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AN OBSERVATIONAL STUDY ON CLINICAL SAFETY AND EFFICACY OF MEDICATIONS USED IN THE TREATMENT OF BENIGN PROSTATE HYPERPLASIA

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ABSTRACT

Background: BPH is a condition that occurs in males, where there is an enlargement of the prostate gland and is non-cancerous. This enlargement will exert pressure on the urethra, resulting in various urinary symptoms. BPH is also known as a "prostate gland enlargement that is not cancerous". Alpha blockers and inhibitors of the 5-alpha reeducates are the effective medications which are applied to treat BPH. **Methods:** This is an observational study on clinical safety and efficacy of medications used in the treatment of BPH which includes case reports of 70 individuals that was carried out for duration of six months. This study was conducted by surveying patients in both the IP and OP Departments. **Results**: In a research study conducted which includes 70 male patients; the patients were split into 6 classes based on age criteria: 40-50, 50-60, 60-70, 70-80, 80-90, and 90-100. In that the majority of the cases were seen in the patients[19] of age group 80-90, followed by[14] patients within the age range of 70-80, followed by same count of patients[13] fall within the age groups of 60-70 and 50-60, followed by[7] patients were seen in the age group of 40-50 and a least number of patients[4] were seen in the category of 90-100. The patients with all the age groups were prescribed with the medications of both combination and individual therapy. So, the total number of patients[55] who have received the combination therapy had shown their effectiveness in enhancing the patient's quality of life. **Conclusion:** From the study which was conducted we can summarize that those patients who had received the combination therapy (78.01%) had shown their effectiveness in reducing the symptoms of BPH and enhances the quality of life for the patient when compared to individual therapy (21.39%).

INTRODUCTION

Benign prostatic hyperplasia (BPH) refers to the nonmalignant growth or hyperplasia of prostate tissue and is a common cause of lower urinary tract symptoms (LUTS) in older men. Disease prevalence has been shown to increase with advancing age. The histological prevalence of BPH at autopsy is as high as 50% to 60% for males in their 60s, increasing to 80% to 90% of those older than 70 years of age.[1]

Several definitions exist in the literature when describing BPH. These include bladder outlet obstruction, LUTS, and benign prostatic enlargement (BPE). BPH describes the histological changes, BPE refers to the increased size of the gland (usually secondary to BPH), and bladder outlet obstruction is defined as the blockage to urinary flow.[2,3] Those with BPE who present with bladder outlet obstruction are also termed benign prostatic obstruction.[4]

LUTS describe the urinary abnormalities shared by disorders affecting the bladder and prostate typically caused by BPH. These terms have largely replaced those symptoms historically termed "prostatism."

The development of BPH is characterized by stromal and epithelial cell proliferation in the prostate transition zone, which surrounds the urethra. This leads to urethral compression and the development of bladder outflow obstruction, which can result in clinical manifestations of LUTS, urinary retention, or infections due to incomplete bladder emptying.[5] Long-term, untreated disease can lead to the development of chronic high-pressure retention (a potentially life-threatening condition) and long-term or permanent changes to the bladder detrusor muscle.

BPH treatment options range from watchful waiting to various medical and surgical interventions. Risk factors may be divided into non-modifiable and modifiable. Other factors such as age, genetics, geographical location, and obesity have all been shown to influence the development of BPH.[6,7]

BPH arises due to the loss of homeostasis between prostatic cellular proliferation and apoptosis or cell death. This imbalance favors cellular proliferation without intervention. The result is increased numbers of prostatic periurethral epithelial and stromal cells,

which can be seen histopathologically.[5] The etiology of BPH is influenced by a wide variety of risk factors, in addition to the direct hormonal effects of testosterone on prostate tissue. Men who are castrated before puberty or who have an androgen-related disorder do not develop BPH.

There is conflicting data on the role of non-steroidal anti-inflammatory medications (NSAIDs) in promoting BPH, with some studies indicating a positive association and others discounting any association.[8,9,10] Allopurinol is somewhat protective for BPH, possibly secondary to reduced oxidative stress from hyperuricemia effects.[11]

Testicular androgens are required to develop BPH as dihydrotestosterone (DHT) promotes tissue growth and cellular proliferation by interacting directly with prostatic epithelium and stroma.[5,12] Testosterone is converted to DHT by 5-alpha-reductase 2 in prostatic stromal cells and accounts for 90% of total intraprostatic androgens.[7] DHT directly influences prostatic stromal and adjacent cells, which affect cellular proliferation and apoptosis.[13] Interestingly, there does not appear to be any relationship between testosterone or DHT levels and the development of symptomatic BPH.[14]

The need for study is Alpha blockers function by blocking adrenoreceptors, relaxation the smooth muscles in the prostate and neck of the bladder. These relaxation leads to an enhancement in urine flow rate. 5-Alpha Reductase prostate shrinking results from inhibitors that prevent testosterone from being converted to dihydrotestosterone. To know the effectiveness of Medications used in the treatment of Benign Prostatic Hyperplasia. In evaluating the drug's safety, including any side effects.

The main aim is evaluating the clinical safety and effectiveness of medications used in the treatment of Benign Prostate Hyperplasia.

The objectives are Conducting a comprehensive assessment to gauge the clinical safety and effectiveness of medications utilized when treating benign prostatic hyperplasia. Examining the effectiveness of alpha blockers and 5-alpha Reductase Inhibitors in enhancing urine flow rate and alleviating symptoms associated with Benign Prostate Hyperplasia (BPH). Examining the adverse drug reactions related to medications utilized in the treatment of benign hyperplasia of the prostate.

MATERIALS AND METHODOLOGY

- **STUDY DESIGN:** An Observational study on clinical safety and efficacy of medications used in the treatment of Benign Prostate Hyperplasia.
- **SAMPLE SIZE:** 70 Patients
- **STUDY PERIOD:** 6 months.
- **STUDY SITE:** Aware Gleneagles Global Hospitals, Lb Nagar.
- **SOURCE OF DATA COLLECTION**

- All the relevant and necessary data was collected from patient data collection form.
- Patients case sheets of out-patients and in-patients.
- Laboratory data.
- Treatment chart.
- Interviewing patients or patients care takers about the patient.
- Any other relevant sources.

- **INCLUSION CRITERIA**

- Patients of age above 40 Years.
- Patients with confirmed diagnosis of Benign prostate hyperplasia.
- Patients who are conscious and co-operative.
- Patients who can provide written informed consent.
- Patients who have received alpha blockers and inhibitors of 5-alpha reductase, in treating Benign Prostatic Hyperplasia may be included if their most recent treatment was at least 4 weeks prior to the study.

- **EXCLUSION CRITERIA**

- Patients who are not conscious/ not co-operative.
- Psychiatric patients.
- Female patients

RESULTS

DISTRIBUTION OF PATIENTS BASED ON AGE: Total age was categorized at the interval of 10. Of the 70 patients, 7 (10%) were under 40–50 years old, 13 (18.57%) were in the 50–60 age group, 13 (18.57%) were in the 60–70 age group, 14 (20%) were in the 70–80 age group, 19 (27.14%) were in the 80–90 age group, and 4 (1.71%) were in the 90–100 age range.

Table 1: Distribution of patients based on age.

AGE GROUPS	TOTAL NO. OF PATIENTS
40-50	7
50-60	13
60-70	13
70-80	14
80-90	19
90-100	4

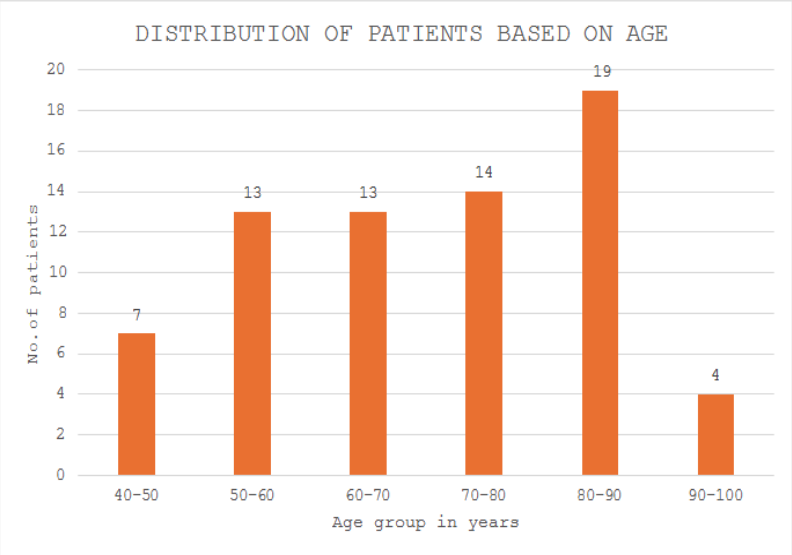

Figure: 1- Distribution of patients based on age.

PERCENTAGES OF AGE WISE DISTRIBUTION

Table 2: Percentages of age wise distribution.

AGE GROUPS	PERCENTAGES
40-50	10%
50-60	18.57%
60-70	18.57%
70-80	20%
80-90	27.14%
90-100	5.71%

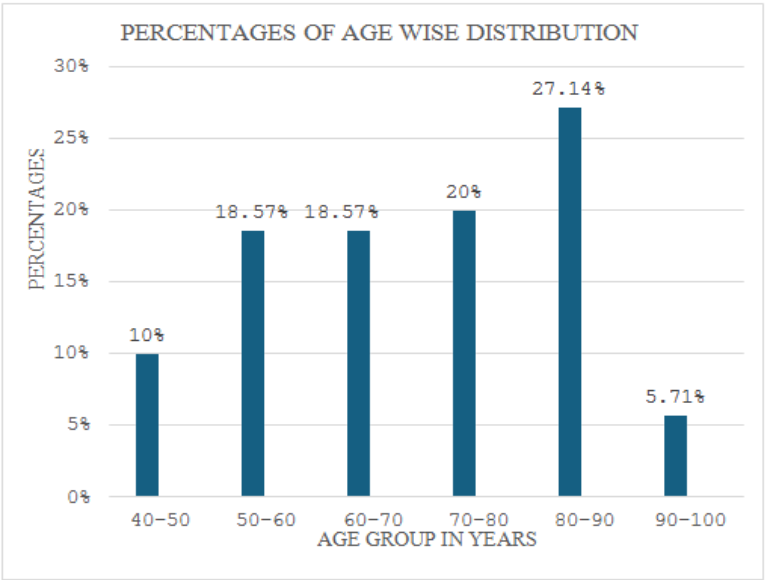

Figure: 2- Percentages of age wise distribution.

DISTRIBUTION OF PATIENTS ACCORDING TO CO-MORBIDITIES

Out of 70 patients, 37 patients (52.8%) had co-morbidities and 33 patients (47.14%) had no co-morbidities.

Table 3: Distribution of patients according to co-morbidities.

CO-MORBIDITIES	TOTAL NO. OF PATIENTS
With co-morbidities	37
Without co-morbidities	33

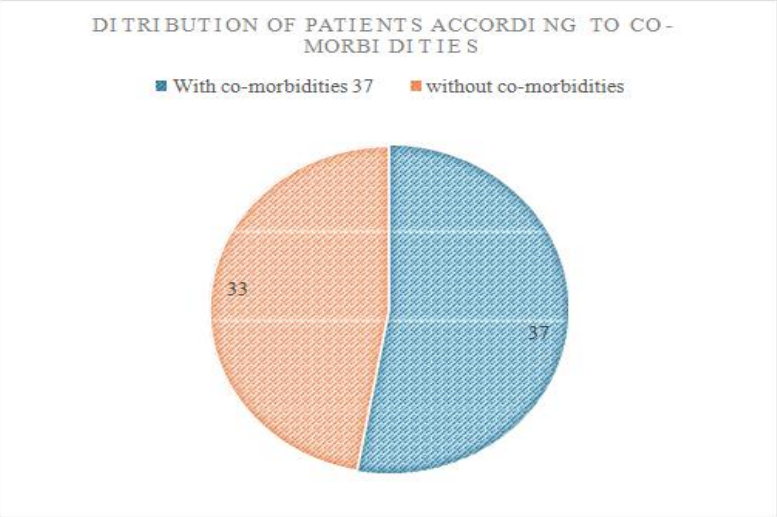

Figure: 3-Distribution of patients according to co-morbidities.

PERCENTANGES DISTIBUTION OF PATIENTS ACCORDING TO CO- MORBIDITIES

Table 4: Percentages distribution of patients according to co-morbidities.

COMORBIDITIES	PERCENTAGES
With co-morbidities	52.8%
Without co-morbidities	47.14%

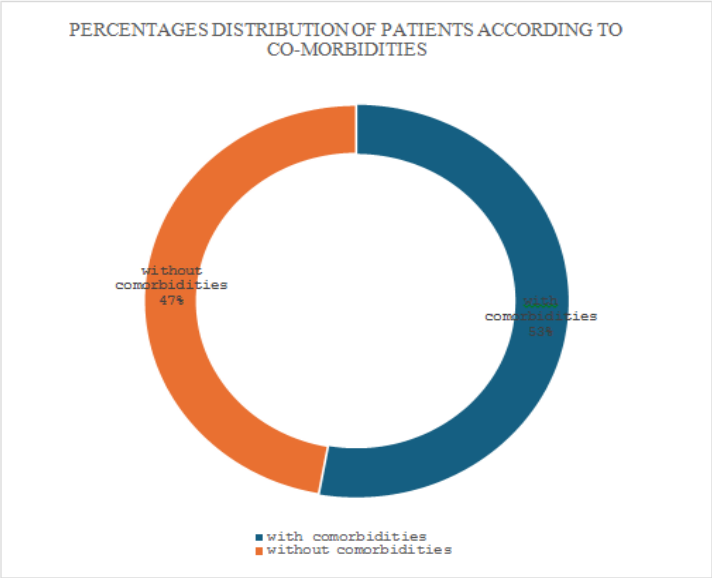

Figure: 4- Percentages distribution of patients according to co-morbidities.

AGE WISE DISTRIBUTION OF PATIENTS BASED ON CO - MORBODITIES: Out of 70 patients, 0 patients were under the age range of 40-50, 7 Patients (10%) were under the age group of 50-60, 6 Patients (8.57%) were under the age group of 60-70, 9 Patients (12.87%) were under the age group of 70-80, 12 Patients (17.1%) were age group of 80-90, 3 Patients (4.28%) were under the age group of 90-100.

Table 5: Age wise distribution of patients based on co-morbidities.

AGE GROUPS	TOTAL NO. OF PATIENTS
40-50	0
50-60	7
60-70	6
70-80	9
80-90	12
90-100	3

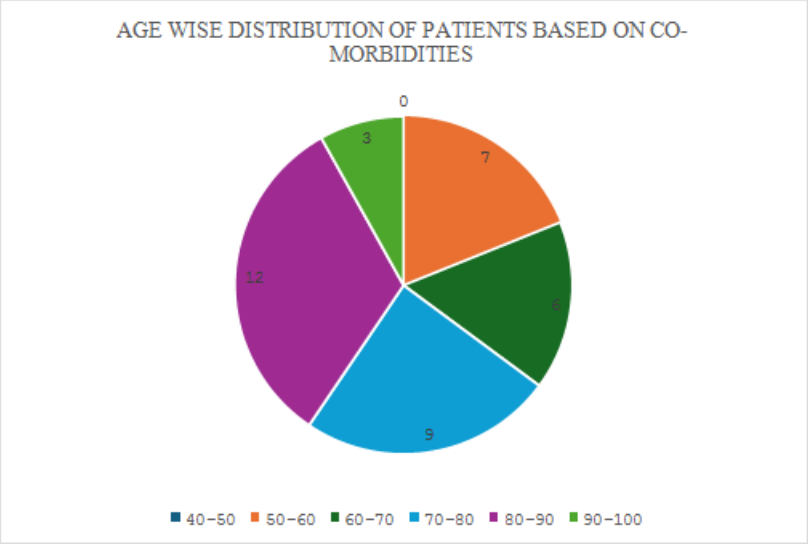

Figure: 5-Age wise distribution of patients based on co-morbidities.

PERCENTAGES OF AGE WISE DISTRIBUTION OF PATIENTS BASED ON CO-MORBIDITIES

Table 6: Percentage wise distribution of patients based on co-morbidities.

AGE GROUPS	PERCENTGES
40-50	0%
50-60	10%
60-70	8.57%
70-80	12.87%
80-90	17.1%
90-100	4.28%

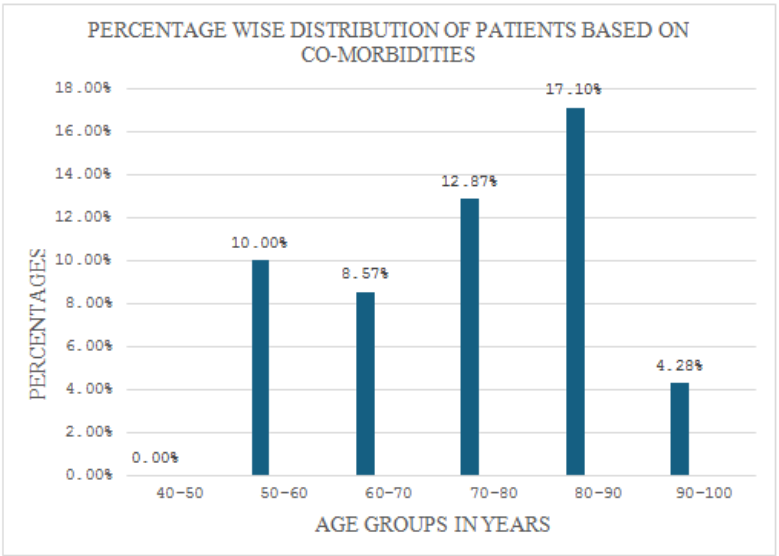

Figure: 6-Percentages of age wise distribution of patients based on co-morbidities.

DISTRIBUTION OF PATIENTS BASED ON SYMPTOMS: Out of 70 patients, 31 patients are with storage symptoms, 21 patients are with voiding symptoms and 18 patients are with combined symptoms.

Table 7: Distribution of patients based on symptoms.

TYPES OF SYMPTOMS	TOTAL NO. OF PATIENTS
Voiding symptoms (VS)	21
Storage symptoms (SS)	31
Combined symptoms (CS)	18

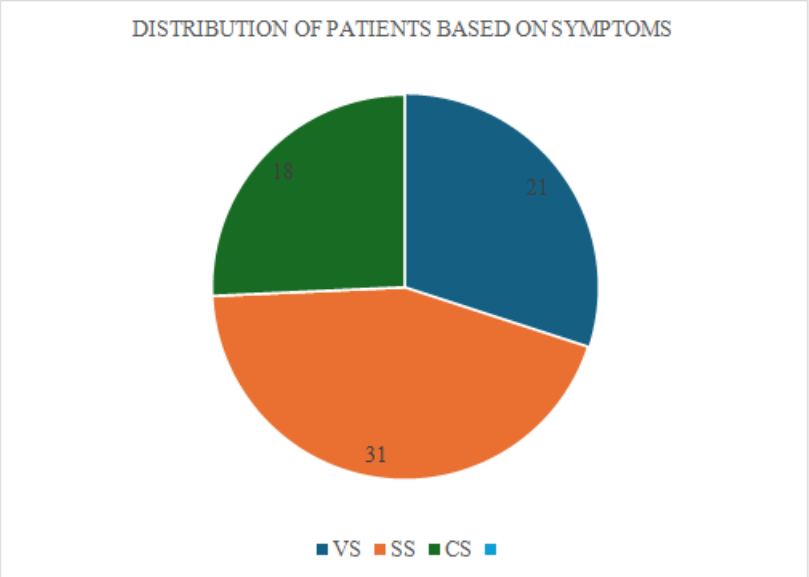

Figure: 7- Distribution of patients based on symptoms.

PERCENTAGE DISTRIBUTION OF PATIENTS BASED ON SYMPTOMS: Out of 70 patients, 31 patients (44.28%) are with storage symptoms, 21 patients (30%) are with voiding symptoms and 18 patients (25.72%) are with combined symptoms.

Table 6.8: Percentage Distribution of patients based on symptoms.

TYPES OF SYMPTOMS	PERCENTAGES
Voiding symptoms (VS)	30%
Storage symptoms (SS)	44.28%
Combined symptoms (CS)	25.71%

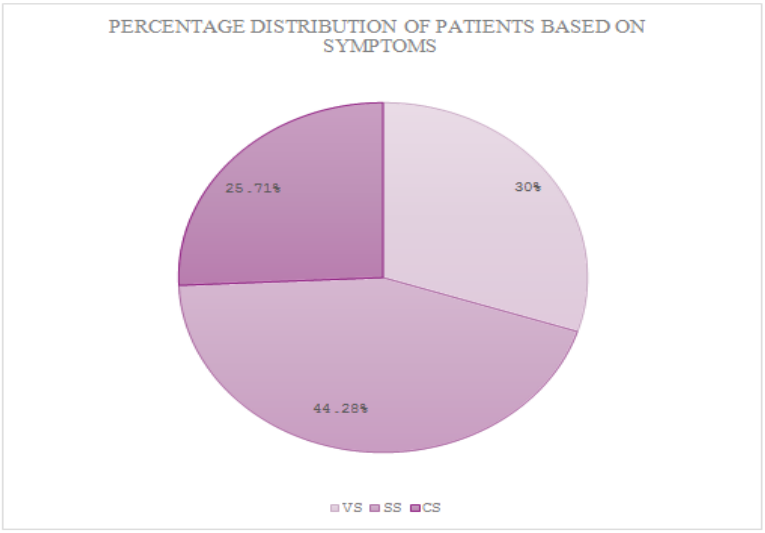

Figure: 8- Percentage distribution based on symptom.

AGE WISE DISTRIBUTION OF PATIENTS BASED ON VOIDING AND STORAGE SYMPTOMS

Out of 70 patients, 4 (5.71%) patients are with voiding symptoms and 2 (2.85%) patients are with storage symptoms under the age group of 40-50, 7 (10%) patients are with voiding symptoms and 4 (5.71%) patients are with storage symptoms under the age group of 50-60, 4 (5.71%) patients are with voiding symptoms and 7 (10%) patients are with storage symptoms under the age group of 60-70, 2 (2.85%) patients are with voiding symptoms and 8 (11.42%) patients are with storage symptoms under the age group of 70-80, 3 (4.28%) patients are with voiding symptoms and 9 (12.85%) patients are with storage symptoms under the age of 80- 90, 1 (1.42%) patients are with voiding symptoms and 1 (1.42%) patients are with storage symptoms under the age of 90-100.

Table 9: Age wise distribution of patients based on voiding and storage symptoms.

AGE	TOTALNO.OFPATIENTS WITH VOIDING SYMPTOMS	TOTALNO. OF PATIENTS WITH STORAGE SYMPTOMS
40-50	4	2
50-60	7	4
60-70	4	7
70-80	2	8
80-90	3	9
90-100	1	1
Total	21	31

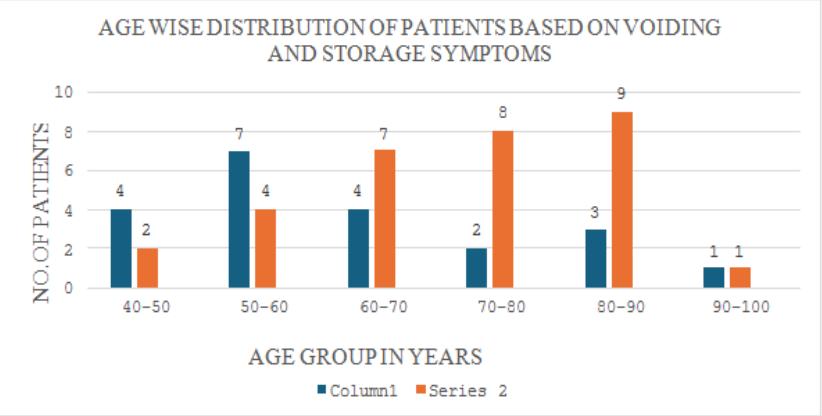

Figure: 9-Age wise distribution of patients based on voiding and storage symptoms.

PERCNTAGES OF AGE WISE DISTRIBUTION OF PATIENTS BASED ON VOIDING AND STORAGE SYMPTOMS

Table 10: Percentages of age wise distribution of patients based on voiding and storage symptoms.

AGE	%VOIDING	% STORAGE
40-50	5.71%	2.85%
50-60	10%	5.71%
60-70	5.71%	10%
70-80	2.85%	11.42%
80-90	4.28%	12.85%
90-100	1.42%	1.42%
Total	29.97%	44.25%

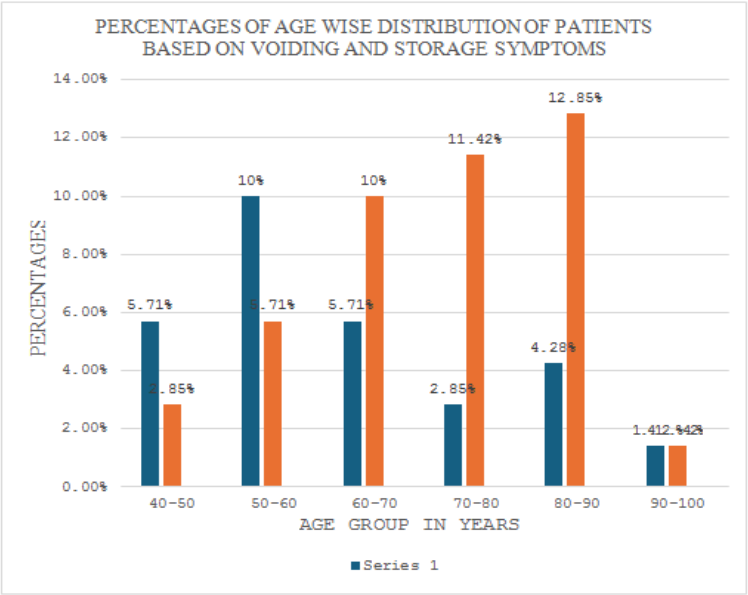

Figure: 10-Percentages of age wise distribution of patients based on voiding and storage symptoms.

GE WISE DISTRIBUTION OF PATIENTS BASED ON COMBINED SYMPTOMS (VOIDING AND STORAGE SYMPTOMS): In relation to 70 patients, 1 patients were with combined symptoms under the age group of 40-50, no patients were with combined symptoms under the age group of 50-60, 3 (0.04%) patients were with the combined symptoms under the age group of 60-70, 4 (0.05%) patients fall within the age group of 70-80, 4 (0.08%) patients were in the age group of 70-80, 6 (0.08%) patients fall within the age group of 80-90, 2 (0.02%) patients were the under the age group of 90-100**.**

Table 11: Age wise distribution of patients based on combined symptoms.

AGE GROUPS	TOTAL NO. OF PATIENTS
40-50	1
50-60	2
60-70	3
70-80	4
80-90	6
90-100	1
Total	18

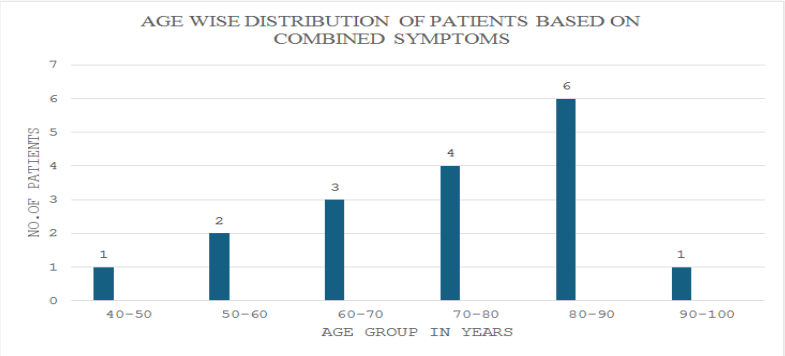

Figure: 11-Age wise distribution of patients based on combined symptoms.

PERCENTAGES OF AGE WISE DISTRIBUTION OF PATIENTS BASED ON COMBINED SYMPTOMS (VOIDING+STORAGE)

Table 12: Percentages of Age wise distribution of patients based on combined symptoms.

AGE GROUPS	PERCENTAGES
40-50	1.42 %
50-60	2.85%
60-70	4.28%
70-80	5.71%
80-90	8.57%
90-100	2.85%
Total	25.68%

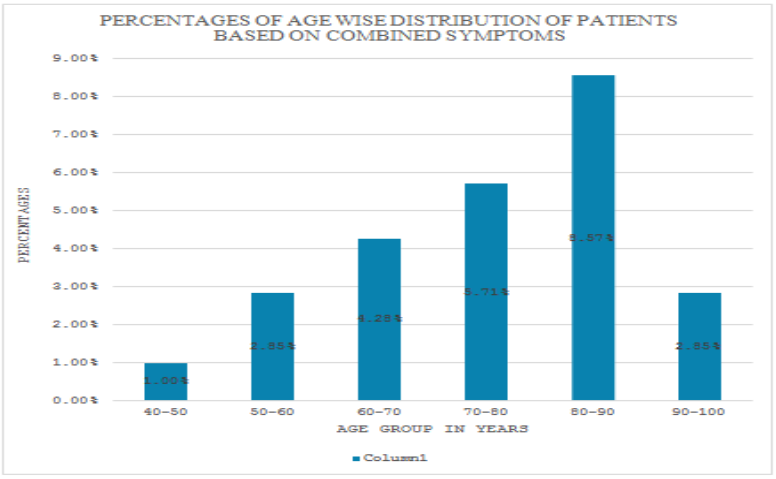

Figure: 12- Percentage of age wise distribution of patients based on combined symptoms.

DISTRIBUTION OF PATIENTS BASED ON DIAGNOSIS TESTS: Out of 70 patients, 3 (4.28%) patients are confirmed based on Prostate specific antigen (PSA) + Prostate size (PS), 4 (5.71%) patients are confirmed based on Post void residual volume (PVR) + Prostate size (PS) and 5 (7.14%) patients are confirmed based on Prostate specific antigen (PSA) + Post void residual volume (PVR) + Prostate size (PS), 30 (42.85%) patients are confirmed based on Prostate size (PS), 13 (18.57%) patients are confirmed based on Prostate specific antigen (PSA), 15 (21.42%) patients are confirmed based on Post void residual volume (PVR).

Table 13: Distribution of patients based on diagnosis tests.

DIAGNOSIS TESTS	TOTAL NO. OF PATIENTS
PSA+PS	3
PVRV+PS	4
PSA+PVR+PS	5
PS	30
PSA	13
PVR	15

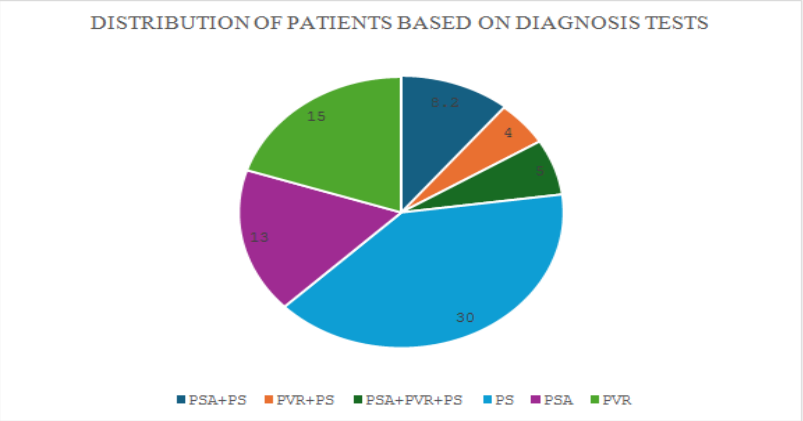

Figure: 13-Distribution of patients based on diagnosis tests.

DISTRIBUTION OF PATIENTS BASED ON COMBINED DIAGNOSIS: Out of 70 patients, 3 (4.28%) Patients are confirmed based on Prostate specific antigen (PSA) + Prostate size (PS), 4 (5.71%) Patients are confirmed based on Post void residual volume (PVRV) + Prostate size (PS) and 5 (7.14%) patients are confirmed based on Prostate specific antigen (PSA) + Post void residual volume (PVRV) + Prostate size (PS).

Table 14: Distribution of patients based on combined diagnosis.

COMBINED DIAGNOSIS	TOTAL NO. OF PATIENTS
PSA+PS	3
PVRV+PS	4
PSA+PVRV+PS	5

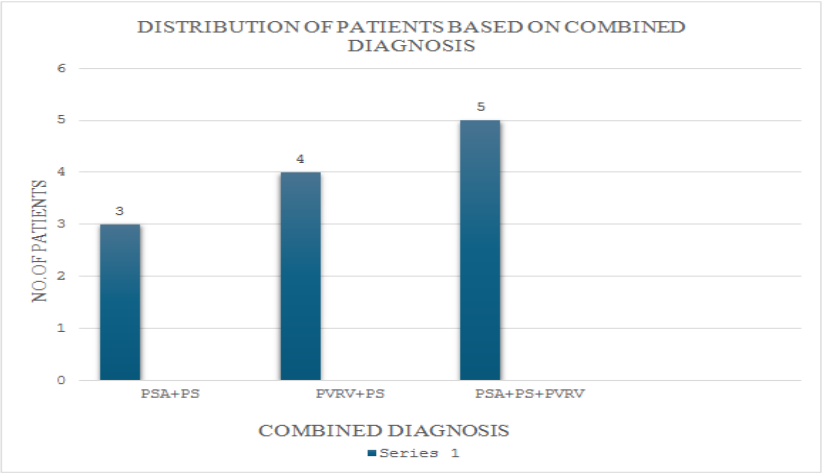

Figure: 14- Distribution of patients based on combined diagnosis.

PERCENTAGE DISTRIBUTION OF PATIENTS BASED ON COMBINED DIAGNOSIS

Table 15: Percentages distribution of patients based on combined diagnosis.

COMBINED DIAGNOSIS	PERCENTAGES
PSA+PS	4.28%
PVRV+PS	5.71%
PSA+PVRV+PS	7.14%

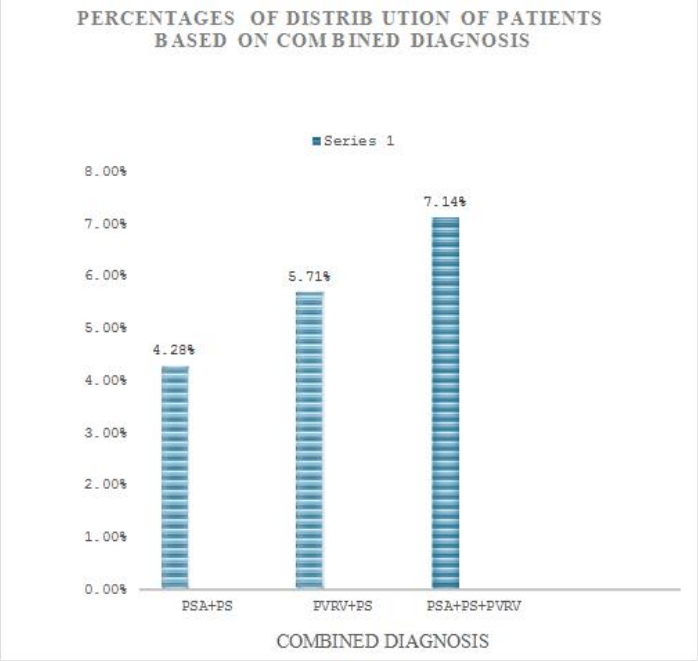

Figure: 15-Percentage distribution of patients based on combined diagnosis.

DISTRIBUTION OF PATIENTS BASED ON INDIVIDUAL DIAGNOSIS: Out of 70 patients, 30 (42.85%) patients are confirmed based on Prostate size (PS), 13 (18.57%) patients are confirmed based on Prostate specific antigen (PSA), 15 (21.42%) patients are confirmed based on Post void residual volume (PVRV).

Table 6.16: Distribution of patients based on individual diagnosis.

INDIVIDUAL DIAGNOSIS	TOTAL NO. OF PATIENTS
PS	30
PSA	13
PVRV	15

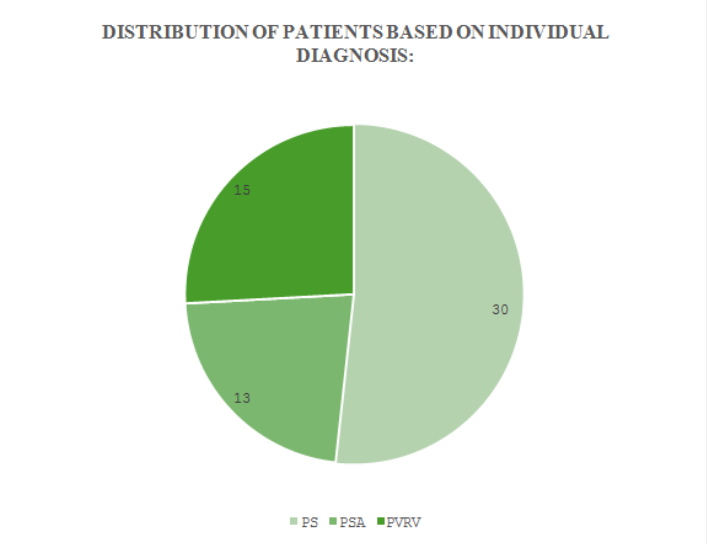

Figure: 6.16- Distribution of patients based on individual diagnosis.

PERCENTAGE DISTRIBUTION OF PATIENTS BASED ON INDIVIDUAL DIAGNOSIS

Table 17: Percentage distribution of patients based on individual diagnosis.

INDIVIDUAL DIAGNOSIS	PERCENTAGES
PS	42.85%
PSA	18.57%
PVRV	21.42%

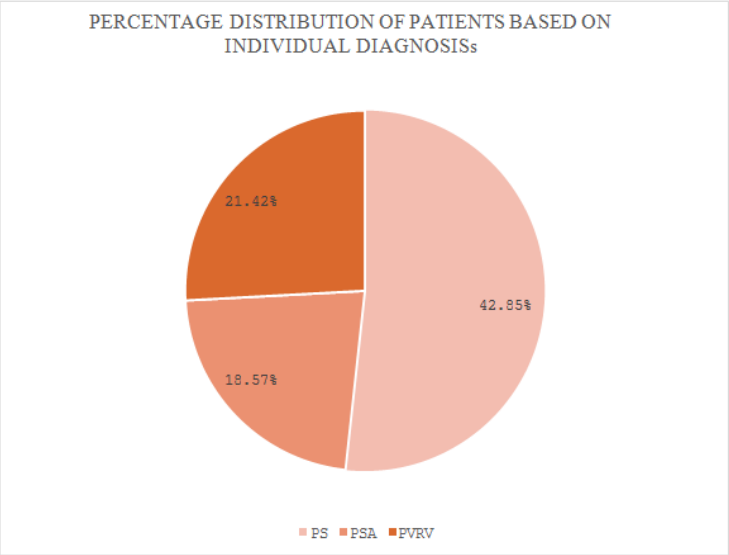

Figure: 17-Percentage distribution of patients based on individual diagnosis.

SAFETY

The safety results of medications used in the treatment of BPH in a sample of 70 patients are as follows: - Out of 70 patients involved in the study, 3 patients have experienced low blood pressure. 2 patients have experienced sexual side effects. 4 patients have experienced dizziness. It is important to note that the remaining 61 individuals did not have reported any side effects. These findings provide an overview of side effects associated with the medications.

Table 18: Safety results of medications used in the treatment of BPH.

SIDE EFFECTS	NO. OF PATIENTS
No side effects	61
Low blood pressure	3
Sexual side effects	2
Dizziness	4

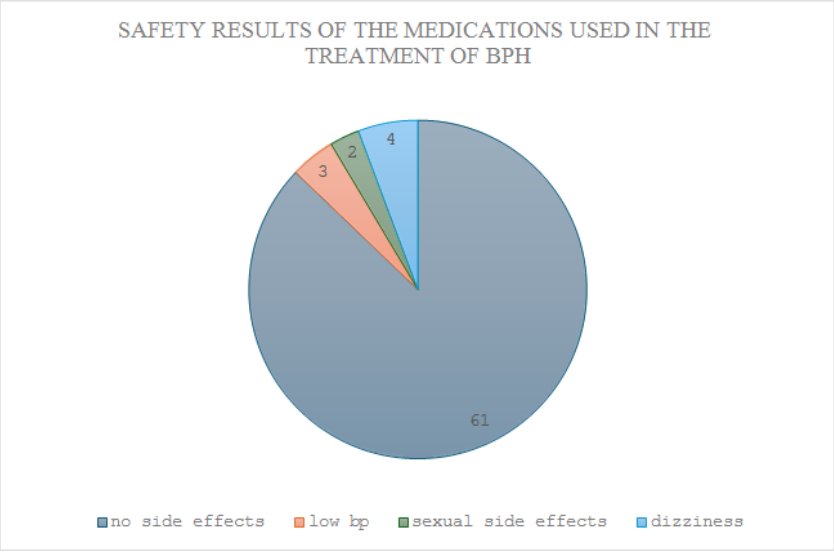

Figure: 18-Safety results of medications used in the treatment of BPH.

EFFICACY: DISTRIBUTION OF PATIENTS BASED ON THE THERAPY: The efficacy of medications such as the combination therapy (TAB.VELTAM PLUS and TAB. SILODOL-D) and individual therapy (TAB. VELTAM) were used for the management of BPH. From the above study, the combination therapy (978.57%) has shown its effectiveness and the standard of living of the patient's when compared to individual drug therapy. Out of 70 patients, 55 patients are given with combination therapy and 15 patients are given individual therapy.

Table 19: Distribution of patients based on therapy.

THERAPY	TOTAL NO. OF PATIENTS
Combination Therapy (CT)	55
Individual Therapy (IT)	15

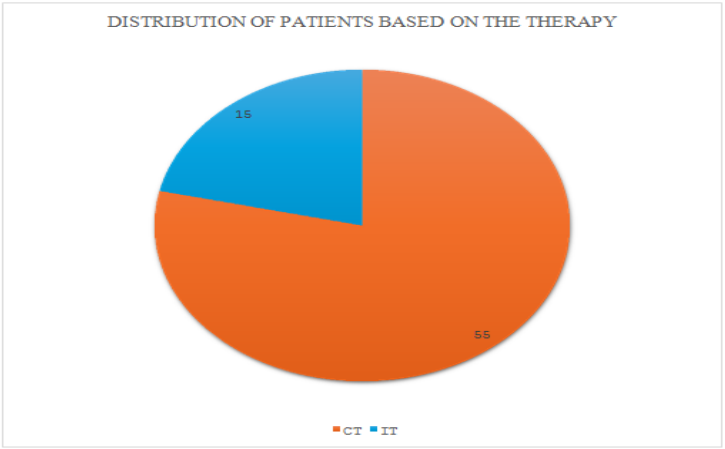

Figure: 19- Distribution of patients based on the therapy.

PERCENTAGE DISTRIBUTION OF PATIENTS BASED ON THE DRUG THERAPY
Out of 70 patients, 55patients (78.57%) are given with combination therapy and 15 patients (21.42%) are given individual therapy.

Table 20: Distribution of patients based on the drug therapy.

THERAPY	PERCENTAGES
Combination Therapy (CT)	78.57%
Individual Therapy (IT)	21.42%

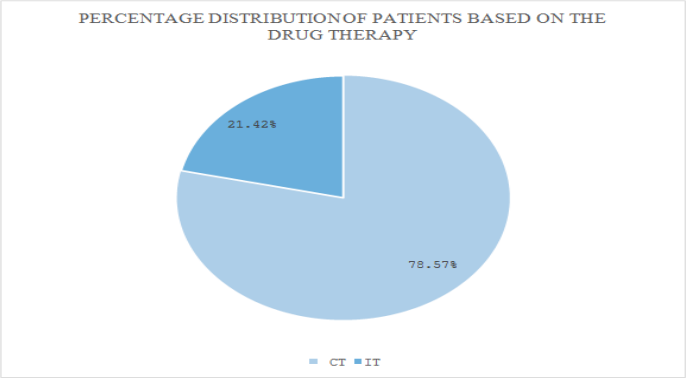

Figure: 20- Percentage distribution of patients based on the drug therapy.

AGE WISE DISTRIBUTION OF PATIENTS BASED ON THE COMBINATION THERAPY: Out of 70 patients, 3 (4.28%) patients are given with TAB. VELTAM PLUS and 3 (4.28%) patients are given with TAB. SILODOL-D under the age group of 40-50, 5 (7.14%) patients are given with TAB. VELTAM PLUS and 2(2.85%) patients are given with TAB.SILODOL-D under the age group of 50-60, 8 (11.4%) patients are given with TAB. VELTAM PLUS and 5(7.14%) patients are given with TAB. SILODOL-D under the age group of 60-70, 5 (7.14%) patients are given with TAB.VELTAM PLUS and 6 (8.57%) patients are provided with TAB. SILODOL under the age group of 70-80, 12 (17.14%) patients are provided with TAB. VELTAM PLUS and 4

(5.71%) patients are given with TAB. SILODOL-D under the age group of 80-90, 1 (1.42%) patients are provided with TAB. VELTAM PLUS and 1 (1.42%) patients are given with TAB. SILODOL-D.

Table 21: Age wise distribution of patients based on the combination therapy.

AGE GROUPS	NO. OF PATIENTS WITH TAB.VELTAM PLUS	NO. OF PATIENTS WITH TAB.SILODOL-D
40-50	3	3
50-60	5	2
60-70	8	5
70-80	5	6
80-90	12	4
90-100	1	1
TOTAL	34	21

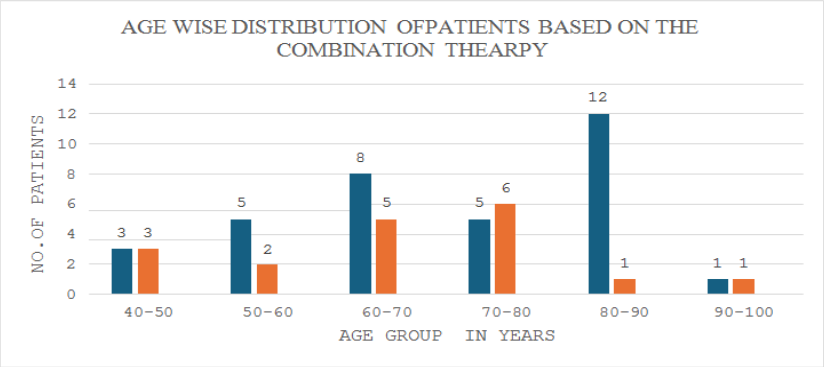

Figure: 21- Age wise distribution of patients based on the combination therapy.

PERCENTAGES OF AGE WISE DISTRIBUTION OF PATIENT BASED ON COMBINATION THERAPY

Table 22: Percentage of age wise distribution of based on combination therapy.

AGE GROUPS	%OF VELTAM PLUS	% OF TAB.SILODOL-D
40-50	4.28%	4.28%
50-60	7.14%	2.85%
60-70	11.4%	7.14%
70-80	7.14%	8.57%
80-90	17.14%	5.17%
90-100	1.42%	1.42%
TOTAL	48.52%	29.43%

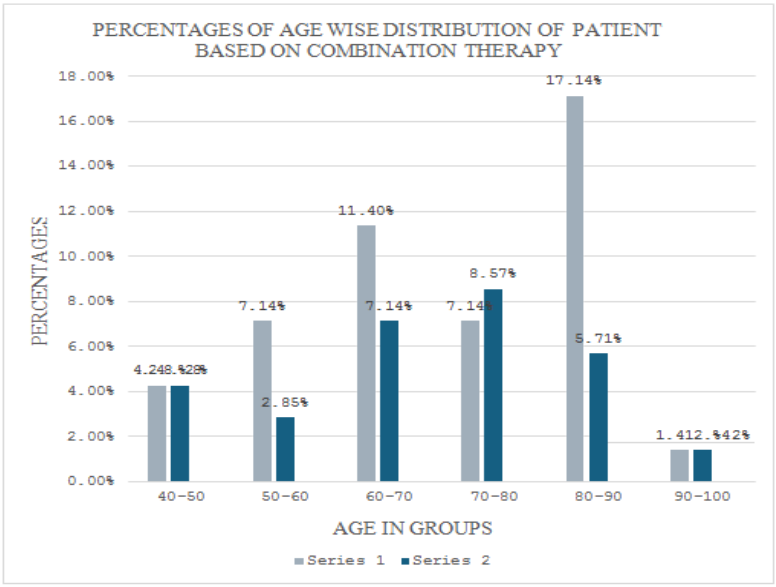

Figure: 22-Percentages of age wise distribution of patients-based on combination therapy.

AGE WISE DISTRIBUTION OF PATIENTS BASED ON INDIVIDUAL DRUG THERAPY: Out of 70 patients, 1 (1.42%) patient is given with individual drug therapy under the age group of 40-50, 6 (8.57%) patients are given with individual drug therapy under the age group of 50-60, 1 (1.42%) patient is given with individual drug therapy under the age group of 60-70, 3 (4.28%) patients are given with individual drug therapy under the age group of 70-80, 2 (2.85%) patients are given with individual drug therapy under the age group of 80-90, 2 (2.85%) patients are given with individual drug therapy under the age group of 90-100.

Table 23: Age wise distribution of patients based on individual drug therapy.

AGE GROUPS	TOTAL NO. OF PATIENTS
40-50	1
50-60	6
60-70	1
70-80	3
80-90	2
90-100	2
TOTAL	15

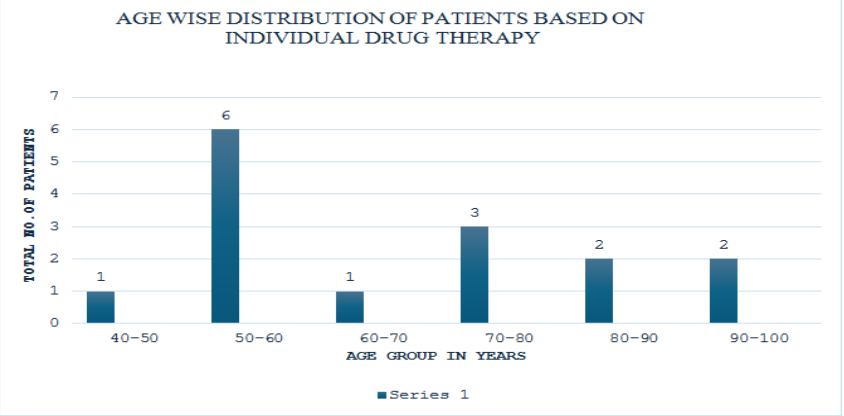

Figure: 23-Age wise distribution of patients based on individual drug therapy.

PERCENTAGES OF AGE WISE DISTRIBUTION BASED ON INDIVIDUAL DRUG THERAPY

Table 24: Percentages of age wise distribution based on individual drug therapy.

AGE GROUPS	PERCENTAGES
40-50	1.42%
50-60	8.57%
60-70	1.42%
70-80	4.28%
80-90	2.85%
90-100	2.85%
TOTAL	21.39%

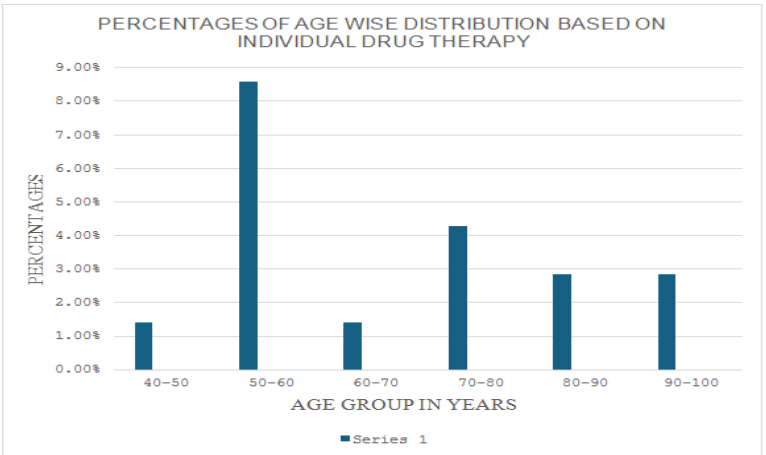

Figure: 24- Percentages of age wise distribution based on individual drug therapy.

DISCUSSION

We have conducted an observational study to examine the clinical safety and efficacy of medications used in the treatment of Benign Prostate Hyperplasia. This study was carried out for a period of six months, involving 70 individuals meeting the inclusion and exclusion criteria. Concerning BPH, this disease is only seen in the males due to the presence of prostate gland Patients' age was also taken into consideration.

The patient's age was categorized into six classes: 40-50, 50-60, 60-70, 70-80, 80-90, and 90-100. The highest number of patients 19 (27.14%) fell in the 80-90 age group, followed by 14 (20%) patients fall within the range of 70-80, and then 13 (18.57%) patient fall within the category of 50-60 and 60-70 age group, followed by 7 (10%) individuals within the age range of 40-50 and least number of patients 4 (5.71%) fall within the range of 90-100. BPH predominantly occurred in the age group of 80-90 and 70-80.

Out of 70 patients, over 37 patients (52.48%) were having co-morbidities and 33 (47.14%) were not having co-morbidities.

Out of 70 patients, 31 (29.97%) patients are having storage symptoms, 21 (44.25%) patients are having the voiding symptoms, and 18 (25.68%) patients are having the combined symptoms.

Concerning the symptoms, The highest number of patients[7] having voiding symptoms fall within the range of 50-60 whereas the least number of patients[1] having storage symptoms fall within the rage age of 90-100. The highest number of patients[9] having the storage symptoms fall within the age bracket of 80-90 whereas the least number of patients[1] having the storage symptoms fall within the category of 9. The highest number of patients[6] having the combined symptoms fall within the range of 80-90 whereas the least number of patients 9[1] having the combined symptoms fell in the age group of 40-50.

Out of 70 patients, 3 patients (4.28%) are confirmed based on PSA+PS diagnosis, 4 patients (5.71%) are based on PVRV+PS diagnosis, 5 patients (7.14%) are confirmed based on PS+PVRV+PSA diagnosis, 30 patients (42.85%) are confirmed based on PS diagnosis, 13 patients (18.57%) are confirmed based on PSA diagnosis and 15 patients (21.42&) are confirmed based on PVRV diagnosis.

Out of 70 patients, 34 patients (48.52%) are receiving the TAB. VELTAM PLUS, 21 patients (29.49%) are receiving the TAB. SILODOL-D and 15 patients (18.54%) are receiving the TAB. VELTAM.

Regarding the symptoms based on age groups, the highest number of patients[12] receiving the TAB. VELTAM PLUS fell in the age of 80-90 whereas the least number of patients[1] receiving the TAB. VELTAM PLUS fell in the range of 90-100. The highest number of patients[6] receiving the TAB. SILODOL-D fall within the age range of 70-80 whereas the least number of patients[1] receiving the TAB. SILODOL-D fall within the range of 90-100. The highest number of patients[6] receiving the TAB. VELTAM fall in to the bracket of 50-60 whereas the least number of patients[1] receiving the TAB.VELTAM fell in the age group of 70-80.

Majority of the patients who are receiving the combination therapy i.e. TAB. VELTAM PLUS and TAB. SILODOL-D are enhancing its effectiveness to enhance the patient's quality of life.

CONCLUSION

An observational study was conducted at AWARE GLENAGLES GLOBAL HOSPITALS carried out in the urology and andrology department to study the clinical safety and efficacy of medications used in the treatment of Benign Prostate Hyperplasia. This study includes a total of 70 individuals carried out for a period of six months only in male patients.

Among 70 patients, the highest number of patients (19) with BPH under the age group of 80- 90 and the least number of patients (19) with under the age group of 70-80.

In research performed, 37 patients (52.48%) are present with co-morbidities and 33 patients (47.14%) are present without co-morbidities.

Among the 70 patients considered for the study, 31 patients are with storage symptoms, 21 patients are with voiding symptoms and 18 patients are with combined symptoms.

Overall, 58 patients are confirmed with BPH based on individual diagnosis and 12 patients are confirmed with BPH based on combined diagnosis. So, individual diagnosis (PS, PSA, and PVRV) is useful for early detection of BPH.

During the research performed, the medications such as Inhibitors of alpha reeducates and alpha blockers are given to the patients and monitored. So, among 70 patients, 55 patients were received combination therapy (Alpha blockers + inhibitors of 5-Alpha reductase) and 21 patients were received individual therapy (Alpha blockers). From, this the patients who received the combination (Alpha blockers+5-Alpha reductase inhibitors) had improved their living standards in the BPH management and no side effects are seen during the research work. So, finally we can conclude that Alpha blockers are combined with 5-alpha reductase inhibitors to enhance its effectiveness and enhance the standard of living in BPH management.

REFERENCES

1. Roehrborn CG. Benign prostatic hyperplasia: an overview. Rev Urol; 2005; 7 Supple 9 (Supple 9): S3-S14. [PMC free article] [PubMed].
2. Abrams P. LUTS, BPH, BPE, BPO: A Plea for the Logical Use of Correct Terms. Rev Urol; 1999; spring; 1(2): 65. [PMC free article] [PubMed].
3. Silverman WM. "Alphabet soup" and the prostate: LUTS, BPH, BPE, and BOO. J Am Osteopath Assoc; 2004 Feb; 104(2 Supple 2): S1-4. [PubMed].
4. Abrams P. New words for old: lower urinary tract symptoms for "prostatism". BMJ; 1994 Apr 09; 308(6934): 929-30. [PMC free article] [PubMed].
5. Roehrborn CG. Pathology of benign prostatic hyperplasia. Int J Impot Res; 2008 Dec; 20 Suppl 3: S11-8. [PubMed].
6. Parsons JK. Benign Prostatic Hyperplasia and Male Lower Urinary Tract Symptoms: Epidemiology and Risk Factors. Curr Bladder Dysfunct Rep; 2010 Dec; 5(4): 212-218. [PMC free article] [PubMed].
7. Chughtai B, Forde JC, Thomas DD, Laor L, Hossack T, Woo HH, Te AE, Kaplan SA. Benign prostatic hyperplasia. Nat Rev Dis Primers, 2016 May 05; 2: 16031. [PubMed].
8. Schenk JM, Calip GS, Tangen CM, Goodman P, Parsons JK, Thompson IM, Kristal AR. Indications for and use of nonsteroidal antiinflammatory drugs and the risk of incident, symptomatic benign prostatic hyperplasia: results from the prostate cancer prevention trial. Am J Epidemiol, 2012 Jul 15; 176(2): 156-63. [PMC free article] [PubMed].
9. Sutcliffe S, Grubb Iii RL, Platz EA, Ragard LR, Riley TL, Kazin SS, Hayes RB, Hsing AW, Andriole GL., Urologic Diseases in America Project. Non-steroidal anti-inflammatory drug use and the risk of benign prostatic hyperplasia-related outcomes and nocturia in the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. BJU Int; 2012 Oct; 110(7): 1050-9. [PMC free article] [PubMed].
10. Nygård LH, Talala K, Taari K, Tammela TLJ, Auvinen A, Murtola TJ. The effect of non-steroidal anti-inflammatory drugs on risk of benign prostatic hyperplasia. Prostate, 2017 Jun; 77(9): 1029-1035. [PubMed].
11. Kukko V, Kaipia A, Talala K, Taari K, Tammela TLJ, Auvinen A, Murtola TJ. Allopurinol and risk of benign prostatic hyperplasia in a Finnish population-based cohort. Prostate Cancer Prostatic Dis; 2018 Sep; 21(3): 373-378. [PubMed].
12. Foster CS. Pathology of benign prostatic hyperplasia. Prostate Suppl, 2000; 9: 4-14. [PubMed].
13. Isaacs JT. Antagonistic effect of androgen on prostatic cell death. Prostate, 1984; 5(5): 545-57. [PubMed].
14. Gann PH, Hennekens CH, Longcope C, Verhoek-Oftedahl W, Grodstein F, Stampfer MJ. A prospective study of plasma hormone levels, nonhormonal factors, and development of benign prostatic hyperplasia. Prostate, 1995 Jan; 26(1): 40-9. [PubMed].