test assessment.

Conclusion: Benign hypertrophy of prostate or benign prostatic hyperplasia (BPH) is very commonly affecting to the age group 50-70 years, Modern system of medicine only offers a palliative mode of treatment and Surgery to the patients suffering from Benign hypertrophy of prostate. Homoeopathy being a distinct mode of therapeutics offers curative treatment. If the disease in early stage particularly at the functional level be treated with Homoeopathy it can be cured. Sabal Serrulata, which has predominant action over Prostate, was confirmed by this study. Present study shows marked efficacy of sabal Serrulata in the homoeopathic management of cases of BPH.

KEYWORDS: Benign hypertrophy of prostate, Sabal Serrulata, Homoeopathic management, Diet & Regimen, Yoga, Quality of Life (QoL), etc.

INTRODUCTION:-

Benign Prostatic Hyperplasia (BPH) is an age-related and progressive neoplastic condition of the prostate gland. BPH may only be defined histologically. BPH in the clinical setting is characterized by lower urinary tract symptoms. There is no causal relationship between benign and malignant prostatic hypertrophy. Clinically apparent BPH represents a considerable health problem for older men, due to the negative effects it has on quality of life (QoL) Despite the deceptively simple description of benign prostatic hyperplasia (BPH), the actual relationship between BPH, lower urinary tract symptoms (LUTS), benign prostatic enlargement, and bladder outlet obstruction is complex and requires a solid understanding of the definitional issues involved. The etiology of BPH and LUTS is still poorly understood, but the hormonal hypothesis has many arguments in its favor.

An overall prevalence of 10.3%. With an overall incidence rate of 15 per 1000 manyears, increasing with age (3 per 1000 at age 45-49 years, to 38 per 1000 at 75-79 years). For a symptom free man at age 46, the risk of clinical BPH over the coming 30 years, if he survives, is 45%. In conventional system of medicine, there is no permanent cure for benign hypertrophy of prostate without surgery.

Homoeopathy as a distinct mode of therapy can offer curative treatment for many diseases, which has been labeled as incurable by the modern system of medicine. In Homoeopathy the demarcation line between curable and incurable disease is arbitrary. Homoeopathy believes in the dynamic concept of the disease and so long the vital force of the individual is in the position to react synergistically with medicine, the chances of cure are fair. Though Homoeopathy has a restricted scope in advanced irreversible stage of the disease, it can well control the disease in its initial and progressing phage where permanent damage is to be to occur.

AIMS AND OBJECTIVES:-

Official Title: "To Study of the Efficacy of Sabal Serrulata in the Homoeopathic Management of Benign Hypertrophy of Prostate: A randomized single blind placebo control study".

Aim: To Study of the Efficacy of Sabal Serrulata in the Homoeopathic Management of Benign Hypertrophy of Prostate: A randomized single blind placebo control study.

Objectives:

1. To study of Benign Hypertrophy of Prostate in details.

2. To assess the role of Sabal Serrulata along with yoga and diet in cases of Benign hypertrophy of prostate

3. To assess the role of Placebo along with Yoga and Diet in cases of Benign Hypertrophy of Prostate.

MATERIAL AND METHODS:-

Study Setting: The study was conducted at SKH Medical College, Beed (M.S.). Patients for the study were selected from the College OPDs & IPD Department, as well as from the specialized health check up and diagnostic camps.

Study Design: A Randomized Single Blind Placebo Control Trial

<u>Sample Size & Selection of Sample:</u> Approximately 30 cases were selected by simple random sampling technique. Selected 30 cases are divided in two groups i.e. Group A and Group B respectively.

Both the group comprised 15 cases each.

- Group A (i.e. Treatment Group) received Homoeopathic Medicine Sabal Serrulata along with Yoga & Dietary advice.
- Group B (i.e. Control Group) received Placebo along with Yoga & Dietary advice.

Inclusion & Exclusion Criteria:

Inclusion Criteria:

- a) Patient of age group 50 years to 75 years of age.
- b) Patients suffering from BPH confirmed on the basis of clinical feature along with the positive ultrasound sonography were randomly selected.
- c) Purely benign cases

Exclusion Criteria:

- a) Cases with high serum PSA levels
- b) Cases with DRE findings suggestive of C.A. Prostate
- c) Persons with known immune compromised and other systemic diseases were excluded.

- d) Patients who refused to give proper case history were also excluded.
- e) Patient who are not cooperative and without any follow up were excluded.

Informed Written Consent: Patient fulfilling the inclusion criteria mentioned above was given the information sheet having details regarding the nature of the study and the treatment methodology. Participants were given enough time to go through the study details mentioned in the information sheet. They were given opportunity to ask any question and if they agree to participate in the study they were asked to sign the informed consent form.

Selection of Tools: The diagnosis was made on the basis of ICD 10 Criteria, USG, and IPSS score questionnaire

Selection and Administration of Medicine: Homoeopathic medicine Sabal Serrulata was be prescribed to the patient of Group A along with Yoga & Diet. While, patients belongs to Group B received placebo along with Yoga & Diet.

Selection of Potency: Selection of the potency was done based entirely upon the nature, seat and phase of disease, nature of medicine and "susceptibility" of the patient.

Repetition Schedule: The doses of the Medicine were repeated as per the need of patient.

Dietetic & Hygienic Measures: Proper dietetic and hygienic measures was taken before administration of medicines, which are used as specific stimuli to rouse the vital force to react against the morbific agent and overcome their noxious influences (Hahnemann's Organon 5th edition sec. 259-269).

Follow-Up and Monitoring: All the patients were advised to report at weekly intervals. Each case was followed up to 6 months and more if required. During follow-up not only the subjective but also objective symptoms were assessed.

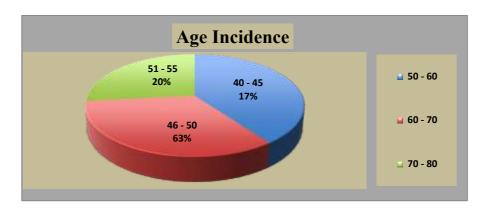
Outcome Assessment: The treatment efficacy was assessed on the basis of comparing the International Prostate Symptom Score (IPSS) which was done before starting the treatment and was done at the end of the treatment.

<u>Statistical Techniques:</u> The descriptive statistics as Mean, Median, Standard Deviation, Range, Percentage or Proportion was applied to get the results.

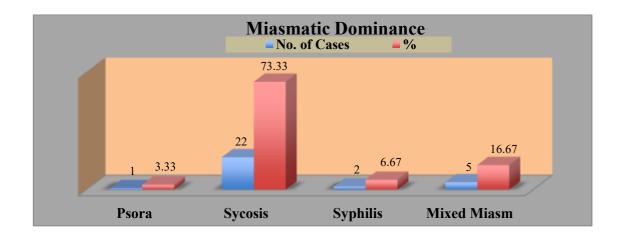
<u>Data Analysis:</u> The data analysis was done by applying appropriate tests of significance Paired t test of proportions will be applied at 5% and 1% level of significance.

RESULTS:-

| Age Group | No. of Cases | % |
|-----------|--------------|--------|
| 50 - 60 | 12 | 40.00 |
| 60 - 70 | 10 | 33.33 |
| 70 - 80 | 8 | 26.67 |
| Total | 30 | 100.00 |

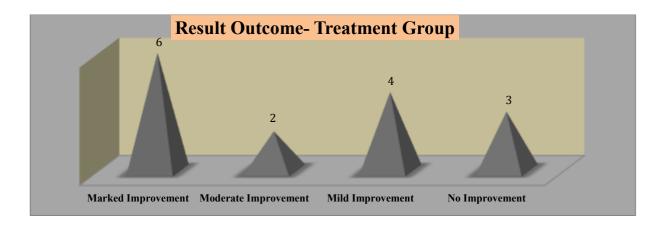


| Dominant Miasm | No. of Cases | % |
|----------------|--------------|--------|
| Psora | 1 | 3.33 |
| Sycosis | 22 | 73.33 |
| Syphilis | 2 | 6.67 |
| Mixed Miasm | 5 | 16.67 |
| Total | 30 | 100.00 |



RESULT OUTCOME - TREATMENT GROUP

| Result | No. of Cases | % |
|----------------------|--------------|--------|
| Marked Improvement | 6 | 40.00 |
| Moderate Improvement | 2 | 13.33 |
| Mild Improvement | 4 | 26.67 |
| No Improvement | 3 | 20.00 |
| Total | 15 | 100.00 |



RESULT OUTCOME - CONTROL GROUP

| Result | No. of Cases | % |
|----------------------|--------------|--------|
| Marked Improvement | 1 | 6.67 |
| Moderate Improvement | 2 | 13.33 |
| Mild Improvement | 1 | 6.67 |
| No Improvement | 11 | 73.33 |
| Total | 15 | 100.00 |



IPSS SCORES - Pre-Test & Post-Test Scores

| | Treatment Group | | Contro | Control Group | |
|---------|-----------------|-----------|----------|---------------|--|
| | Pre-Test | Post-Test | Pre-Test | Post-Test | |
| | 30 | 20 | 30 | 28 | |
| | 24 | 8 | 24 | 24 | |
| | 32 | 18 | 32 | 28 | |
| | 34 | 25 | 32 | 32 | |
| | 28 | 16 | 28 | 28 | |
| | 26 | 6 | 28 | 26 | |
| | 26 | 10 | 26 | 26 | |
| | 22 | 8 | 24 | 24 | |
| | 24 | 12 | 28 | 28 | |
| | 19 | 4 | 20 | 15 | |
| | 18 | 6 | 20 | 20 | |
| | 21 | 6 | 28 | 28 | |
| | 20 | 5 | 24 | 24 | |
| | 23 | 5 | 24 | 26 | |
| | 22 | 4 | 30 | 30 | |
| Total | 369 | 153 | 398 | 387 | |
| Average | 24.60 | 10.2 | 26.5 | 25.8 | |

| Group | Calculated t | Table t value | |
|--|--------------|---------------|------|
| агоир | value | 5% | 1% |
| Treatment Group (Sabal Serrulata + Diet + Yoga) | 18.33 | 2.15 | 2.98 |
| Control Group (Placebo + Diet + Yoga) | 1.58 | 2.15 | 2.98 |

Benign Hypertrophy of Prostate will disturb the patient mentally as well as physically. It is one of the common in old aged people as the age progresses the immune power of the person reduces slowly. Hence during this phase of life, they are exposed to various dynamic derangements and prone to suffer from them because of the life style of advancing generation.

The present study comprises 30 cases of Benign Hypertrophy of Prostate who attended to OPD, IPD of SKH Medical College & the specialized Diagnostic and treatment camps conducted by the college. Cases were presented both with common symptoms of Benign Hypertrophy of Prostate as well as peculiar, characteristic symptoms of the patient. While selecting the Remedy due importance was given to Specific remedy Sabal Serrulata along with Yoga and Diet. Regarding the selection of the cases and the repetition schedule of the prescribed medicines, the general principles were followed. Medicines were prescribed in both centesimal and 50- millesimal potencies and Mother Tincture.

The age distribution the majority of cases (63.34%) were observed in the age group 50 to 60 years. Out of 30 cases, in 22 cases (73%).

Regarding Benign Hypertrophy of Prostate miasmatic background of cases shows a higher incidence in sycotic patients, and lowers in Psoric miasm.

USG and International Prostate Symptom Score (IPSS) done in all of the case. During the remission of disease by International Prostate Symptom Score (IPSS) treatment tends towards normal

End results shows, Out of 15 cases of treatment group, 06 cases were showed marked improvement, 02 were closed for the study as moderately improved, 04 cases showed mild improvement, while 03 cases were closed for the study as not improved.

Out of 15 cases of control group, 01 case was showed marked improvement, 02 were closed for the study as moderately improved, 01 case was closed for the study as mildly improved, while 11 cases of the study control group showed no any improvement, hence closed for the study as not improved cases.

CONCLUSION:

Benign hypertrophy of prostate is one of the oldest diseases. Very commonly affecting to the age group 50-70 years, Modern system of medicine only offers a palliative mode of treatment and Surgery to the patients suffering from benign hypertrophy of prostate. Homoeopathy being a distinct mode of therapeutics offers curative treatment. If the disease

in early stage particularly at the functional level be treated with Homoeopathy it can be cured. Structural changes (organic pathology) in early reversible stage can also be cured through homoeopathic treatment, but if structural changes become irreversible cure is not possible through homoeopathy, only suitable palliation from time to time will help to decrease the suffering of the patients. Sabal Serrulata, which has predominant action over Prostate, was confirmed by this study. It will be more proved if more number of cases and prolonged time is given to the study.

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