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A PROSPECTIVE COHORT OBSERVATIONAL STUDY ON TYPE OF LOWER URINARY TRACT SYMPTOMS IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA

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Keywords:

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ABSTRACT: Patients with diagnosed BPH, suffer very frequently from lower urinary tract symptoms (LUTS). It is very crucial to find the types, prevalence, and impact of LUTS in association with age, glycaemic index, and modifiable risk factors for developing targeted management strategies. The research seeks to determine types of LUTS present in BPH patients across various age groups and their impact on QoL; and impact of glycaemic levels, as well as the sociodemographic factors like smoking and alcohol use on the severity of the LUTS/BPH. This is a prospective observational study conducted from September 2023 to February 2024 at Narayana Medical College and Hospital of Nellore district, Andhra Pradesh. 200 male patients above 45 years old with LUTS/BPH were selected by the random sampling technique. Data was collected using an IPSS questionnaire, and therefore analysed using qualitative and quantitative approaches, as well as multiple regression analysis and ANOVA. This study captures the multifactorial impacts of LUTS in BPH patients and underscores the importance of addressing modifiable risk factors and co-existing conditions like Diabetes Mellitus. Critical findings allow for improving patient outcomes and guiding clinical practice management strategies.

INTRODUCTION: The prostate gland is a walnut-shaped male's largest accessory reproductive organ which contributes enzymes to the seminal fluid and surrounds the urethra near the urinary bladder's neck. In elderly men, the prostate is the site of origin for the most prevalent diseases such as benign prostatic hyperplasia, prostatitis and prostate cancer. Benign prostatic hyperplasia, also known as BPH, is defined as the progressive non-malignant growth or benign enlargement of the prostatic tissue accompanied by lower urinary tract symptoms. Also, recent studies have shown that BPH is an immune inflammatory disease [1].

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Anatomically BPH may lead to the bladder outlet obstruction by blocking the urethra. BPH is more prevalent about 50% in men aged 50 and above and the incidence of the disease increases with rising age. In simpler terms the BPH is the most common disease among ageing men and also the most common cause of LUTS. The absolute burden of BPH is rising at an alarming rate in the world, proper monitoring and treatment is necessary to avoid future health strain [2].

The exact aetiology and pathogenesis of the BPH is not clearly known. Age, race, ethnicity, family history, tobacco smoking, hormonal changes, obesity, and chronic diseases such as hypertension, CAD, hyperinsulinemia, low HDL-cholesterol levels and mainly NIDDM are the potential risk factors for the BPH. BPH primarily originates in the transitional zone near urethra. It could be possibly due to the uncharacterised long-term urological toxin exposure which disrupts the

homeostasis of the stroma and epithelial cells. Furthermore, the intraprostatic dihydrotestosterone and chronic inflammation can aggravate the BPH progression. Some studies also suggest that altered oestrogen levels can contribute to the stroma cell proliferation which can further cause BPH progression. Also some studies suggest that increase in total prostatic stem cells can cause abnormal prostatic growth, and can also be a cause of BPH [3].

Primarily, the clinical manifestations of BPH includes lower urinary tract symptoms, frequent urination, and poor bladder emptying. Other manifestations include urinary retention, UTIs, haematuria, renal insufficiency and detrusor instability. LUTS can be classified as obstructive or voiding symptoms and irritable or storage symptoms. Obstructive symptoms include urinary frequency, urgency, nocturia, and urinary urge incompetence. Whilst the irritable symptoms include hesitancy, weak or intermittent streaming, dribbling at the end of the urination and incomplete bladder emptying. These symptoms are slowly progressive in nature and if left untreated can cause irreversible bladder damage. LUTS is a common complaint among patients visiting urology and it negatively affects the quality of life of the patients. According to a global analysis, LUTS is highly prevalent in male patients, especially older individuals with Asian ethnicity [4, 5].

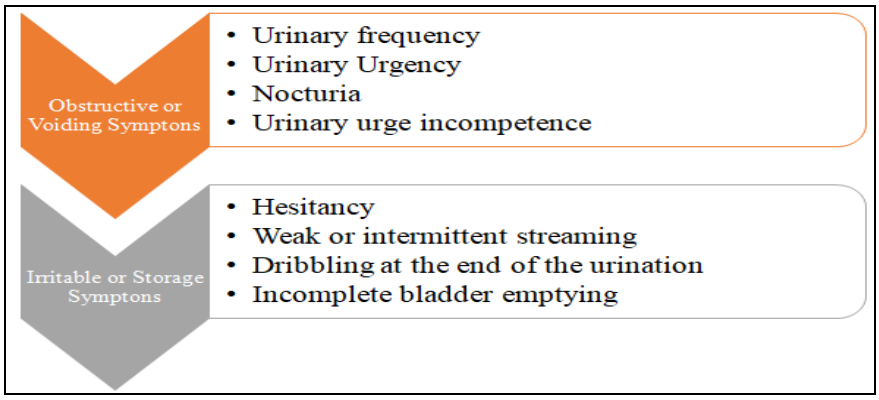

FIG. 1: TYPES OF LUTS AND THEIR SYMPTOMS

As the BPH progresses, the severity of LUTS increases causing poor quality of life, decreased peak flow rate, and further increase in prostate size, and may also result in unfavourable conditions such as acute urinary retention, and surgery. Some of the complications include urinary retention, haematuria, UTIs, bladder stones, and renal dysfunction.

In the diagnosis of BPH/LUTS, a detailed medical history rules out as the most critical component over other aspects. In this study the symptoms assessment was done by using International Prostate Symptom Score (IPSS) questionnaire form, a modification of American Urological Association (AUA) symptom index. The symptoms severity of LUTS can be classified into mild, moderate and severe categories, scoring 0-7, 8-19, and 20-35 respectively. This questionnaire helps to identify the severity or degree of LUTS and quality of life of the patients diagnosed with BPH/LUTS. Other diagnostic tests include physical examination like digital rectal examination and neurological examination, and laboratory tests like urinalysis to evaluate glycosuria, pyuria, haematuria, serum creatinine, prostate-specific antigen, and other testing such as urine cytology post-void residual, transrectal ultrasound, cystourethroscopy, and urodynamic studies [6].

The primary goal of the treatment plan is to improve the quality of life and relieve the symptoms. The medical therapy involves a wide range of drug classes like alpha blockers such as alfuzosin, doxazosin, silodosin, tamsulosin, or terazosin for the treatment of moderate to severe LUTS/BPH, 5-alpha reductase inhibitors include finasteride, dutasteride and phosphodiesterase-5 inhibitors like tadalafil or combination therapy can also be preferred based on the patient's condition. If the condition is severe and demands immediate response, surgical therapy will be adapted. Open or simple prostatectomy can be performed if the prostate size is very large [7].

As the famous quote says "Prevention is better than Cure," it is true if an individual follows a proper lifestyle. Moderate physical activity reduces the risk of BPH and LUTS. Consumption of a diet rich in vegetables, healthy weight loss and decreasing the alcohol consumption and cigarette smoking can have a positive impact to prevent these conditions. Maintaining blood glucose levels can also help to reduce the impact on BPH/LUTS.

There are a wide range of opinions among the research work done so far to assess the relationship between diabetes and severity of BPH causing LUTS. Few studies state that there is no interrelation between hyperglycaemia, hyperinsulinemia, or insulin resistance and LUTS/BPH, especially in the African American men. But, other research works reveal that there is significant association between metabolic disturbances and LUTS/BPH. It is also seen that men with Diabetes Mellitus not taking medications are more prone to the moderate/severe LUTS when compared to those who are on medications properly. It suggests that poor glycaemic control might aggravate LUTS. Also, diabetes or poor glycaemic control is associated with greater BPH symptoms severity. Metabolic syndrome is a group of clinical conditions, which also includes impaired glucose metabolism and is associated with higher risk for increased severity of the BPH [8, 9].

Several studies suggested a significant association between the BPH and diabetes or hyperglycemia. The presence of higher blood glucose levels in the patients has shown more large-sized prostatic volume in BPH. In general, both BPH and diabetes present urological symptoms. If the individual BPH associated with LUTS has diabetes then it acts a catalyst as it also exhibits the urological symptoms, furthermore enhancing the BPH symptom severity. Also, in a pathogenic view, vascular damage due to diabetes can cause hypoxia, and further contributes to the development of BPH [10, 11]. This study contributes to a better understanding of the complex relationship between metabolic health and neurological symptoms, by evaluating the link between glycaemic range and the severity of LUTS among BPH patients, thus, the healthcare practitioners can better understand the condition of the patient and can prescribe the personalised treatment management.

METHODOLOGY:

Study Design: A prospective observational cohort study (according to Strobe guidelines) [12] was conducted to evaluate the type of LUTS/BPH across different age groups for a period of 6 months i.e., September 2023 to February 2024.

Study Area and Study Size: The study area in this research work was the urology out-patient and in-patient departments of Narayana Medical College and Hospital, Chinthareddypalem, Nellore, Andhra Pradesh, India. The study size of this research work includes 200 participants with BPH/LUTS associated with or without diabetes.

Study Population: This study was conducted in the urology out-patient and in-patient departments, fulfilling inclusion and exclusion criteria during data collections and were considered as study participants.

Study Period: The study was conducted approximately for about 6 months from September 2023 to February 2024.

Study Criteria:

Inclusion Criteria: The study participants should satisfy the following criteria.

- It is a gender specific study and all the patients included should be males.
- Adults aged 45 years and older.
- Patients with or without diabetes.
- Each male patient included should have LUTS/BPH.

Exclusion Criteria: Patients with the following characteristics were not included in the study.

- Female patients were not included as it is a gender specific study.
- Patients below age 45 years.
- Patients with other urological conditions such as bladder cancer, urethral stricture, or urinary tract infections that may confound the impact of diabetes on LUTS [13].
- Patients with lack of intent to provide information.

Sampling Methods and Recruitment Process: Random sampling technique was used to select study participants. The BPH patients with or without diabetes mellitus suffering from irritable and/or obstructive LUTS were selected for evaluation.

Data Collection and Procedures: The data was collected from the study participants by chart review method, using a IPSS questionnaire form and followed up through telecommunication.

Data Analysis: Qualitative and quantitative analysis was performed on the generated data. Frequency distribution has also been taken among the parameters. Statistical analysis, like multiple regression analysis, has also been performed to determine the association between the variables.

RESULTS AND DISCUSSION: In this study 200 participants who were diagnosed with LUTS/BPH were selected under the inclusion criteria and followed up for about 6 months.

Sociodemographic Factors:

TABLE 1: SOCIODEMOGRAPHIC FACTOR STATUS IN THE STUDY PARTICIPANTS

Sociodemographic Factors		No of Participants (Frequency)
Age Group	45-50	6 (3%)
	51-60	45 (22.5%)
	61-70	77 (38.5%)
	71-80	58 (29%)
	>80	14 (7%)
Alcohol	Yes	118 (59%)
	No	82 (41%)
Smoking	Yes	129 (64.5%)
	No	71 (35.5%)

From **Table 1**, the 61-70 age group emerges as the most prominent category in this study. In numerical, there were 77 (38.5%). Sociodemographic factors like smoking, alcohol consumption was also taken into consideration along with the metabolic risk factor diabetes mellitus, which may negatively impact the health of the patients. Also, there was an established relationship between the consumption of alcohol, smoking and diabetes with lower urinary tract symptoms. They were the risk factors exacerbating the lower urinary tract symptoms. Our study revealed, there were 118 (59%) participants who was alcoholic and 129 (64.5%) daily smokers. Given the age is a non-modifiable risk factor, even though the increasing age increases the severity of the LUTS/BPH, it cannot be reversed. But the modifiable risk factors like smoking and alcoholism can be controlled, which may contribute to the little positive effect on the patients' health.

Frequency of Irritable vs Obstructive LUTS:

TABLE 2: FREQUENCY OF IRRITABLE VS OBSTRUCTIVE LUTS

Types of LUTS	Number of Participants (Percentage)
Irritable LUTS	83 (41.5%)
Obstructive LUTS	117 (58.5%)

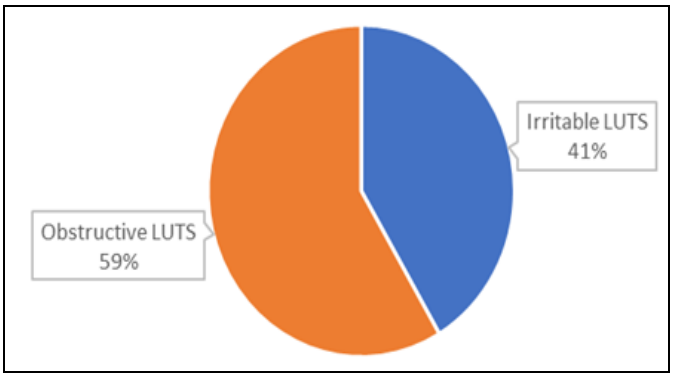

FIG. 2: FREQUENCY OF IRRITABLE VS OBSTRUCTIVE LUTS

The **Table 2** and **Fig. 2** indicates the distribution of types of lower urinary tract symptoms (LUTS) across all age groups, irrespective of specific demographic categories. The percentages suggest that within the study participants, 41.5% of participants experience irritable LUTS, while 58.5% exhibit obstructive LUTS.

Frequency of Irritable vs Obstructive LUTSA Cross Various Age Groups:

TABLE 3: FREQUENCY OF IRRITABLE VS OBSTRUCTIVE LUTS ACROSS VARIOUS AGE GROUPS

Age Group	No of Participants (Frequency %)	
	Irritable LUTS	Obstructive LUTS
45-50	4 (4.81%)	2 (1.70%)
51-60	22 (26.50%)	23 (19.65%)
61-70	33 (39.75%)	44 (37.60%)
71-80	19 (22.89%)	39 (33.33%)
>80	5 (6.024%)	9 (7.69%)

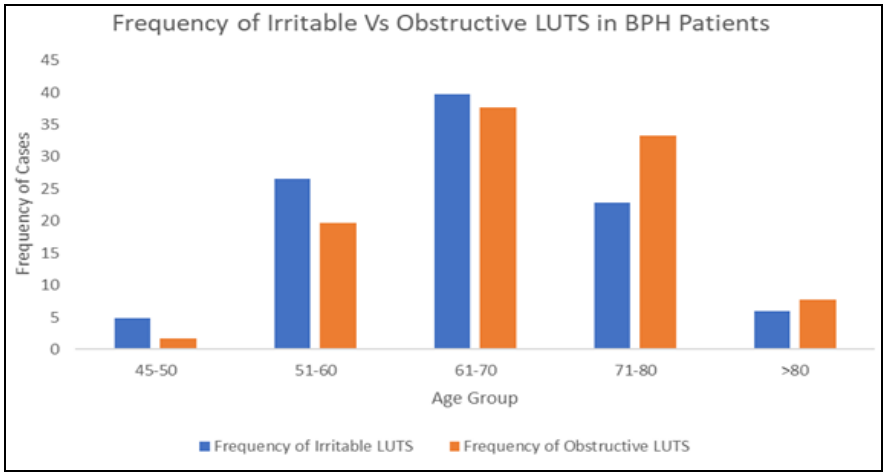

FIG. 3: FREQUENCY OF IRRITABLE VS OBSTRUCTIVE LUTS ACROSS VARIOUS AGE GROUPS

Table 3 and **Fig. 3** represents the frequency of irritable and obstructive lower urinary tract symptoms across the selected age groups. In the 45-50 age group, 4 participants exhibit irritable LUTS, while 2 participants experience obstructive LUTS. This provides an initial insight into the prevalence of different types of LUTS in the early age range.

In the 51-60 age group, 22 participants present with irritable LUTS, while 23 participants report obstructive LUTS. The comparable numbers in both types of symptoms suggest a potentially balanced distribution across these middle-aged individuals. Among the participants falling under the category of age group 61-70 involves 33 individuals with irritable LUTS, whereas 44 individuals with the symptoms of obstructive LUTS. This age range exhibits a higher prevalence of both types of LUTS, with obstructive LUTS being slightly more prevalent. In the 71-80 age group, 19 participants report irritable LUTS, while 39 individuals present with obstructive LUTS.

This age range reflects a noticeable increase in the prevalence of obstructive LUTS compared to irritable LUTS. For participants aged over 80, 5 individuals experience irritable LUTS, and 9 individuals report obstructive LUTS. This older age group demonstrates a consistent pattern with a higher prevalence of obstructive LUTS. Given the pattern on the types of LUTS, obstructive LUTS exhibit higher prevalence in comparison to irritable LUTS.

Statistical Analysis using Anova-Single Factor:

TABLE 4: COMPARING THE PROBABILITY OF IRRITABLE VS OBSTRUCTIVE LUT

ANOVA-Single Factor						
Source of Variation	***SS***	***df***	***MS***	***F***	***P-value***	***F crit***
Between Groups	115.6	1	115.6	0.479072	0.508431	5.317655
Within Groups	1930.4	8	241.3	-	-	-

Null Hypothesis: There is no significant association between the irritable and obstructive LUTS. Here, we prove that there is no significant association between the irritable and obstructive LUTS, i.e., we accept the null hypothesis, as the F value is >0.05.

Average Quality of Life based on the IPSS Score:

TABLE 5: AVERAGE QUALITY OF LIFE BASED ON THE IPSS SCORE

Age group	Average Quality of Life based on the IPSS Score
45-50	2.5
51-60	3.06
61-70	3.84
71-80	4.06
>80	4.5

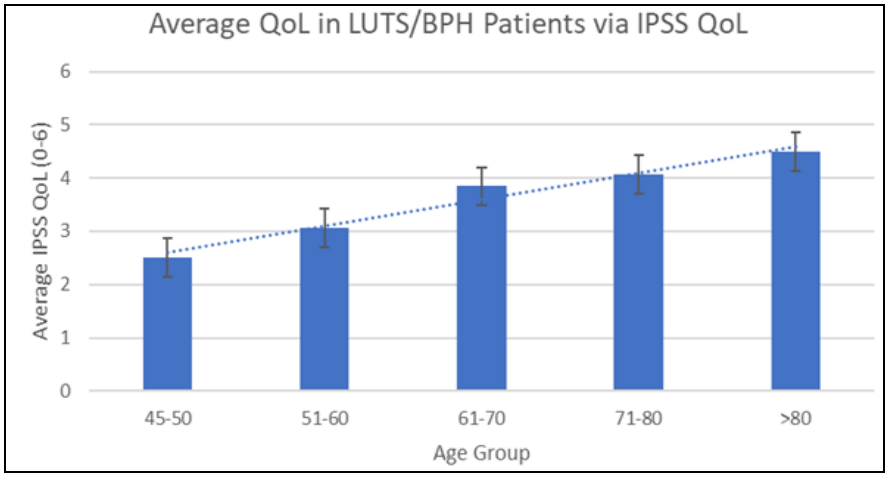

FIG. 4: AVERAGE QUALITY OF LIFE BASED ON THE IPSS SCORE

Table 5 and **Fig. 4** represents the average quality of life of the study participants based on the IPSS. In the 45-50 age group, participants report a QoL score of 2.5, indicating a relatively favourable quality of life.

Moving into the 51-60 age range, the QoL score increases slightly to 3.07, reflecting a potential moderate impact of Lower Urinary Tract Symptoms (LUTS) on participants' quality of life. Among individuals aged 61-70, the QoL score further rises to 3.84, suggesting an increased influence of LUTS on the perceived quality of life.

In the 71-80 age group, the QoL score reaches 4.07, suggesting a considerable impact on participants' quality of life. Participants over 80 report the highest QoL score at 4.5, highlighting a pronounced negative effect of LUTS on their quality of life.

As the age increases, the quality of life of a patient with LUTS/BPH has significantly decreased, leaving its impact on the patient's daily life. These QoL scores help to improve the safety and well-being of the patient's life, by providing tailored treatment with proper life-style changes. If the patient's QoL is highly affected, then performing a surgery might be useful. Standard Error Observations

Statistical Analysis using Multiple Regression Analysis:

TABLE 6: MULTIPLE REGRESSION ANALYSIS

Regression Statistics	
Multiple R	0.643529704
R Square	0.41413048
Adjusted R Square	-0.17173904
Standard Error	0.869432165
Observations	5

TABLE 7: MULTIPLE REGRESSION ANALYSIS

	Coefficients	Standard Error	t Stat	P-value
Intercept	3.38640769	0.71060167	4.76555	0.04132
Irritable LUTS	-0.075810912	0.08024041	-0.9448	0.44449
Obstructive LUTS	0.063214335	0.05422291	1.165823	0.36391

Multiple Regression analysis was performed to determine the association between dependent and independent variables. They are used in clinical practice and to aid in diagnosis to prescribe proper treatment and predictable outcomes.

QoL has been taken as the dependent factor, whereas the LUTS score of both types has been accepted as an independent variable. Correlation coefficient (R2 = 0.999): if R2 < 0.9, it is non-linear. From the analysis, we observe that the R2 value = 0.41413048, which implies it is a non-linear distribution. Anova table in the regression analysis shows the reliability of our model.

The most important part of the regression analysis 'p' value = (< 0.05) observed from the table shows that we can reject the null hypothesis and say this particular independent variable significantly improves the fit of the model, i.e., there is an association between dependent and independent variables.

IPSS Percentile:

TABLE 8: IPSS PERCENTILE

Severity of LUTS/BPH based on IPSS Score	No of Participant (IPSS Percentile)
Mild	10 (5%)
Moderate	97 (48.50%)
Severe	93 (46.50%)

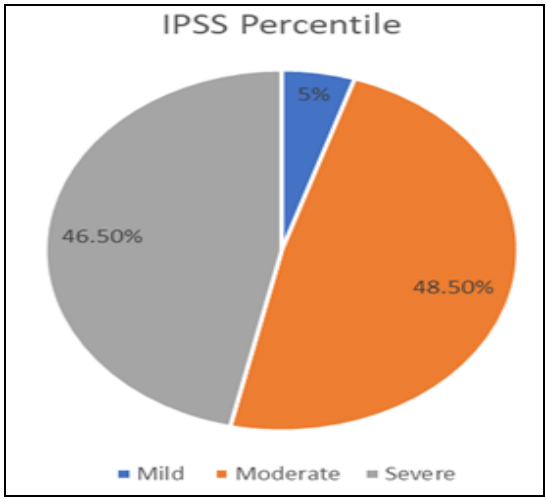

FIG. 5: IPSS PERCENTILE

Based on the IPSS, the symptoms can be classified into three types, mild (1-7), moderate (8-19) and severe (20-35). In our study, the severity of lower urinary tract symptoms was evaluated based on IPSS. As per **Table 8** and **Fig. 5**, there were only 5% of participants suffering from mild symptoms, whereas the maximum participants fit into the moderate and severe category of LUTS/BPH. The overall observation on the severity revealed that there were 48.50% of participants suffering from moderate LUTS and 46.50% of study participants suffering from severe LUTS. In overall selected participants, the severity of the LUTS goes from moderate to severe.

Glycaemic Range in Different Age Groups:

TABLE 9: GLYCAEMIC RANGE IN DIFFERENT AGE GROUPS

Age Group	Glycaemic Range				
	<140 mg/dl	140-199 mg/dl	200-299 mg/dl	300-399 mg/dl	>400 mg/dl
	3	3	0	0	0
	5	10	21	10	0
	2	3	20	32	20
	1	6	7	40	16
	0	4	1	8	1

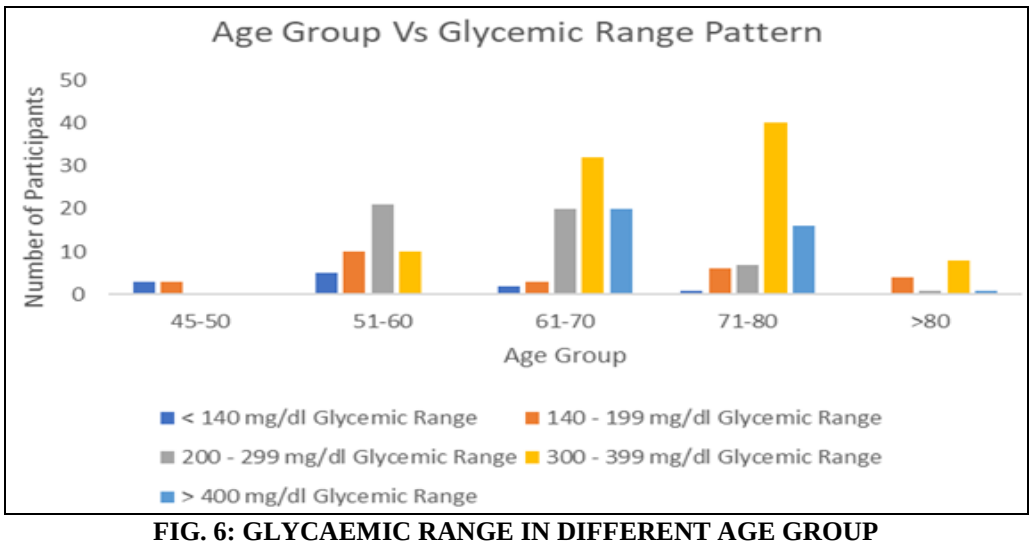

FIG. 6: GLYCAEMIC RANGE IN DIFFERENT AGE GROUP

In **Table 9** and **Fig. 6**, the data outlines the distribution of participants across different age groups concerning their respective glycaemic ranges, categorised in milligrams per decilitre (mg/dl). The prominent age group affected is the participants between 61-70 years age limit. The maximum participants affected are within the glycaemic range of 300-399 mg/dl.

Glycaemic Range vs IPSS Score:

TABLE 10: GLYCAEMIC RANGE VS IPSS SCORE

Glycaemic Range	IPSS Score		
	Mild	Moderate	Severe
<140 mg/dl	4	6	1
140 - 199 mg/dl	4	9	11
200 - 299 mg/dl	2	37	9
300 - 399 mg/dl	0	31	54
>400 mg/dl	0	15	17

The **Table 10** and **Fig. 7** represent the distribution of the severity of lower urinary tract symptoms across the glycaemic index. People with normal random blood glucose levels, the majority of participants experience either mild or moderate LUTS based on the IPSS score. Only a small fraction reports severe symptoms.

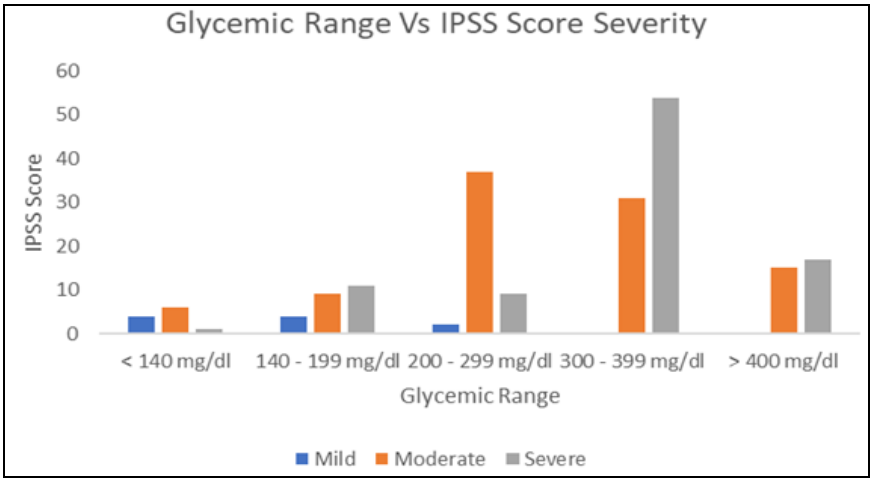

FIG. 7: GLYCAEMIC RANGE VS IPSS SCORE

In pre-diabetic participants range, a higher number of participants report moderate to severe LUTS. The distribution indicates an increasing prevalence of moderate to severe symptoms as glycaemic levels rise. This could imply a significant correlation between elevated blood glucose levels and the severity of urinary symptoms. In diabetic range 1 shows a substantial increase in the number of participants reporting moderate symptoms. While severe symptoms were present, they are less prevalent compared to the moderate category. This might suggest a transition phase where individuals with higher glycaemic levels was more likely to experience moderate rather than severe LUTS. In diabetic range 2, the absence of participants with mild symptoms was notable. The majority report moderate to severe symptoms, with a substantial proportion experiencing severe symptoms. This indicates a potential association between elevated blood glucose levels and a higher likelihood of severe LUTS. In the diabetic range 3, no participants report mild symptoms. A significant number of participants report moderate and severe symptoms, suggesting that individuals with very high blood glucose levels or glycaemic range were more prone to experiencing moderate to severe urinary symptoms. The data implies a correlation between elevated blood glucose levels and the severity of LUTS, with a trend towards more severe symptoms as glycaemic levels increase. The study results help the clinicians in tailoring management strategies for individuals with BPH, considering their glycaemic control status.

Frequency of Symptoms among Population:

TABLE 11: FREQUENCY OF SYMPTOMS AMONG POPULATION

Symptoms	Frequency among participants
Incomplete Emptying	26 (13%)
Frequency	69 (34.5%)
Intermittency	101 (50.5%)
Urgency	51 (25.5%)
Weak Stream	101 (50.5%)
Straining	22 (11%)
Nocturia	48 (24%)

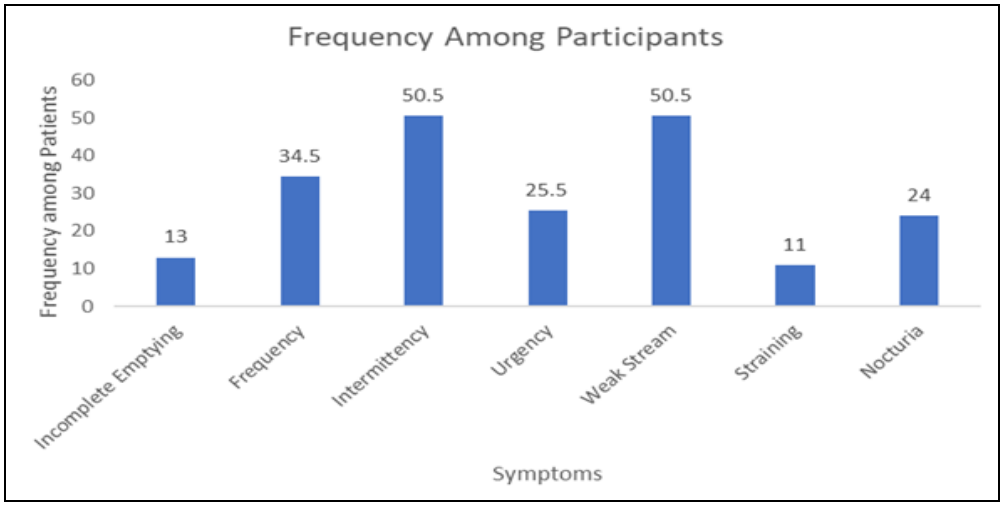

FIG. 8: FREQUENCY OF SYMPTOMS AMONG POPULATION

As per **Table 11** and **Fig. 8,** the most observed symptom among the study population is weak stream and intermittency with the frequency of 50.5%. While the frequency and urgency stand out as the second and third most common symptom across the study population with the frequencies of 34.5% and 24.5%. The least common symptom across the study population is straining.

CONCLUSION: In conclusion, our prospective observational study involving 200 participants diagnosed with LUTS/BPH provides valuable insights on the evaluation of the types of lower urinary tract symptoms in BPH patients. The predominant age group of 61-70 years exhibited the highest prevalence of both LUTS and glycaemic variations. Obstructive LUTS of frequency 58.5% were consistently more prevalent than irritable LUTS across all age groups, aligning with existing literature. The severity of LUTS, evaluated through the IPSS, indicated a substantial proportion of participants experiencing moderate to severe symptoms. Also, the LUTS/BPH has affected the QoL of the participant. As the age increases, the quality of life of a patient with LUTS/BPH has significantly decreased. Through multiple regression analysis, we established a significant association between Quality of Life (QoL) and LUTS scores, with an R2 value of 0.41413048 indicating a non-linear distribution. The 'p' value (< 0.05) in the ANOVA table confirms the effectiveness of the model hence the null hypothesis can be said to be rejected and it can be concluded that there is a correlation between QoL and LUTS scores. In addition, it is plausible to state that the higher the blood glucose levels the more severe the LUTS, reinforcing the call for optimal blood sugar management in BPH treatment. Many participants, especially smokers and alcohol drinkers, indicated sociodemographic factors that affirm the importance of lifestyle medicine in the management of LUTS/BPH. The study shows that weak stream and intermittency were among the most reported symptoms across the population, thus it is crucial to manage these symptoms in benign prostatic hyperplasia. Overall, our study contributes to a comprehensive understanding of the multifaceted factors influencing the presentation and management of LUTS/BPH in a diverse participant population.

Author Contributions Statement: SP had done work on title selection, plan of work, methodology and statistical analysis. AN, BY, MN, NR contributes for data collection, analysis of data and documentation.

Ethical Committee Approval: Not applicable

Informed Consent: Yes, because we have to collect the data from the patients through Questionnaire form.

Funding: Funding is not applicable.

CONFLICTS OF INTEREST: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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