# QUALITY OF LIFE OF BENIGN PROSTATIC ENLARGEMENT PATIENTS UNDERGOING TREATMENT WITH TAMSULOSIN AT MUHIMBILI NATIONAL HOSPITAL

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**Department of Surgery**

# QUALITY OF LIFE OF BENIGN PROSTATIC ENLARGEMENT PATIENTS UNDERGOING TREATMENT WITH TAMSULOSIN AT MUHIMBILI NATIONAL HOSPITAL

**By**

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**A dissertation submitted in Partial Fulfillment of the Requirements for Degree of Masters of Medicine (Urology) of the**

**Muhimbili University of Health and Allied Sciences**

**October, 2017**

## CERTIFICATION

The undersigned certifies that he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **"*Quality of Life for Benign Prostatic Enlargement Patients Undergoing Treatment with Tamsulosin at Muhimbili National Hospital*"** in (partial) fulfillment of the requirement for the degree of Master of Medicine (Urology) of the Muhimbili University of Health and Allied Sciences.

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**Prof. Muhsin Aboud**

Supervisor

_____

Date

## DECLARATION AND COPYRIGHT

I, **Baraka Christopher Ngaja,** declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

**Signature: ……..** **Date:……..**

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## ABSTRACT

**Introduction:** Benign prostatic enlargement (BPE) is a condition that most commonly occurs in aging males between the ages of 50 to 90years.The condition cause slower urinary tract symptoms (LUTS) which is the most common presentation at various urological clinics. Most of the patients with mild to moderate symptoms diagnose dusing the international prostate symptom score (IPSS) are usually treated medically. Tamsulosin is an alpha adrenergic receptor blocker mostly used in the medical treatment of BPE in Tanzania.

**Broad Objective:** To evaluate the quality of life and improvement of symptoms of BPE patients undergoing treatment with Tamsulosin at MNH.

**Methodology:** This was quasi pre and post-test Study design to investigate the quality of life of BPE patients undergoing treatment with Tamsulosin at MNH. A structured questionnaire was used to assess symptoms before treatment with Tamsulosin and three months after treatment, evaluation included improvement of symptoms and quality of life, and side effects associated with use of Tamsulosin. Patients were followed up monthly for three months.
Data were analyzed by SPSS version 20; Chi-square test was conducted to determine the association between the proportions of social demographic characters, IPSS, quality of life and side effects. The $p< 0.05$ was considered statistically significant.

**Results: A** total of 192 patients were enrolled in the study, 39 patients were drop outs from the study, due to incomplete follow up, 153 patients were available for analysis after three months. Mean age was 67.67(±6.64). There was an improvement in symptoms after three months of use of Tamsulosin from Initially 3.3%, mild, 96.7% moderate symptoms to61.45% had (no or mild symptoms), 32.7% (moderate symptoms), and5.9% (progressed to severe symptoms)

In terms of quality of life before treatment50.3% of participants were dissatisfied with their quality of life, and 49.7% of participants considered their quality of life to be terribleor unhappy. Three months after treatment 61.4% of participants had either felt delighted, pleased or happy with their quality of life and 32% had remained dissatisfied with their quality of life

while 6.5% had still experienced terrible or unhappy quality of life. Improvement of symptoms and QOL were not associated with prostate size or residual urine volume.
Enumerated side effects, with the use of Tamsulosin, were as follows; headache (9.8%), dizziness (9.2%), poor ejaculation (2.6%) and nausea (2.6%).

**Conclusion:** Both Quality of life and international prostate symptom score improved 3 months after Tamsulosin use. In this study prostate sizeand residual volume were not associated with outcome on use of the drug. Few side effects were observed during the treatment of BPE with the use of Tamsulosin.

**Recommendations:** Tamsulosin should continue to be used as a medical therapy for patients with benign prostatic enlargement with lower urinary tracts symptoms given the improvement in both qualities of life and prostate symptoms

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| BPE | Benign Prostatic Enlargement |
| BPH | Benign Prostatic Hyperplasia |
| HRQOL | Health Related Quality Of Life |
| IPSS | International Prostatic Symptoms Score |
| LUTS | Lower Urinary Tract Symptoms |
| MMED | Masters of Medicine |
| MNH | Muhimbili National Hospital |
| MUHAS | Muhimbili University of Health and Allied Sciences |
| OPD | Outpatient Department |
| PSA | Prostatic specific antigen |
| Qmax | Peak urinary flow rate |
| QOL | Quality of life |
| TURP | Trans urethral resection of prostate |
| UFM | Uroflowmetry |
| UK | United Kingdom |
| USA | United States of America |

## DEFINITION OF KEY TERMS

**Quality of life** – Person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment

**Symptoms severity**

1) **Mild** - Refers to international prostate symptoms score between 1-7
2) **Moderate -** Refers to international prostate symptoms score between 8—19
3) **Severe -** Refers to international prostate symptoms score between 20---35

# CHAPTER ONE

## 1.0 INTRODUCTION

Benign prostatic enlargement (BPE) is a common condition affecting aged men. Several studies have shown that the adrenergic nerves innervating prostatic smooth muscle may contribute to the dynamic component of bladder outlet obstruction [1,2] . Since 1976, alpha-blockers have been used to treat the obstructive symptoms and improve urinary flow rate in bladder outlet obstruction due to BPH. [3,4,5,6] .Alpha-receptors are further grouped into α1 and α2subtypes. The α1 receptors are located primarily in the smooth muscle of the prostate gland and bladder neck[7,8]. Many α-adrenergic-receptor antagonists have been evaluated in the treatment of LUTS; all of these agents were initially developed and approved for the treatment of hypertension, until the development of Tamsulosin.

Tamsulosin, A selective $\alpha_{1A}$-adrenergic-receptor antagonist, has been shown to improve lower urinary tract symptoms associated with benign prostatic hyperplasia. It has a better side effect profile than earlier α-adrenergic-receptor antagonists, which were initially developed as antihypertensive agents. Clinical trials with Tamsulosin show high tolerability for the 0.4 mg dose and no significant interaction with other antihypertensive medications.

Tamsulosin is a more selective $\alpha_{1A}$ subtype antagonist, which maintains the α-antagonist effect on the prostatic capsule and bladder neck but has no effect on the vascular system and blood pressure. In fact, Tamsulosin is ineffective and not indicated in the treatment of hypertension. Tamsulosin has a favorable side effect profile in regard to problems related to hypotension and dizziness compared to those of terazosin and doxazosin.

Tamsulosin is the primary therapy for patients with BPE, presenting with LUTS, most widely used by clinicians as the first line agent to treat this common condition in aging males.

In testing the efficacy of Tamsulosin, most studies use IPS score form as assessment tool so they can assess the severity of symptoms and to see whether there is improvement in symptoms as well as quality of life. Until the 1990s, transurethral resection of the prostate (TURP) was the mainstay of therapy for BPH. In 1987, over 250,000 TURPs were performed

in the United States; however, with the advent of effective medical therapies and alternative surgical interventions, the number of TURPs had plummeted to less than 90,000 per year by the year 2000.

IPSS form has seven questions to assess the severity of symptoms and one about QOL.
The main purpose of the present study was to evaluate the, QOL, side effects and factors associated with improvement of symptoms in the treatment of BPE patients with Tamsulosin.

**1.1 Literature Review**

Benign prostatic enlargement (BPE) is a common disease affecting aged men commonly above 50 years. It has been shown that the adrenergic nerves innervating prostatic smooth muscle may contribute to the dynamic component of bladder outlet obstruction [1,2] . Since 1976, alpha-blockers have been used to treat the obstructive symptoms and improve urinary flow rate in bladder outlet obstruction due to BPH. [3,4,5,6]Alpha-receptors are further grouped into α1 and α2subtypes. The α1 receptors are located primarily in the smooth muscle of the prostate gland and bladder neck[7,8].

Tamsulosin is third thealpha 1 blocker to be approved for the treatment of BPH. It was brought to market as the first subtype selective alpha 1 antagonist for the treatment of BPH. Tamsulosin, was supported by binding studies, which showed that it is approximately more selective for the alpha 1a versus alpha 1b subtype [9,10].There was no demonstrable subtype selectivity of Tamsulosin for the alpha 1a versus alpha 1d subtypes. The modest receptor selectivity of Tamsulosin is not sufficient to result in a clinically meaningful advantage. Typically, clinical advantages attributed to pharmacological selectivity require receptor selectivity well beyond the tenfold difference observed with Tamsulosin.

Studies on Tamsulosin efficiency and quality of life for the treatment of symptomatic BPE patients[11,12],show that both 0.4 and 0.8 mg of Tamsulosin achieved clinically significant improvements in symptom scores and quality of life. However, the prescribing community placed a greater value on eliminating the dose response at the expense of increasing the incidence of retrograde ejaculation as a result of relaxation of the bladder neck. This study also is correlated with the study done by Abrams and associates, which was undertaken to establish the safety and efficacy of Tamsulosin,[13].One hundred sixty nine patients with symptomatic BPE were enrolled In this study, 126 patients were eventually randomized to placebo, 0.2 mg, 0.4 mg, or 0.6 mg of Tamsulosin once daily. Boyarsky symptom scores were improved with all dosages of Tamsulosin. The greatest reduction in symptoms occurred in those on either 0.4 mg (−4.1) or 0.6 mg (−4.3), compared to 0.2 (−3.4) and placebo (−2.9). The two highest dosages also provided the greatest improvement in peak urinary flow rates

$Q_{max}$ compared to placebo, with improvements of 2.2 and 2.4 mL/sec for the 0.4 mg and 0.6 mg dosages, respectively.

Also the tolerance of Tamsulosin among several groups of populations has been studied and pointed out ,the results from two observational surveillance studies in German, of which 9507 and 9858 men treated with Tamsulosin demonstrated excellent tolerability among all groups of patients [14]. Ninety-four percent of patients in one study and 97% of those in the other reported either good or very good tolerability. Also it has been shown that Patients with chronic diseases like diabetes, hypertension and coronary artery disease reported a slightly poorer tolerability than those without it, but global tolerability was still rated as good or very good in more than 90% of patients questioned in one study and 95% of those in the other.

In a study done by Suzuki and colleague in Japan[15] which examine efficiency of Tamsulosin treatment on disease-specific and quality of life (QOL) in men with clinically diagnosed benign prostatic hyperplasia (BPH), the improvement of QOL scores with International prostate symptom score (I-PSS) was prospectively analyzed. Patients received Tamsulosin for 12 weeks. Other objective variables, such as prostate size, and post void urinary volumes were alsoevaluated. After 12 weeks where the findings are decrease in I-PSS of 27% compared with baseline. All questionnaires in the I-PSS showed improvement after Tamsulosin treatment and the I-PSS was improved from 4.51 +/- 1.14 to 3.17 +/- 1.38 at 12 weeks after Tamsulosin administration.

In Akin and Glumez study[16], investigate if effects of Tamsulosine 0.4 mg on uroflowmetry parameters would predict treatment response at the third month. Where men over 40 years old with complaints of lower urinary tract symptoms associated with benign prostatic hyperplasia were studied. All parameters were recorded as baseline, and changes in the uroflometry (UFM)parameters, IPSS and QoL were evaluated in clinical visits. As a total, 48 men (mean 60.17 ± 1.18 years) were recruited. There was a significant increase in maximum urine flow rate and average urine flow rate and decrease in PVR from baseline with the first dose of Tamsulosin as well as and month of treatment. IPSS and QoL scores significantly improved at the first month in correlation with UFM parameters. Tamsulosintreatment was effective in 33 (68.7 %) patients at the first administration and 35 (72.9 %) at the third month. The same was

observed in the study by Lin and his colleagues study [17] aimed to evaluate safety and efficacy of Tamsulosin tablets in Taiwanese patients with BPH. The study enrolled 45 patients over age 50 years. All 45 patients received Tamsulosin orally daily and were evaluated at weeks 0, 4, 8, 12 of the 12-week treatment period. Tamsulosin efficacy was evaluated by International Prostate Symptom Score (I-PSS). Patients' mean ± SD age was 62.47±7.77. Statistically significant changes from baseline were found in post-test I-PSS and quality of life. I-PSS decreased from (Mean ± SD), 14.30±9.34 to 6.73±0.88 at patients' final visit. Statistically significant increases in mean maximum flow rate and mean flow rate were found over 12-week study period. No adverse events were reported.

Alpha blockers have a low incidence of sexual side-effects. However, they can cause reversible ejaculatory dysfunction, in particular retrograde ejaculation. The mechanism for sexual dysfunction relates to the antagonism of the alpha receptors, located in the smooth muscle of the bladder neck, preventing closure of the bladder neck, allowing for retrograde ejaculation during climax [18]. This is also correlated with Osman and colleagues study[19]which aimed at safety, efficacy and quality of life of silodosin 8 mg, and a 0.4mg Tamsulosin once daily in men with LUTS/BPH.A total of 500 patients were enrolled in the 9-month open-label study. Treatment-emergent adverse events were experienced by 33.4% patients. Ejaculation dysfunction was the most common adverse effects (9.0%) but led to study discontinuations in only 1.6% of patients. Dizziness without orthostatic hypotension occurred in 0.8%. A marked reduction in total IPSS (-2.7 ± 3.8) was documented at the first visit. Improvements were maintained throughout the study. QoL also improved.

Compared with other treatment modalities studies has also been done, Hadi. and Aminsharifi[20] evaluated the impact of transurethral resection of the prostate (TURP) versus selective α-adrenergic blocker treatment on health-related quality of life (HRQOL) in men with clinically diagnosed benign prostatic hyperplasia. A total of 219 patients with lower urinary tract symptoms (LUTS) caused by BPH were recruited in this study. Treatment modalities consisted of standard TURP (n = 104) and Tamsulosin medical treatment (n = 115). HRQOL was assessed by SF-36-Item Health Survey. LUTS were estimated by The

International Prostate Symptom Score. Baseline characteristics were similar in both groups except for the duration of disease before treatment that was longer in TURP group. Both treatments resulted in statistically significant improvements from pre-treatment in all scales of QOL after 4 weeks, with no significant differences observed between the two groups.

## 1.2 Problem Statement

Benign prostatic enlargement is one of the major causes of urinary bladder outlet obstruction among patients seeking urological services at Muhimbili National Hospital. On average 400 BPE patients are medically treated at MNH in a year, yet the quality of life with BPE patients undergoing treatment with Tamsulosin is not well documented. There are many medical treatment options available for BPE patients, Tamsulosin is one of them. Those treatment options need to be individualized, symptoms improvement and outcome on quality of life on medical treatment in BPE patients' needs to be evaluated special. The Outcome of any treatment option to special patient population may not be the same. At MNH there is little documentation of outcomes on quality of life with patient undergoing treatment with Tamsulosin.

## 1.3 Study Rationale

BPE is a major problem which involves patients of older age, commonly above 50 years, yet there are few studies which have been conducted to address the problem in MNH, despite having many studies about treatment outcome and quality of life worldwide. This study for the first time will document the treatment outcome and quality of life for BPE patients undergoing medical treatment with Tamsulosin alone at MNH. In relation to treatment outcome also there is a need to inform on the factors that are associated with treatment outcome, so that medical treatment could be individualized.

## 1.4 Research Questions

1. Do urinary symptoms and quality of life improve with the use of Tamsulosin for BPE patients at MNH?
2. What are the side effects of Tamsulosin for BPE patients at MNH?
3. What are the factors associated with improvement in symptoms with the use of Tamsulosin?

## 1.5 Objectives

### 1.5.1. Broad Objectives

To evaluate quality of life, side effects and factors associated with improvement of symptoms in the treatment of BPE patients with Tamsulosin at Muhimbili national hospital.

### 1.5.2 Specific Objectives

1. To compare the IPSS score and quality of life before and after treatment with Tamsulosin among patients with BPE at MNH.
2. To determine the factors associated with improvement of IPSS and quality of life on the use of Tamsulosin among patients with BPE at MNH.
3. To determine the magnitude and kind of side effects associated with the use of Tamsulosin among patients with BPE at MNH.

# CHAPTER TWO

## 2.0 MATERIALS AND METHODS

### 2.1 Study design

This was, pretest and post-test quasi experimental study that involved patients presenting to urology clinics and are newly diagnosed with BPE and underwent treatment with Tamsulosin alone during the period of study. Patients were followed up for the period of 3 months. Data was collected through personal interviews and from patient case notes records focusing on the treatment outcome and quality of life during follow up period and transferred on to the questionnaire. Some patients were contacted over the phone for IPS scoring on their micturation habit during follows up while others were assessed as they came to the clinic.

### 2.2 Study area

The study was conducted at MNH, which is the national referral hospital receiving patients from district and regional hospitals within the country but in addition it serves as city hospital by receiving more patients from the three municipalities in the city and nearby district hospitals of Coast Region due its geographical location. The hospital is a teaching hospital for MUHAS students, both undergraduates and postgraduates located within Dar es Salaam city, which has a population of about 4 million people. All the clinical visits, interview, investigation and documentations were performed at urology clinics at MNH. There are two days in a week which the urology clinics are operating.

### 2.3 Study population

The study included outpatients attending urology clinics at MNH, within the period of study, from September 2015 to May 2016 involving newly diagnosed BPE patients and who are Tamsulosin naive. New patients were recruited in the study and were followed up for three months. All patients satisfying medical treatment requirement were included.

### 2.4 Sampling technique

All patients who came to urology clinic with diagnosis of benign prostatic enlargement and have the criteria for medical treatment during the period of study were initiated on treatment

and were followed up until the sample size was reached. After three months of treatment, those who improved were continued with treatment and followed up at urology clinic.

**2.5 Inclusion criteria**

The study included the newly diagnosed patients with BPE who fit the criteria for medical treatment. The criteria included LUTS, no previous history of medical treatment, no complications like retention of urine, stone, hydronephrosis, or hematuria,

**2.6 Exclusion criteria**

This study excluded all the patients with co morbidities like diabetic mellitus (DM), neurological diseases and any patients on treatment with alpha blockers for any other medical indication.

**2.7 Sample size**

Formula; $N= \frac{Z^2p(100-p)}{\sum 2}$

Where;

N= sample size

Z= 1.96

$\sum$= margin of error;

P=0.45 (prevalence on outcome for quality of life for BPH patients treated with Tamsulosin)

$Z= \frac{(1.96)^2 \times 0.45\ (100-0.45)}{0.95}$

Z= 190

Therefore, Estimated Sample Size was 190 patients.

## 2.8 Patient recruitment and follow up

### 2.8.1 Recruitment procedure,

Patients were captured from the outpatient urology clinic of Muhimbili national hospital, the patient who agreed to buy the medication for at least a period of three months and agreed to sign informed consent were recruited in the study. Tamsulosin is used as a standard of care for patient with BPE; the drug is also licensed to be used worldwide. In this study there was no intervention and instead it was focused on already prescribed patients with Tamsulosin. The newly diagnosed patients with BPE by the doctors at the urology clinics in MNH were fully investigated and data was collected through the special forms. There was an initial filling of the form, at the start of the treatment and after three month of treatment, where a comparison of IPS score and quality of life before and after three months was made. Also information on the side effects was obtained at the end of three months of treatment.

## 2.9 Investigation procedure

Both imaging investigation and blood investigation were observed and included;

1. Full blood picture
2. Prostatic specific antigen
3. Serum creatinine
4. Urinalysis
5. Abdominal pelvic ultrasound where by residual urine volume, prostate size was recorded. Patients with hydronephrosis or stone were excluded.
6. Blood pressure was recorded on each visit at the clinic.

## 2.10 Data collection procedures

Information about the study was given to the doctors and nurses in urology clinics in MNH.

1. Diagnosis was made by the doctors attending patients in the respective urology outpatient clinics in MNH
2. The case notes of patients who satisfied medical treatment requirement were reviewed and the information on socio-demographic factors, main complaint, investigation findings, management given and any complication was collected.

Collection of information was by face to face interview and filled in the structured questionnaire.

The International Prostate Symptom Score (I-PSS) is based on the answers to seven questions concerning urinary symptoms and one question concerning quality of life. Each question concerning urinary symptoms allows the patients to choose one out of six answers indicating increasing severity of the particular symptom.

The answers are assigned points from 0 to 5. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic). Monthly data collection through IPS scores system as the patient's attendance in the clinics

The IPS score refer to the following urinary symptoms:

1. Incomplete emptying
2. Frequency
3. Intermittency
4. Urgency
5. Weak Stream
6. Straining
7. Nocturia

Question eight refers to the patient's perception on quality of life

Data was collected through a questionnaire. The questionnaire was filled before and after three months of treatment. The questionnaire included clinical data form, and the IPS score form, and quality of life score.

1. Clinical assessment included status of the symptoms, immediate and early side effects. Initial treatment and the date from start of treatment were noted.
2. All patients were followed up on monthly bases for general evaluation and not scored, where at 3$^{rd}$ months visit reassessment was done and scored, and then they were discharged from the study.

### 2.11 Data analysis

Datasheet used was coded, the information were entered to the Statistical Package for Social Science computer software (SPSS) version 20. Mean and standard deviations were used to summarize variables. P value was considered statistically significant if equal or less than 0.05. Results were analyzed and summarized and conclusions drawn. Means were compared before and after three months of treatment. Improvement (change) in IPSS and quality of life after 3months of treatment was documented and compared with any associated factors like prostate size, residual urine volume, and PSA.

### 2.12 Ethical Consideration

The proposal was discussed at different levels at MUHAS, and approved by the MUHAS Research and Publications Committee by giving the ethical clearance, patients were informed about the study; those who agreed and consented were included. . All patients' information was kept confidential. This was a minimal risk study. The involved intervention was an approved standard of care, the side effect, of Tamsulosin are known and not severe in other patient's populations.

# CHAPTER THREE

## 3.0 RESULTS

A total of 192 patients were recruited in the study,39patients were dropped out due to incomplete follow up and153 patients were able to be followed up for 12weeks and are included in the analysis. This makes the completion rate of 79.2% for all patients recruited in the study.

### Socio-demographic characteristics

**Table 1: The distribution of patient's demographic characteristics N=153.**

| Patient's demography | Number (N) | Variable | Cases | Percentage (%) |
|---|---|---|---|---|
| Age group | 153 | 50-69 | 78 | 51 |
| | | 70-89 | 72 | 47.1 |
| | | 90+ | 3 | 2 |
| | | Total | 153 | 100 |
| Level of education | 153 | No formal education | 30 | 19.6 |
| | | Primary education level | 100 | 65.4 |
| | | Secondary education | 21 | 13.7 |
| | | Higher education | 2 | 1.3 |
| | | Total | 153 | 100 |
| Patient`s occupation | 153 | Peasant | 116 | 75.8 |
| | | Formal employment | 19 | 12.4 |
| | | Petty trader | 14 | 9.2 |
| | | Unemployed | 4 | 2.6 |
| | | Total | 153 | 100 |

**Table 2: the table below shows symptoms severity as per international prostate symptoms score (IPSS) before and after treatment with Tamsulosin among BPE patients at MNH**

| **Treatment duration** | **Symptom severity** | | | | P-value ($X^2$) |
|---|---|---|---|---|---|
| | Mild (%) | Moderate (%) | Severe (%) | Total | |
| Before | 5(3.3) | 148 (96.7) | 0(0) | 153(100) | 0.019 |
| After | 94(61.4) | 50(32.7) | 9(5.9) | 153(100) | |
| Total | 99 | 198 | 9 | 306 | |

**Quality of life of the patients before and after three months of treatment with Tamsulosin:**

**Table 3a. The distribution of BPE patient's demographic characteristics with patient's quality of life before Tamsulosin treatment at Muhimbili National Hospital. N=153.**

| | | QOL BEFORE TREATMENT | | | |
|---|---|---|---|---|---|
| VARIABLES | | Dissatisfied | Unhappy and terrible | Total | P value(Pearson's X2) at 95 CI |
| Age groups | 50-69 | 48(31.4%) | 30(19.6%) | 78(51%) | |
| | 70-89 | 29(19%) | 43(28.1%) | 72(47.1%) | 0.007 |
| | 90+ | 0(0%) | 3(2%) | 3(2%) | |
| | Total | 77(50.3%) | 76(49.7%) | 153(100%) | |
| Level of education | No formal education | 15(9.8%) | 15(9.8%) | 30(19.6%) | |
| | Primary education level | 50(32.7%) | 50(32.7%) | 100(65.4%) | |
| | Secondary education | 11(7.2%) | 10(6.5%) | 21(13.7%) | 0.998 |
| | Higher education | 1(0.7%) | 1(0.7%) | 2(1.3%) | |
| | Total | 77(50.3%) | 76(49.7%) | 153(100%) | |
| Patient`s occupation | Peasant | 54(35.3%) | 62(40.5%) | 116(75.8%) | |
| | Formal employment | 13(8.5%) | 6(3.9%) | 19(12.4%) | |
| | Petty trader | 9(5.9%) | 5(3.3%) | 14(9.2%) | 0.153 |
| | Unemployed | 1(0.7%) | 3(2%) | 4(2.6%) | |
| | Total | 77(50.3%) | 76(49.7%) | 153(100%) | |

A total of 77patients (50.3%) were dissatisfied with their quality of life, and 76patients (49.7%) were unhappy and terrible with their quality of life before treatment, as the table 3a above shows in relation to different age groups ,level of education and participant's occupation. As expected age has influence on the quality of life before treatment.

**Table 3b: The distribution of BPE patient's demographic characteristics with patient quality of life after Tamsulosine treatment at Muhimbili National Hospital. N=153.**

| | | QOL SCORE AFTER TREATMENT | | | | |
|---|---|---|---|---|---|---|
| | | Pleased and happy | Dissatisfied | Unhappy and terrible | Total | Value(Pearson's $X^2$) at 95 CI |
| Age groups | 50-69 | 44(28.8%) | 29(19%) | 5(3.3%) | 78(51%) | |
| | 70-89 | 48(31.4%) | 19(12.4%) | 5(3.3%) | 72(47.1%) | 0.693 |
| | 90+ | 2(1.3%) | 1(0.7%) | 0(0%) | 3(2%) | |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |
| Level of education | No formal education | 14(9.2%) | 12(7.8%) | 4(2.6%) | 30(19.6%) | |
| | Primary education | 69(45.1%) | 26(17%) | 5(3.3%) | 100(65.4%) | |
| | Secondary education | 9(5.9%) | 11(7.2%) | 1(0.7%) | 21(13.7%) | 0.075 |
| | Higher education | 2(1.3%) | 0(0%) | 0(0%) | 2(1.3%) | |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |
| Patient`s occupation | Peasant | 74(48.4%) | 34(22.2%) | 8(5.2%) | 116(75.8%) | |
| | Formal employment | 9(5.9%) | 9(5.9%) | 1(0.7%) | 19(12.4%) | |
| | Petty trader | 9(5.9%) | 4(2.6%) | 1(0.7%) | 14(9.2%) | 0.773 |
| | Unemployed | 2(1.3%) | 2(1.3%) | 0(0%) | 4(2.6%) | |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |

After treatment with Tamsulosin for three months out of 153 patients94(61.4%) felt pleased and happy with their quality of life, and 49 (32%) patients were dissatisfied with their quality of life, and 10(6.5%) felt terrible and unhappy with their quality of life.

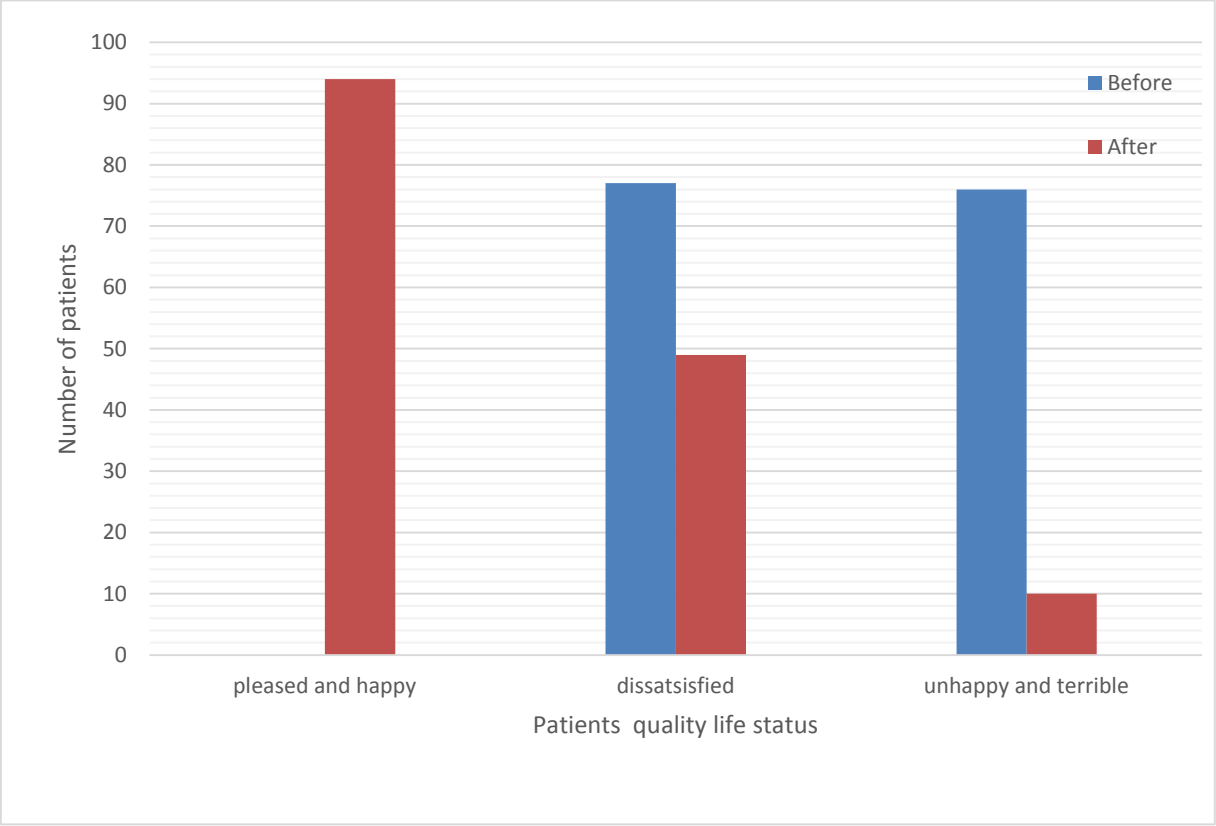


**Figure 1: The figure below shows the comparison of participant's quality of life before and after three months of treatment with Tamsulosin**

When compared with quality of life before treatment and after treatment it has been shown, that there was an improvement with perception of patient's quality of life after three months of treatment as the figure above shows.

**Factors associated with symptoms improvement on the use of Tamsulosin among patients with BPE at Muhimbili National Hospital.**

From the study, factors associated with outcome among patients with BPE were assessed whether they had an impact on outcome after the treatment with Tamsulosin. Neither of all factors assessed showed to be associated with the outcome after Tamsulosin use, Prostate size residual volume. Hence above factors showed no association in improvement of IPS score and quality of life, as the figure 3 and 4 below shows.

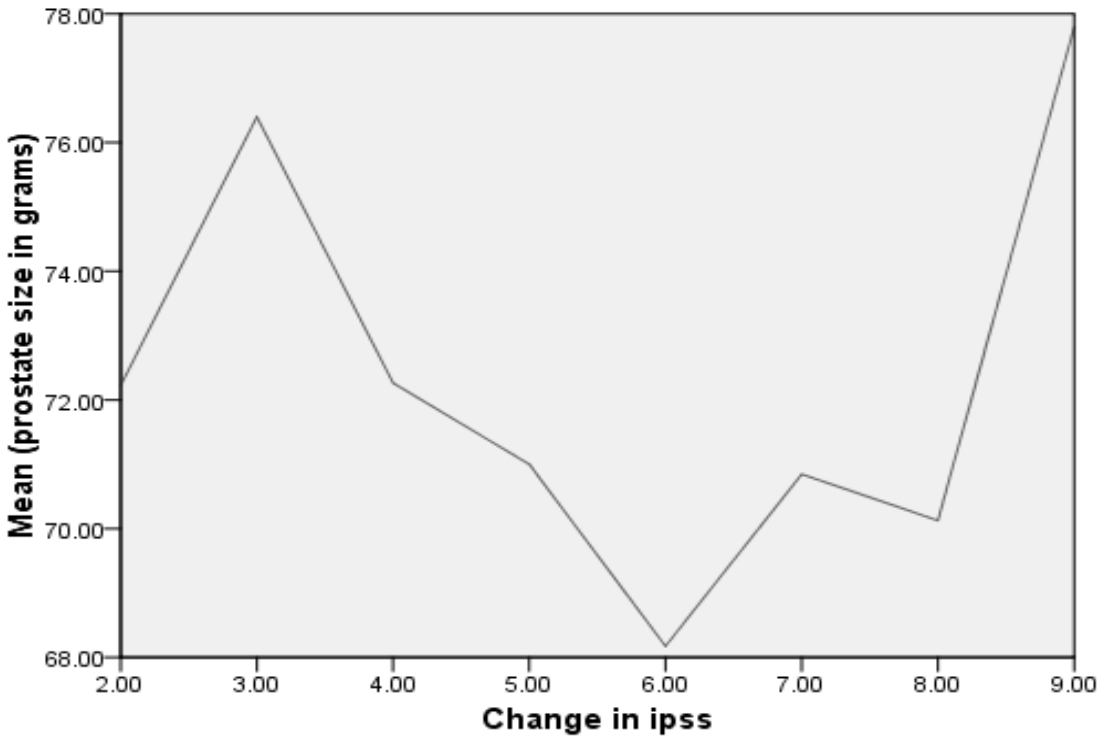


**Figure 2: Shows prostate size association with the change in IPSS on Tamsulosin use among BPE patients at MNH.**

**NB: specifically in figure 3 above the all cases with negative value of change in IPSS has been excluded during analysis.**

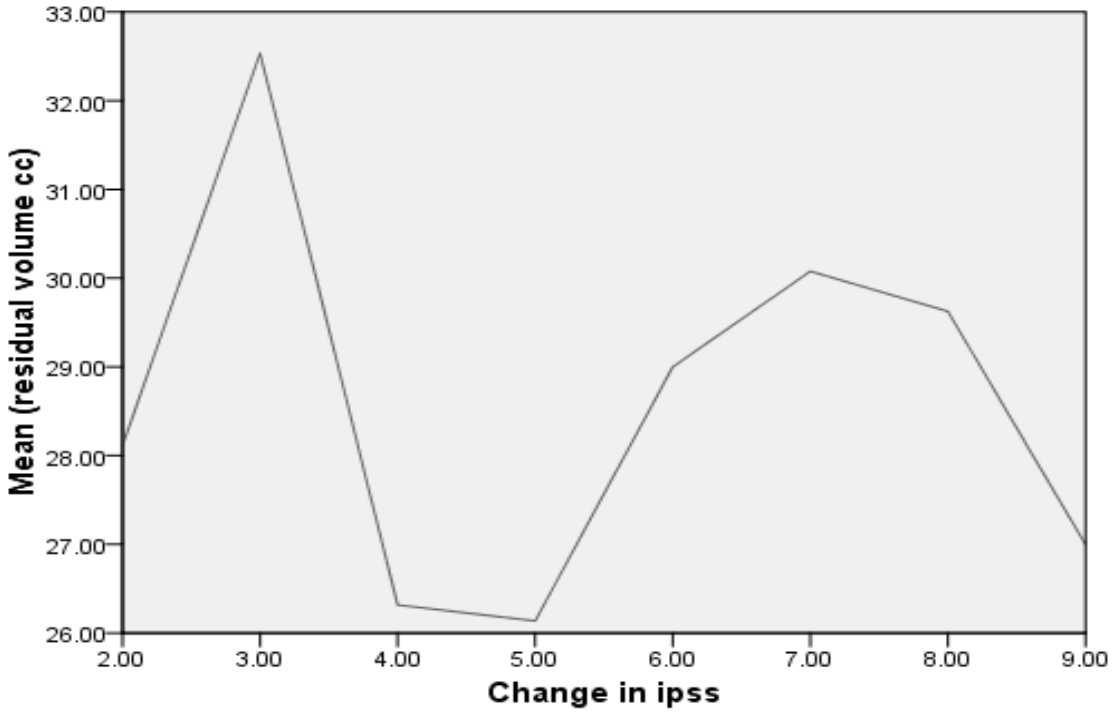


**Figure 3: Shows residual urine volume associated with change in IPSS on Tamsulosin use among BPE patients at MNH.**

**NB; specifically, in figure 4 above cases with negative change in IPSS values has been excluded from the analysis**

**F**rom above figure 4 it shows that there is no association between change in IPS score and residual urine volume

**The distribution of side effects with the use of Tamsulosin among patients with BPE at Muhimbili National Hospital.**

The table below shows dizziness, headache, poor ejaculation and nausea as a side effect occurred in BPE patients after use of Tamsulosin.

**Table 4: The distribution of the side effects with the use of Tamsulosin among patient with BPE at Muhimbili National Hospital N=153.**

| | | Quality of life score after treatment | | | | |
|---|---|---|---|---|---|---|
| | | Pleased and happy | Dissatisfied | Unhappy and terrible | Total | P value(Pearson's X2) at 95 CI |
| Dizziness | Yes | 11(7.2%) | 3(2%) | 0(0%) | 14(9.2%) | |
| | No | 83(54.2%) | 46(30.1%) | 10(6.5%) | 139(90.8%) | 0.319 |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |
| Headache | Yes | 12(7.8%) | 3(2%) | 0(0%) | 15(9.8%) | |
| | No | 82(53.6%) | 46(30.1%) | 10(6.5%) | 138(90.2%) | 0.25 |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |
| Poor ejaculation | Yes | 4(2.6%) | 0(0%) | 0(0%) | 4(2.6%) | |
| | No | 90(58.8%) | 49(32%) | 10(6.5%) | 149(97.4%) | 0.276 |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |
| Nausea | Yes | 4(2.6%) | 0(0%) | 0(0%) | 4(2.6%) | |
| | No | 90(58.8%) | 49(32%) | 10(6.5%) | 149(97.4%) | 0.276 |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |
| Hypotension | Yes | 2(1.3%) | 1(0.7%) | 0(0%) | 3(2%) | |
| | No | 92(60.1%) | 48(31.4%) | 10(6.5%) | 150(98%) | 0.898 |
| | Total | 94(61.4%) | 49(32%) | 10(6.5%) | 153(100%) | |

The side effects among 153 patients uses Tamsulosin for three months are 14 (9.2%) experienced dizziness, headache 15(9.8%), poor ejaculation 4patients (2.6%). Nausea 4patients (2.6%), and hypotension 3(2%).side effect are not statistically associated with quality of life

# CHAPTER FOUR

## 4.0 DISCUSSION

This study has shown all age groups of patients with benign prostatic enlargement in our ethnic population evidently show improvement of international prostate symptoms score and quality of life after three months of treatment with Tamsulosin use.

In this study majority of patients presenting with bladder outlet obstruction were ranging between 50 years and 69,This findings can be correlated with study done by Lin and colleagues[17], where patients with BPE and developed lower urinary symptoms were assessed., It was found that most of the patients are above the age 50 years , with mean age of 62.47 and standard deviation of (SD) 7.77

In this study patients with BPE who developed lower urinary tract symptoms were evaluated using validated international prostate symptoms score (IPSS) of which patients were assessed at weeks 0, 4, 8 and 12weeks, where at 12 weeks IPSS was evaluated and documented, and it was found that there is improvement of IPSS from baseline when compared after three months of treatment. Based on IPS score with Tamsulosin, initially 5patients (3.3%) had mild symptoms before treatment. (IPS score 0 to 7).and 148(96.7%) had moderate symptoms, with IPS score (8 to19). After three months of treatment 94patients (61.45%) had no or mild symptoms (0 to 8). And 50 patients (32.7%) had moderate symptoms score 9 to 19, and9patients (5.9%) had progressed to severe symptoms score (20 to 35). There was a significant overall improvement in patients symptoms after three months of Tamsulosin use *p=0.019*.This findings is similar to a study by Lin and colleagues[17] where,45 patients were enrolled in the study and used Tamsulosin for three months, at 12 weeks patients were scored using IPS score and I-PSS decreased from 14.30±9.34 to 6.73±0.88 at patients' final visit**,** and at post-test both showed statistically significance changes where *(p<0.001*) for both IPS score and quality of life.

In term of quality of life this study shows that there is a significant change in quality of life 3 months after use of Tamsulosin. From the assessment tool it was shown that before, patients had poor quality of life, as,77 (50.3%) of all patients in the study were dissatisfied with their quality of life, and 76(49.7%) of all respondents considered their quality of life to be either terrible or unhappy, as table 2 shows, and after three months of treatment with Tamsulosin most of the patients had quality of life improved where , 40 out 77 patients who claimed to be dissatisfied were happy and pleased with their quality of life. This significant positive response also was shown by those who claimed to be unhappy and terrible before treatment and that their numbers change from 76 to 54 that had improved quality of life, were happy and pleased after Tamsulosin use. After treatment, out of 153 patients, 94patients (61.4%) had felt, pleased or happy with their quality of life, and 49(32%) had remained with dissatisfaction with their quality of life and only 10(6.5%) were still terrible or unhappy with quality of life. These findings could be correlated with Suzuki and colleagues [15] where they studied the efficacy of Tamsulosin and quality of life for the patients with BPH. The study enrolled the newly diagnosed patients who fit the inclusion criteria and were followed for 12 weeks where the reassessment was done and found there was a decrease of IPS score by 27% and improvement of quality of life from 4.51 +/- 1.14 to 3.17 +/- 1.38 at 12 weeks after Tamsulosin administration. It was concluded there was significant improvement.

This study has revealed side effects associated with the use of Tamsulosin. The types of side effect and their frequencies are as follows; dizziness 14(9.2%), headache 15(9.8%), poor ejaculation 4(2.6%), nausea9(2.6%). This study could be compared with that by Osman and colleagues[19]. They enrolled 500 men with moderate symptoms of BPH. In term of side effects sexual dysfunction was the most common effect in 9%, of all participants but it was found to be not significant, followed by dizziness. Also in Lin and his colleague[17] who studied the association of the side effects, with the use of Tamsulosin ,showed that there was no adverse events that were reported. No significant differences were found in blood pressure or sexual function reported**.** It has shown to have similar findings with this study

### 4.1 Study Limitations

1. There was a limited follow up period of 12 weeks, long term outcomes of Tamsulosin use could not being assessed.
2. There was a relatively high dropout (loss to follow up) of 20%.

# CHAPTER FIVE

## 5.0 CONCLUSION AND RECOMMENDATIONS

### 5.1 Conclusion

- Benign prostatic enlargement is the condition which occurs in aging males commonly above 50years.Similar age range to those seen in other ethnic population
- International prostate symptoms score improved for benign prostatic enlargement patients with lower urinary tracts symptoms after 12 weeks of use of Tamsulosin.
- Quality of life improved for benign prostatic enlargement patients with lower urinary tract symptoms after 12 weeks of Tamsulosin use.
- Prostate size, and residual urine volume was associated with outcome of Tamsulosin use for benign prostatic enlargement patients with lower urinary tract symptoms.
- The common side effects observed during the use of Tamsulosin in the treatment of BPE were headache, dizziness, poor ejaculation and nausea.

### 5.2 Recommendations

Tamsulosin should continue being used for benign prostatic obstruction treatment in patients with lower urinary tract symptoms, also more and long term studies about Tamsulosin should be done in our settings so that long term outcomes can be documented.

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# APPENDICES

## Appendix I: Informed consent Form

**ID no _____**

Consent to participate in the study assessing the quality of life, of benign prostatic enlargement patients undergoing treatment with Tamsulosin among patients seeking urology services at Muhimbili National Hospital

**Greetings! My name is Dr Baraka Ngaja**, a postgraduate student at Muhimbili University of Health and Allied Sciences

**The purpose of the study**

To evaluate the quality of life among benign prostatic enlargement patients taking Tamsulosin at Muhimbili National Hospital.

**What participation involves**

If you agree to participate in the study, you will be requested to submit various supportive documents about your illness to the researcher but also you will be requested to answer the questions on the questionnaire**.** Also to show willingness to purchase and take Tamsulosin as medical treatment for your urinary problem.

**Confidentiality**

All information collected on questionnaires will be entered into computer with identification number. The questionnaires will be handled with confidentiality.

**Risks**

There is no direct risk associated with this study. Few patients will experience mild side effect of Tamsulosin medication.

**Right to withdraw and alternatives**

Taking part in this study is completely voluntary. If you choose not to participate in the study, you will continue to receive all services that you would normally get from the hospital**.**

**Benefits**

If you agree to take part in this study, you will benefit from knowing fine details about your illness but also close follow up will be beneficial**.**

**In case of any injury**

Apart from you providing us various supportive documents about your illness, we do not expect any harm from your participation**.**

**Who to contact**

If you have any question about the study, you should contact Dr. Baraka C. Ngaja +255 659 666 326

If you have any questions/concerns about your rights as a participant, you may contact Dr, Joyce masallu, Chairman of MUHAS Research and Publications Committee. P.O.BOX 65001 Dar es Salaam. Tel 2150302-6

Signature

I …… have read the content of this form. My questions have been answered. I agree to participate in this study.

Signature of participant …….

Signature of witness …….

Participant agrees / Participant does NOT agree

**Appendix II: Informed Consent (Swahili version)**

**ID no _____**

Hati ya kukubaliwa kushiriki kwenye utafiti Unaoangalia ubora wa maisha kwa wagonjwa wanaotibiwa ugonjwa wa tezi dume na dawa ya Tamsulosin katika hospitali ya taifa Muhimbili

Salaam! Naitwa Daktari **Baraka C. Ngaja,** mwanafunzi wa shahada ya uzamili katika chuo kikuu cha Tiba za Afya cha Muhimbili.

**Lengo la Utafiti**

Kuangalia ubora wa maisha, kwa wagonjwa wanaotibiwa ugonjwa wa tezi dume katika kitengo cha mkojo hospitali ya Taifa Muhimbili, Dar es salaam.

**Ushiriki wako ni wa namna gani?**

Ukikubali kushiriki, utaombwa kutoa vielelezo vihusuvyo ugonjwa wako pamoja na kujibu maswali yaliyopo kwenye dodoso.

**Usiri**

Taarifa zote zilizochukiliwa kupitia dodoso letu, pamoja na vipimo vitatambulika kwa namba na siyo jina ili kuongeza usiri. Usiri huo utalindwa hata baada ya kukamilika kwa utafiti huu.

**Madhara**

Mbali na muda utakaotumika kwa mahojiano, hatutegemei kwamba utapata madhara yoyote.

**Faida**

Kama ulikuwa haujui undani juu ya tatizo, utapata bahati ya kufahamu.Pia tatizo lako litafuatiliwa kwa kina zaidi.

**Haki ya kujitoa**

Ushiriki wako ni wa hiari, unaweza kujitoa wakati wowote katika utafiti huu. Ukiamua kutokushiriki, utaendelea kupati wahuduma kama kawaida.

**Mawasiliano**

Ukiwa na maswali kuhusu utafiti huu, au umeshindwa kuhudhuria cliniki, wasiliana nami Dr. Baraka C. Ngaja kwa nambari ya simu +255 659 666 326

Ukiwa na maswali kuhusu haki yako kama mshiriki, wasilianana Dr. Joyce Masallu, mwenyekiti wa Kitengo cha Utafitiwa Chuo Kikuu cha Afya ya Tiba Muhimbili S.L.P 65001 Dar es Salaam. Tel 2150302-6

**Sahihi Mimi _____ nimekubali kushiriki utafiti huu baada ya maswali yangu yote kujibiwa.**

**Sahihi ya mshiriki _____**

**Mshiriki amekubali / Amekataa**

**Appendix III: Questionnaire**

**SECTION ONE**

**Phone number……....**

**ID number.....**

1. Age (years)

    1) 30 – 49
    2) 50 –69
    3) 70-89
    4) 90- and above

2. Level of education
    1) No formal education
    2) Primary education level
    3) Secondary education level
    4) Higher education level

3. Occupation

    1) Peasant
    2) Formal employment
    3) Petty trader
    4) Unemployed
    5) Others (specify)……

**SECTION TWO**

**4.** Main complains

a. ……

b. ……

c. ……

d. …….

e. ……

5. Duration ……..

6. Investigation done

- Serum creatinine ……..
- Urinalysis……
- Residual volume before …… After……..
- Prostate size ……..

7. TOTAL IPS SCORE BEFORE TREATMENT ……..

Options of severity a) mild……..

b) Moderate ……

c) Severe …….

8. TOTAL IPS SCORE AFTER THREE MONTHS OF TREATMENT……

Option of severity a) mild ……..

b) Moderate……

c) Severe ……

9. QUALITY OF LIFE SCORE BEFORE TREATMENT ……..

Options a) Delighted……..

b) Pleased……..

c) Mostly satisfied…….

d) Dissatisfied……

e) Unhappy……

f) Terrible…….

10. QUALITY OF LIFE AFTER TREATMENT……

Options a) Delighted……..

b) Pleased……..

c) Mostly satisfied…….

d) Dissatisfied……

e) Unhappy……

f) Terrible……..

11. Side effects, 1) Dizziness ……

2) Headache……..

3) Poor ejaculation……..

4) Nausea…….

5) Others (specify) ……..

## International Prostate Symptom Score (I-PSS)

| Patient Name:<br>Date: | Not At All | Less Than 1 Time In 5 | Less Than Half The Time | About Half The Time | More Than Half The Time | Almost Always | YOUR SCORE |
|---|---|---|---|---|---|---|---|
| **1. Incomplete Emptying**<br>Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating? | 0 | 1 | 2 | 3 | 4 | 5 | |
| **2. Frequency**<br>Over the past month, how often have you had to urinate again less than two hours after you have finished urinating? | 0 | 1 | 2 | 3 | 4 | 5 | |
| **3. Intermittency**<br>Over the past month, how often have you found you stopped and started again several times when you urinated? | 0 | 1 | 2 | 3 | 4 | 5 | |
| **4. Urgency**<br>Over the past month, how often have you found it difficult to postpone urination? | 0 | 1 | 2 | 3 | 4 | 5 | |
| **5. Weak Stream**<br>Over the last month, how often have you had a weak urinary stream? | 0 | 1 | 2 | 3 | 4 | 5 | |
| **6. Straining**<br>Over the past month, how often have you had to push or strain to begin urination? | 0 | 1 | 2 | 3 | 4 | 5 | |
| | None | Once | Twice | 3 times | 4 times | 5 or more | YOUR SCORE |
| **7. Nocturia**<br>Over the past month how many times did you most typically get up each night to urinate from the time you went to bed until the time you got up in the morning? | 0 | 1 | 2 | 3 | 4 | 5 | |
| **Total I-PSS Score** | | | | | | | |

| **Quality of Life due to Urinary Symptoms** | Delighted | Pleased | Mostly satisfied | Mixed | Mostly unhappy | Unhappy | Terrible |
|---|---|---|---|---|---|---|---|
| If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that? | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

The I-PSS is based on the answers to seven questions concerning urinary symptoms. Each question is assigned points from 0 to 5 indicating increasing severity of the particular symptom. The total score can therefore range from 0 to 35 (asymptomatic to very symptomatic).

Although there are presently no standard recommendations into grading patients with mild, moderate or severe symptoms, patients can be tentatively classified as follows: **0 - 7 = mildly symptomatic; 8 - 19 = moderately symptomatic; 20 - 35 = severely symptomatic.**

The International Consensus Committee (ICC) recommends the use of only a single question to assess the patient's quality of life. The answers to this question range from "delighted" to "terrible" or 0 to 6. Although this single question may or may not capture the global impact of BPH symptoms on quality of life, it may serve as a valuable starting point for doctor-patient conversation.