

CLINICAL TRIAL OF BANGSHIL AND FORTEGE IN BENIGN PROSTATIC ENLARGEMENT

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INTRODUCTION:

Benign enlargement of Prostate is considered to be an involutionary stage of old age, though not uncommon in the elderly between 40-50 years. It is mainly a geriatric problem and all the patients for one cause or other, are not in state of health to undergo immediate radical surgery and require postponement, but in some cases surgery may not be indicated at all.

Under these circumstances medical management of the enlarged prostate becomes imperative. Keeping this in view, we undertook the clinical trial of Bangshil and Fortege to evaluate how far this combination is helpful in the management of enlarged Prostate without recourse of prostatectomy.

MATERIAL & METHODS:

The present study was done during July 1982 July 1983 on patients who were either admitted into the hospital or those who attended the O.P.D. of the S.V.B.P. Hospital, Meerut. Sixty cases were

entered for the clinical trial, but the results of only those 50 cases whose records and follow-up were complete were analysed. Only those cases who had risk factor and could not be operated for prostatectomy were included for the trial.

There were 6 cases of Retention of Urine due to Enlarged Prostate, and these were catheterised by indwelling catheter and were included with the other cases after the removal of catheter.

All the patients were given Bangshil plus Fortege, 2 tabs. each, three times a day for four weeks. Only who improved were put on Bangshil 2 tabs. two times a day for a further period of four weeks.

INVESTIGATIONS DONE:

1. P/R exam. before starting the treatment and repeated every month during the duration of clinical trial (two months).
2. Routine and microscopic examination of urine.
3. Urine culture and sensitivity tests.
4. Blood urea.
5. I. V. P.
6. Residual urine measured by catheterisation before starting treatment, and repeated every month during the period of clinical trial.
7. Hesitancy Time before starting treatment and repeated every month during the period of clinical trial.
8. Distance of urine fall (urine spurt) before starting treatment and repeated every month during the period of clinical trial.
9. Cystogram.

AGE GROUPS, OCCUPATION, ECONOMIC STATUS, HABITS

The age of the patients ranged from 50-90 years. Most of them were farmers, and vegetarian by diet. Majority of them were either poor or middle class and were habitual 'hukkah' smokers.

SYMPTOMS

Frequency of Micturition, Dysuria, Hesitancy and Burning Micturition were the presenting symptoms. There were six cases of Retention of Urine and they were catheterised by indwelling catheter and were included with the other cases after removal of the catheter. (Table I)

TABLE – I
Symptoms (Each patient had more than one symptom) N = 50

Symptom	No. of Cases	%
Frequency of Micturition	50	100%
Dysuria	50	100%
Hesitancy	50	100%
Burning Micturition	42	84%
*Retention of Urine	12	24%

*Cases of Retention of Urine were included with the other cases after catheterisation.

Risk Factors

Diabetes (28%), Tuberculosis (20%), Hyper tension (20%) and Ischemic Heart Disease (IHD) (6) were the most important risk factors for not undertaking surgery. (Table II)

TABLE – II
Risk factors for not operating. N = 50

Risk factor	No. of Cases	%
Diabetes	14	28%
Tuberculosis	10	20%
Hypertension	10	20%
Ischemic Heart Disease (IHD)	10	20%
Chronic Bronchitis	2	4%
Hemiplegia	2	4%
Anaemia with Poor General Health	2	4%
Total	50	100%

Grade of Enlarged Prostate

Majority of patients (64%) had Grade II of Enlarged Prostate. (Table III)

TABLE – III
Grade of Enlarged Prostate. N = 50

Grade of Enlargement	No. of Cases	%
Grade I	12	24%
Grade II	32	64%
Grade III	6	12%
Total	50	100%

Residual Urine

Residual urine was measured by catheterisation before treatment and was repeated every month during the period of clinical trial. Details of Residual Urine before and after Bangshil + Fortege treatment are given in Table VI.

Hesitancy Time

Details of Hesitancy Time to start the act of micturition before and after Bangshil & Fortege treatment are given in Table VII.

Distance of Urine Spurt

Details of the fall of urine (spurt) during micturition before and after Bangshil + Fortege treatment are given in Table VIII.

Bangshil + Fortege Treatment

Bangshil 2 tabs and Fortege 2 tabs at a time were given three times a day for 4 weeks. Those who improved were continued on a maintenance dose of Bangshil & Fortege, 2 tabs of each, two times a day for a further period of four weeks. Results were evaluated after 8 weeks of Bangshil + Fortege therapy. However, the patients were advised to continue Bangshil + Fortege 2 tabs of each two times a day as long as necessary as a prophylactic measure.

Results of Fortege + Bangshil Treatment: Symptoms

There was complete relief from Frequency of Micturition and Burning Micturition (100%). There was relief from Dysuria (60%) and Hesitancy (64%) in the majority of cases Overall, Symptomatic Relief was observed in 40 patients (80%) and there was partial or no relief in 10 patients (20%). Table IV

TABLE – IV
Results of Bangshil + Fortege Treatment Symptoms. N = 50

Symptom	Before Treatment	Relief	%	Partial or No Relief	%
Frequency of Micturition	50	50	100%	—	—
Dysuria	50	30	60%	20	40%
Hesitancy	50	32	64%	18	36%
Burning Micturition	42	42	100%	—	—
Mean	50	40	80%	10	20%

Results: Decrease in Prostatic Enlargement/Decongestion of Prostate

There was decongestion and decrease in size in all 12 cases (100%) of Grade-I cases. There was decrease in 75% of cases of Grade-II and only 33.3% of cases showed decrease in Grade-III cases.

Overall, 38 cases (76%) showed decongestion and decrease in size and there was no satisfactory improvement in 12 cases (24%). (Table V)

TABLE – V
Results of Bangshil + Fortege Treatment. Grade of Enlarged Prostate. N = 50

Grade of Enlargement	Before Treatment	After Treatment	Improvement (Decreased)	No Improvement
Grade I	12	0	12	—
Grade II	32	8	24	8
Grade III	6	4	2	4
Total	50	12	38 (76%)	12 (24%)

Results: Decrease in Residual Urine

Residual Urine decreased considerably in 34 cases (68%) and the decrease was not satisfactory in 16 cases (32%). (Table VI)

TABLE – VI
Results of Bangshil + Fortege Treatment. Residual Urine. N = 50

Residual Urine (ml.)	Before Treatment	After Treatment	Improvement (Decreased)	No Improvement
Less than 25 ml.	12	34	12	—
26–50 ml.	32	14	18	14
51–100 ml.	6	2	4	2
Total	50	50	34 (68%)	16 (32%)

Results: Decrease in Hesitancy Time

Before starting Bangshil & Fortege, the mini mum time to start the act of micturition was 30 seconds. After treatment, there were 32 patients (64%) who could start the act of micturition within 30 seconds. Overall reduction in Hesitancy Time was observed in 32 patients (64%) while the improvement was not satisfactory in 18 patients (36). (Table VII)

TABLE – VII
Results of Bangshil + Fortege Treatment. Hesitancy Time. N = 50

Hesitancy Time (Seconds)	Before Treatment	After Treatment	Improvement	No Improvement
0–30 sec.	0	32	—	—
31–60 sec.	12	8	4	8
61–90 sec.	22	10	12	10
91–120 sec.	6	—	6	—
121–180 sec.	10	—	10	—
Total	50	50	32 (64%)	18 (36%)

RESULTS:

Increase in the distance of urine fall (Urine Spurt)

Before starting Bangshil & Fortege treatment majority of cases (30) had urine spurt of less than 1 inch. After treatment 24 of them improved with higher spurt. On the whole Urine Spurt increased in 42 cases (84%) and there was no satisfactory improvement in 8 cases (16%). Table VIII)

TABLE – VIII
Results of Bangshil + Fortege Treatment. Urine Spurt (Distance of the fall of Urine). N = 50

Urine Spurt (inches)	Before Treatment	After Treatment	Improvement	No Improvement
6–8 inch.	2	20	18	2
3 inch.	8	8	—	—
1–2 inch.	10	16	—	—
Less than 1 inch.	30	6	24	6
Total	50	50	42 (84%)	8 (16%)

Overall Improvement with Bangshil & Fortege Treatment in Enlarged Prostate & Associated Symptoms

Out of 50 patients included in the clinical trial, there was Relief of Symptoms in 40 patients (80%), decongestion and decrease in the enlarged prostate in 38 patients (76%), decrease in the amount of Residual Urine in 34 patients (68%), decrease in Hesitancy Time in 32 patients (64%), and increase in the distance of Urine Spurt in 42 patients (84%). Overall results with Bangshil + Fortege treatment showed that there was improve-ment in 37 patients (74%) and the improvement was partial or Poor in 13 patients (26%) (Table IX)

TABLE – IX
Bangshil + Fortege Treatment: Overall Results

Parameter	Before Treatment	Improvement	%	Partial or no Improvement	%
Symptoms Relief	50	40	80%	10	20%
Grade of enlargement (decreased)	50	38	76%	12	24%
Residual Urine (decreased)	50	34	68%	16	32%
Hesitancy Time (decreased)	50	32	64%	18	36%
Urine Spurt (increased)	50	42	84%	8	16%
Mean	50	37	74%	13	26%

SUMMARY AND CONCLUSIONS:

Bangshil and Fortege were given to patient of Enlarged Prostate who were high risk patient and in whom prostatectomy could not be done immediately or was not indicated because of the risk factor involved. The parameters for evaluation of the response to drug therapy were Relief of Urinary Symptoms, decongestion of the prostate and decrease in the size of the prostate, decrease in the amount of Residual Urine, decrease in Hesitancy Time and increase in the distance of Urine Spurt. The following observations are made:

1. Overall results showed that with Bangshil + Fortege treatment there was excellent response in 37 patients (74%) and only in 13 patients (26%), the improvement was either partial or poor.
2. Bangshil + Fortege treatment is specially use-ful in early prostatism.
3. Bangshil + Fortege treatment is highly beneficial for those patients who are temporarily or permanently unfit to undergo surgery of the prostate.
4. In cases of Retention of Urine due to Enlarged Prostate, Bangshil + Fortege is helpful during catheterisation and during the days of indwelling catheter till its removal and preoperatively till the operation is fixed. The patients will be passing urine without any difficulty during the preoperative period.
5. Bangshil and Fortege being non-hormonal drugs, there is no risk of flaring up of any hidden malignancy.
6. Bangshil + Fortege treatment will decrease the amount of residual urine considerably, and so the risk of infection and cystitis due to Urinary Stasis is greatly minimised.
7. These two drugs have antiseptic properties which help to minimise the chances of infection.
8. No toxic or side effects are observed in the use of Bangshil and Fortege.

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