REPORT ON CLINICAL TRIAL OF PROSTAID

Sponsored By:
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INTRODUCTION

The prostate is a small organ about the size of a walnut. It lies below the bladder (where urine is stored) and surrounds the urethra (the tube that carries urine from the bladder). The prostate makes a fluid that becomes part of semen. Semen is the white fluid that contains sperm. In addition, it secretes fluid into the urethra that helps to protect against bladder infections.

Enlargement of the prostate is called Benign Prostatic Hypertrophy. This condition is common in older men. More than half of men in their 60's have BPH. Among men in their 70's and 80's, the figure may go as high as 90%.

Herbal components have been shown to be as effective as some prostate drugs in clinical trials, while not producing the side effects of drugs.

Changes in the prostate as one ages

1. Enlargement
2. Hardening
3. Decreased Fluid Secretions

AIM AND OBJECTS

Different formulations are developed to treat enlarged prostate. The present clinical trial was undertaken for –

1. To evaluate the therapeutic value of "PROSTAID" a poly herbal formulation prepared by M/s. Shree Baidyanath Ayurved Bhawan Pvt. Ltd, Kolkata – 6, in the patients of enlarged prostate.

2. To evaluate the effect of "PROSTAID" on lipid levels of the body to be assessed by bio chemical study.

3. To observe clinical toxicity or side effect, if any, during the clinical study.

MATERIALS AND METHODS

Total 66 patients of obesity were registered during the course of the trial. The study consists clinical patterns in enlarged prostate and management of the enlarged prostate with "PROSTAID". In this trial 66 cases were registered out of which 42 cases had completed the total tenure of the treatment rest 24 cases had discontinued at different point of time.

PLACE OF STUDY

The present clinical study was undertaken at Shyamadas Vaidya Shastrapith Hospital attached to the Institute of Post Graduate Ayurvedic Education and Research, Govt. of West Bengal, Kolkata – 9.

SELECTION OF CASES

All the patients selected for the present study were interrogated and detail history was recorded in the case record form. All the patients were thoroughly examined and findings were recorded. To establish the final diagnosis the selection criteria as noted below was followed.

SELECTION CRITERIA

For the purpose of present study, patients belonging to the age group of 51 – 70 years of age were selected and the diagnostic criteria was the following.

A) Subjective Feature

The clinical features as mentioned in classical Ayurvedic texts regarding enlarged prostate were observed in the patients. The following symptoms were also observed during diagnosis and assessment.

1. A frequent need to urinate, causing you to get up several times during the night to void.
2. A weak, often interrupted urinary stream.
3. A full-bladder feeling, as if you can never completely empty your bladder.
4. Difficulty initiating a urine stream, with involuntarily dribbling at the beginning or end.
5. Sudden – sometimes uncontrollable – urgency to urinate
6. A burning, painful or throbbing sensation when urinating
7. Loss of libido and sexual potency
8. Blood in the urine and any pain or discomfort in the urinary tract

B) Objective Criterias

The following laboratory investigations were carried out for diagnosis and differential diagnosis.

1. Lipid profile
2. Blood sugar (F & PP)
3. Routine Hematological Test
4. Prostate Specific Antigen (PSA)
5. Routine Urine examination
6. U.S.G

EXCLUSION CRITERIAS

A) Patients below 51 years and above 70 years of age.
B) Diabetes mellitus.
C) Malignant Enlarged Prostate
D) Cardiac problem.
E) Renal Disease.

DRUG SELECTED FOR THE STUDY

For the purpose of the clinical trial "PROSTAID", a poly herbal compound formulated by M/s. Shree Baidyanath Ayurved Bhawan Pvt. Ltd., Kolkata – 6, approved by the Director of Drug Control, West Bengal has been selected.

COMPOSITION OF DRUG

• Swarna Makshik Bhasma	212.46 mg
• Sudh Prawal Bhasma	106.23 mg
• Sudh Shilajeet	53.11 mg
• Indragopa (Mutilla occidentalis)	0.25 mg
• Kababchini (Piper cubeba)	1 mg
• Khash (Vetiveria zizanioidis)	1 mg
• Safed Chandan (Santalum album)	1 mg
• Gum Acacia (excipients)	q.s
• Talcum (excipients)	q.s

METHOD OF DRUG ADMINISTRATION

The present study was carried out in the patients of enlarged prostate in consideration with inclusion and exclusion criteria. The eligible patients were randomly divided in two groups, viz.

1. Group – A (trial Group) – to whom the trial product (PROSTAID) was given in the dose of two capsules twice a day morning and evening with water for a period of 90 days.

2. Group – B (Control Group) – to whom the placebo capsules (containing sugar of milk) was given in the similar way like trial group.

FOLLOW UP

Follow up study was conducted in all cases at interval of 30 days for 90 days. Lipid profile, blood sugar, routine hematological test, ultrasonography of lower abdomen and routine urine examination, PSA was done in each case before starting the treatment. All the subjective criterias also assessed at interval of 30 days for 90 days in all cases.

CLINICAL PATTERN

The present study consists of total 66 cases who have symptoms of obesity. Among them 42 cases completed the full course of treatment schedule (i.e. 90 days) and 24 cases had not completed the full course of trial. But the clinical pattern will be discussed in all 66 cases. The result will be analyzed on observation of the findings of 42 cases.

AGE INCIDENCE

Patients of the present study were from 51 to 70 years of age Patients of different age group are given in Table No. 1.

Table No. 1: Showing the incidence of different age group

Sl. No.	Age groups (Years)	No. of patients	Percentage
1	51 – 55	16	24.24
2	56 – 60	24	36.36
3	61 – 65	17	25.76
4	66 – 70	9	13.64
Total		66	100.00

RELIGION INCIDENCE

Patients of various religions were included in this study. Patients belonging to different religion are shown in Table No. 2

Table No. 2: Showing the incidence of religion

Sl. No.	Religion	No. of patients	Percentage
1	Muslim	30	45.45
2	Hindu	32	48.49
3	Christian	04	6.06
Total		66	100.00

OCCUPATIONAL INCIDENCE

In this study patients belonging to various occupations were included. The occupation history as recorded are shown in Table No. 3

Table No. 3: Showing the incidence of occupation

Sl. No.	Occupation	No. of patients	Percentage
1	Service	13	19.70
3	Labour	2	3.03
4	Cultivator	6	9.10
5	Student	4	6.05
6	Businessmen	12	18.18
7	Miscellaneous	29	43.94
Total		66	100.00

ECONOMICAL STATUS INCIDENCE

In this study patients of different income group were recorded and shown in Table No. 4

Table No. 4: Showing the incidence of income status

Sl. No.	Income Status	No. of patients	Percentage
1	LIG	10	15.15
2	MIG	36	54.55
3	HIG	20	30.30
Total		66	100.00

EDUCATIONAL STATUS

When educational status was enquired, patients of both literate and illiterate group were found in this series. The educational status as found is given in Table No. 5.

Table No. 5: Showing the incidence of Educational Status

Sl. No.	Educational Status	No. of patients	Percentage
1	Illiterate	6	9.10
2	Literate	60	90.90
	a) Primary	9	15.00
	b) Madhyamik	11	18.33
	c) Higher Secondary	9	15.00
	d) Graduate	18	30.00
	e) Post Graduate	13	21.67

RURAL URBAN INCIDENCE

This study included patients from urban and rural areas and shown in Table No. 6

Table No. 6: Showing the Rural and Urban Incidence

Sl. No.	Rural/ Urban	No. of patients	Percentage
1	Rural	27	40.90
2	Urban	39	59.10
Total		66	100.00

INCIDENCE OF DIET HABIT

Patients included in the present study were found to have both types of diet habits (vegetarian and non-vegetarian), which are presented in Table No. 7.

Table No. 7: Showing the incidence of diet habits.

Sl. No.	Diet Habits	No. of patients	Percentage
1	Non vegetarian	52	78.78
2	Vegetarian	14	21.20
Total		66	100.00

INCIDENCE OF NATURE OF WORK

In this trial nature of work were studied which are presented in Table No. 8.

Table No. 8: Showing the incidence of nature of work

Sl. No.	Nature of work	No. of patients	Percentage
1	Sedentary	34	51.52
2	Moderate	28	42.42
3	Hardworker	4	6.06
Total		66	100.00

INCIDENCE OF MARITAL STATUS

In this study married, unmarried, both patients are included which are presented in Table No. 9

Table No. 9: Showing the incidence of Marital Status

Sl. No.	Marital Status	No. of patients	Percentage
1	Unmarried	15	22.73
2	Married	51	77.27
Total		66	100.00

RESULT AND OBSERVATION

Trial Group:

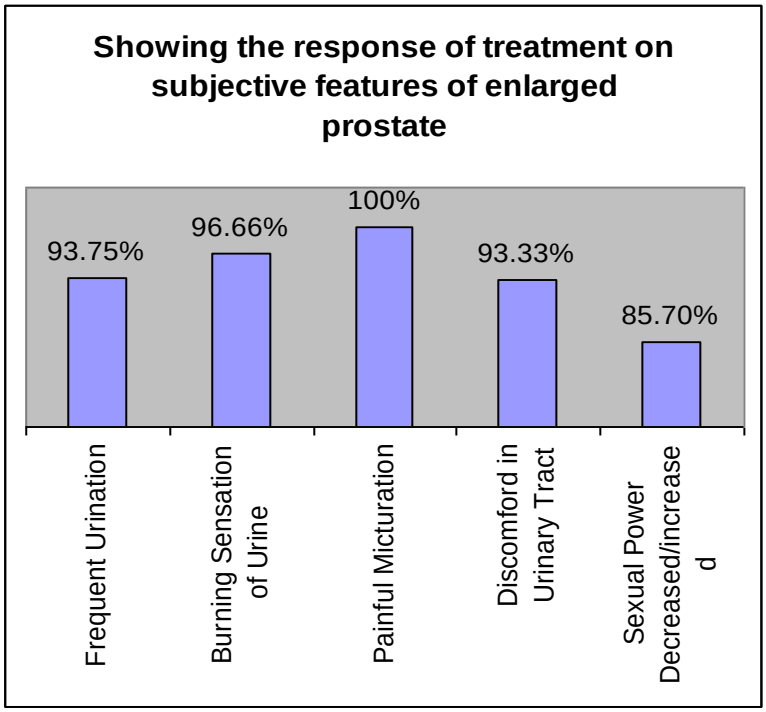
Trial group consisted of 46 patients, among them 32 cases had completed the full tenure of trial and 14 cases had not completed the full trial. All the cases were given the "PROSTAID" capsules in the dose of 2 capsules/tablets twice daily for 90 days, with water.

Patients were observed in terms of subjective improvements before treatment, during treatment and after treatment. The response of treatment on clinical features as observed before treatment and after treatment in 32 cases in trial group are presented below in Table No. 10

Table No. 10: Showing the response of treatment on subjective features of enlarged prostate.

Sl. No.	Chief complains	No. of patients before treatment	No. of patients relieved after treatment	Percentage of relief
1	Frequent urination	32	30	93.75
2	Burning sensation of urine	30	29	96.66
3	Painful micturation	28	28	100.00
4	Discomfort in urinary tract	30	28	93.33
5	Sexual power decreased/ increased	28	24	85.70

From the above table it is revealed that the percentage of relief of different clinical features was highly satisfactory.



CONTROL GROUP

Control Group consisted of 20 patients, among them 10 cases had completed the full tenure of trial and 10 cases had not completed the full trial. All the cases were given the placebo capsules in the dose of 2 capsules/tablets twice daily for 90 days, with water.

Patients were observed in terms of subjective improvements before treatment, during treatment and after treatment. The response of treatment on clinical features as observed before treatment, and after treatment in 10 cases in control group are presented below in Table no. 11.

Table No. 11: Showing the response of treatment on subject features of enlarged prostate in control group.

Sl. No.	Chief complains	No. of patients before treatment	No. of patients relieved after treatment	Percentage of relief
1.	Frequent urination	7	8	-14.28
2.	Burning sensation of urine	6	8	- 33.33
3.	Painful micturation	6	7	- 12.50
4.	Discomfort in urinary tract	6	7	- 16.66
5.	Sexual power decreased/ increased	6	7	- 16.60

From the above table it is clear that there was not any improvement in clinical features on control group of patients and the clinical features had deteriorated.

DISCUSSION:

The present trial included 66 patients suffering from enlarged prostate. The total cases were randomly divided into two groups, viz. trial group and control group. Trial group consisted of 46 patients to whom "PROSTAID" was given in the dose of 2 capsules/tablets twice a day for a period of 90 days. Out of 46 cases of trial group 32 cases could be followed up properly during the treatment schedule (i.e 90 days) and the rest of the cases had dropped out at different point of time. Control group included 20 patients to whom placebo capsule/tablet was given in the dose of two capsules/tablets twice a day for a period of 90 days. Out of the total cases in the control group 10 cases could be follow up for 90 days, the total tenure of the treatment and the rest of cases had discontinued at different times.

The effect of the treatment on both these group of patients were evaluated during the treatment and the response was assessed at the end of the treatment. The response of the treatment was observed on subjective improvement and objective improvements. At the end of the treatment, the result was assessed in term of excellent response, good response and poor response. The patients were included under excellent response group when they showed more than 90% relief of subjective features. The patients were included under good response group when they showed relief of subjective features between 51 to 90%

CONCLUSION

The product "PROSTAID" was found to be an effective product on enlarged prostate and the result was encouraging for further study for its effect. "PROSTAID" has shown encouraging result after 6 week of treatment particularly on the subjective criterias. After 90 days of treatment along with the improvement of subjective criterias significant response Hence, "PROSTAID" can be safely prescribed in enlarged prostate for a long time.

Acknowledgement

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