



A PROSPECTIVE STUDY ON COMPARISON OF α BLOCKER MONOTHERAPY AND COMBINATION THERAPY OF 5 α REDUCTASE INHIBITOR PLUS α BLOCKER IN MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA IN TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Benign prostatic hyperplasia (BPH) is a condition in men in which prostate gland is enlarged and not cancerous. It is also called benign prostatic hypertrophy or benign prostatic obstruction. BPH leads to multiple complication includes, LUTS (lower urinary tract symptoms) i.e., nocturia, frequent urination, urinary urgency and leaking, decreased urine flow rates, sense of incomplete bladder emptying and dribbling of urine. In our study, IPSS (International prostate symptom score) is used to assess the severity of LUTS and USG findings is used to measure the volume of prostate. α blocker drugs helps in relaxing the neck of bladder muscle and prostate which allows the urine to flow more easily. 5 α reductase inhibitor drugs effectively reduce serum and intraprostatic concentration of DHT causing an involution of prostate tissue. The prospective observational study was conducted in Government Cuddalore Medical College and Hospital for the period of 4 months (November 2023 to February 2024). The collected data was analyzed by descriptive data analysis. combination therapy of 5 α reductase inhibitor plus α blocker is more beneficial in treatment of BPH than α blocker monotherapy. Thus, the combination therapy decreases prostate volume, improve LUTS, increases urinary flow rates, reduces the risk of AUR and also reduces the progression of BPH compared to monotherapy.

KEYWORDS : BPH, α blocker, 5 α reductase inhibitor, LUTS.

INTRODUCTION

Benign prostatic hyperplasia (BPH)- enlargement of prostate gland (a walnut-shaped gland), occurs when the cells of the prostate gland begin to multiply, mainly in the transition zone (TZ) of the prostate. These additional cells cause your prostate gland to swell, which squeezes the urethra and limits urine flow. Recently published molecular profiling shows that BPH subtypes have been identified, which were referred to as BPH-A subgroup and BPH-B subgroup. While BPH-A subtype is characterised by stromal-tissue-like features, BPH-B subtype has specific dysregulations involving metabolic pathways in the patients with obesity (BMI>30) and hypertension^[3]. BPH can be a progressive disease, especially if left untreated. BPH is the most common cause of lower urinary tract symptoms (LUTS), which are divided into 1.Storage, 2. Voiding, 3. Symptoms which occur after urination.

Storage symptoms include frequent urination, urinary urgency, nocturia, involuntary urination, or urge incontinence. Voiding symptoms include urinary hesitancy, intermittency, involuntary interruption of voiding, weak urinary stream, straining to void, a feel of incomplete emptying, and uncontrollable leaking after urination. Incomplete voiding results in residual urine or urinary stasis, which leads to urinary tract infection.

Symptom Score Questionnaires

Both the AUA symptom score and IPSS are used to identify significant LUTS, determine their type (obstructive or irritative), assess their severity based on patient respond to questions (i.e., frequency, nocturia, weak urinary stream, hesitancy, intermittency, incomplete emptying, and urgency). The score ranges from 0-5 (NOT present to almost ALWAYS present). This score aids in patients' symptoms classification from mild (total score 0-7) to moderate (8-19), and severe (20-35)^[3]

Diagnosis

The physical exam includes a rectal examination that allows

the doctor to estimate the size and shape of your prostate. Other tests can include: urine analysis, urodynamic test, prostate specific antigen test, post void residual test, cystoscopy. Abdominal ultrasound examination of the prostate: If size of prostate is 30cc or more than 30 cc which shows that prostate is enlarged.

Management

Nonpharmacological Management

Lifestyle: Limit the amount of fluid intake before bedtime, avoid alcohol consumption and products contain caffeine.

Pharmacological Management

α blockers

α blockers are prescribed for BPH patient mainly to relieve their lower urinary tract-related symptoms. α blockers facilitate the flow of urine by relaxing the smooth muscle tone in the bladder neck and prostate region. Treatment with α blockers decreases 4-6 points in the IPSS. Drugs in this group may be non-selective ARAs (i.e., phenoxybenzamine), selective short-acting ARAs (i.e., prazosin, alfuzosin, and indoramin), selective long-acting ARAs (i.e., terazosin, doxazosin, and slow-release (SR) alfuzosin), and partially subtype (ARA-1a)-selective agents (i.e., tamsulosin, and silodosin)^[3].

5 α -reductase inhibitors

5-ARIs act to reduce the serum and intraprostatic DHT concentration by inhibit the 5 α reductase enzyme (a hormone responsible for prostate enlargement), thereby causing involution of the prostatic epithelium and slowing the progression of BPH^[1]. Two of the prototype drugs of this group, i.e., dutasteride and finasteride are particularly efficient in patients with enlarged prostate besides LUTS.^[3]

Combination Therapy

AUA guidelines shows that combinational treatment approach based on ARAs and 5 α -RI is more effective for the treatment of patients with LUTS and prostate enlargement than their individual use. Hence, the FDA approved

formulation of Jalyn containing 0.4 g tamsulosin, and 0.5 dutasteride is more efficient in providing symptomatic relief to the BPH patients than either of the two drugs used alone and successfully improve IPSS⁽³⁾.

Methodology

Study site was hospital based and involves patients in the department of surgery at government Cuddalore medical college and hospital (RMMCH), a 1250 bedded tertiary care teaching hospital located in rural south India, Chidambaram. Study period involves 4 months (October 2023-February 2024) with a prospective observational study design. Proforma (Data collection form) was developed for the data collection purpose from the patient in the surgery ward.

Details of patients like demographic data, chief complaints, past history, past medication history, IPSS, laboratory investigation (USG findings -Prostate volume) and treatment given and duration of hospital stay were collected.

Ipss Questions Includes

- How frequently have you had the sensation of not being able to empty your bladder completely after voiding?
- How frequently have you had to urinate again less than 2 hours after finishing urination?
- How frequently have you found you stopped and started several times when you were voiding?
- How often have you found it difficult to postpone urination?
- Over the past month, how often have you had a weak stream?
- How often have you had to push or strain to begin urination?
- How many times did you get up to urinate from the time you go to bed until you get up in the morning?

Responses are then scored according to the following:

- 0 = Not at all
- 1 = < 1 time in 5 (once in a while)
- 2 = < half the time
- 3 = About half the time
- 4 = > than half the time
- 5 = Almost always or all the time

Drug data: Brand and generic name of all drugs prescribed mainly blockers and 5 -reductase inhibitors, dose frequency, route of administration, duration of administration, monotherapy or combination therapy, duration of hospital stay was collected and documented in a designed patient data collection form. The data was analysed using a suitable statistical tool and Microsoft word and excel have been used to generate graphs, pie charts and table to provide significant results.

RESULT AND DISCUSSION

A total of 15 patient's data were observed, recorded and analysed.

Age Wise Distribution

Table 1

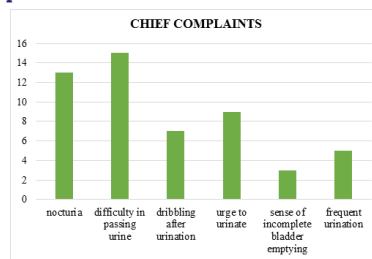
AGE (in years)	NO. OF PATIENTS	PERCENTAGE
40-50	3	20
51-60	4	26.7
Above 60	8	53.3

In our study 20% of patient were in the age group of 40-50 years, 26.7% were in 51-60 years and rest of 53.3% were in above 60 years of age.

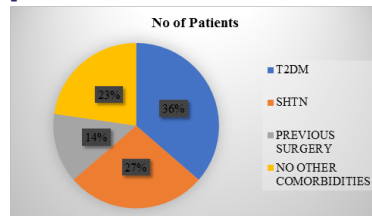
In our study, patients are with chief complaints of difficulty in passing urine (15), nocturia (13), urge to urinate (9), dribbling after urination (7), frequent urination (5) and feel of incomplete bladder emptying (3).

From our study, 8 patients with past history of T2 DM ,6 patients with SHTN ,3 patient had history of PREVIOUS SURGERY and 5 patients with no other comorbidities were observed.

Chief Complaints



Past History



Laboratory Investigations

Physical Examination

All the 15 patients were observed with the enlargement of prostate.

Ipss (international prostate symptom score)

Table 2: Before Treatment

NO. OF PATIENTS	MILD	MODERATE	SEVERE
15	5	8	2

Table 3: After Treatment

NO. OF PATIENTS	MILD	MODERATE	SEVERE
15	7	4	NIL

After administration of drugs, patient symptoms were reduced and 4 Patients were completely recovered from the LUTS (Lower urinary tract symptoms).

Usg Findings

Table 4

VOLUME OF PROSTATE (in cc)	NO OF PATIENTS
20-25	3
26-30	2
31-35	3
36-40	5
Above 40	2

Out of 15 patients, 2 patient has a prostate volume of above 40 cc, 5 patient were in the range of (36-40 cc), 3 patient within 31-35 cc, 2 patient within (26-30 cc) and 3 patients were in the range of (20-25 cc).

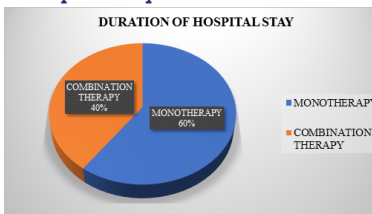
Therapeutic Management

Table 5

TYPE OF THERAPY	NO. OF PATIENTS
MONOTHERAPY	6
COMBINATION THERAPY	9

In our study, 6 patients received monotherapy and 9 patients were received combination therapy

Duration Of Hospital Stay



In our study, patient who receives combination therapy had lesser duration of hospital stay than the patient who receives monotherapy. This study shows combination therapy is more effective in patients with BPH.

CONCLUSION

A comparative study was conducted among 15 patients in surgery ward. Drug therapy is selected based on symptoms and enlargement of prostate. patients receiving combination therapy has faster clinical onset of action, significant reduction in IPSS (i.e., relief from BPH symptoms), Qmax improvement, marked reduction in prostate volume and reduces the duration of hospital stay compared to monotherapy. Our study results show that, combination therapy (5 α reductase inhibitor plus α blocker) is more effective than monotherapy (α blocker) in the treatment of benign prostatic hyperplasia.

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7. Deying Kang, MD1 Caoyang Hu, MS2 Yanyan Fu, MD, PhD3 Dongwen Wang, MD, PhD4,* 1Department of Evidence based Medicine and Clinical Epidemiology, West China Hospital, Sichuan University, Chengdu 2Department of Urology, First Hospital of Shanxi Medical University, Shanxi 3Medical Affairs Department, MSD China, Beijing 4Department of Urology, First Hospital of Shanxi Medical University, Shanxi Combination of α -blocker and 5 α reductase inhibitor for treatment of benign prostatic hyperplasia.
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