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(RESEARCH ARTICLE)

The impact of medical therapy for benign prostatic obstruction on the health-related quality of life at tertiary hospital: A prospective study

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Abstract

Benign prostatic obstruction (BPO) is a common condition in older men that often result in lower urinary tract symptoms (LUTS). LUTS associated with Benign Prostate Enlargement (BPE) may have significant negative impact on patients' health-related quality of life as can certain treatments for the condition. This study aimed to determine the impact of medical therapy on health-related quality of life among patients on treatment for BPO.This was a hospital based descriptive study carried out in urology public and private clinics from April to December 2017. All diagnostic and treatment options of patients were decided by attending clinicians of which Patients aged ≥40 years on medical treatment for BPO were included. Symptom and Health Related Quality Life (HRQL) were measured at baseline and at 3 months using the International Prostate Symptom Score (IPSS) and the Benign Prostatic Hyperplasia Impact Index score (BII) tools. A total 150 patients were included in the analysis with a mean age of 54), mean PSA of 4.45ng/ml and a mean prostate volume 54.62cc. Majority, 144(96.5%) had moderate and severe LUTS and 94(63%) men received a combination of tamsulosin and finasteride and 44(29%) men received tamsulosin alone: Medical therapy was associated with overall improvement of quality of life ($p<0.001$). A combination of tamsulosin and finasteride was associated with more adverse effects. Improvements in Quality of life (QoL) and symptoms were noted across the medical treatments most widely used in real-life practice at MNH to manage patients with BPO. Tamsulosin showed an equivalent efficacy to a combination of tamsulosin and finasteride at third month of therapy with fewer adverse effects.

Keywords: Benign prostatic enlargement; Lower urinary tract symptoms; Quality of life

1. Background

Benign Prostate Obstruction (BPO) has a significant negative impact on the quality of life (QoL) of affected patients [1]. Indeed, symptom bother and interference with normal daily activities, reduction in the quality of sleep, and increased worry over health are the primary drivers for patients with BPO seeking healthcare [2-4]. It is a progressive condition; it can lead to a worsening of symptoms and an increased risk of serious outcomes, such as acute urinary retention (AUR) and disease-related surgery [5]. Recent studies have highlighted that preventing disease progression is priority [6-7] and therefore the main goals for treatment include not only improvement in symptom scores, but also relieving the risk of progression and improving patient-reported QoL and treatment satisfaction.

Over the last decade, there has been a considerable decline in the popularity of surgery to manage BPO, and medical therapy is now the most frequently used treatment option in clinical practice [8]. The mechanisms of action of the drugs is either to relax smooth muscle tone and/or reduce the size (bulk) of the prostate [9].

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Various studies with aim of evaluating changes in symptom severity and health-related quality of life among individuals on various medical treatment modalities for BPO [10-12], are inconsistent and none has been documented in Tanzania. The lack of local data about the subject brings dilemma among clinicians on choice of therapy and brought need for this study to be carried out at MNH. The aim of this study was therefore to determine the impact of medical therapy on health-related quality of life among patients on medical treatment for BPO.

2. Patients and methods

This was a hospital based prospective descriptive study involving patients on medical therapy for BPO attending urology clinics at Muhimbili National Hospital between April to December, 2017. Convenient consecutive sampling was employed whereby clinic attendees who met criteria and newly initiated medical therapy were recruited until sample size was reached. This study excluded all the patients who had other co-morbid conditions like diabetes mellitus (DM), neurological diseases, kidney failure, history of prior prostatectomy and any patients on treatment with alpha blockers or diuretics for other medical indications.

The primary endpoint was change in QoL assessed using the validated version of the Benign Prostatic Hyperplasia Impact Index (BII): a questionnaire consisting of four questions measuring the impact of urinary symptoms on physical discomfort, worries about health, symptom bother, and interference with usual activities during the past month. Items are answered using a Likert scale, with four or five response options per item and scores range from 0 (best QoL) to 13 (worst QoL). Symptoms of BPO were evaluated using the validated version of the International Prostate Symptom Score (IPSS). Scores on this instrument range from 0 to 35 with a higher score indicating more severe symptoms and Question 8 on IPSS chart was used to assess QOL with scores from 0 (delighted) to 6 (terrible). Both instruments were completed at baseline and at the 3-month follow-up visit.

Sociodemographic data collected at baseline included age, level of education and occupation. We also collected data on diagnostic tests (prostate volume, residual urine volume, PSA), and treatment received (alpha-blockers, 5-alpha-reductase inhibitors, phytotherapy, or combined therapy). Adverse events and side effects associated with treatment were recorded at the follow-up visits.

Data was collected through personal interviews and additional information like diagnosis, pharmacy records was obtained from the electronic patient files on data base software for patient management used by the hospital. Descriptive data was analyzed with the aid of SPSS (Statistical Package for the Social Sciences) computer software version 22.0 where various variables were tabulated and probability value of less than 0.05 was considered statistically significant.

3. Results

A total of 168 men were recruited into the study, 18 were excluded from analysis due to the following reasons: poor adherence to medications, change to other medication type and lost during follow up. The mean age of the patients with lower urinary symptoms was 54.6±5.13 years with majority 88(58.7%) between 50 – 60 years, mean serum Prostate Specific Antigen was 4.45±5.13ng/ml and mean prostate size at ultra-sonography was 54.62±33.6cc. Most of the patients were employed and had formal education 145 (96.7%) and 143 (95.3%) respectively.

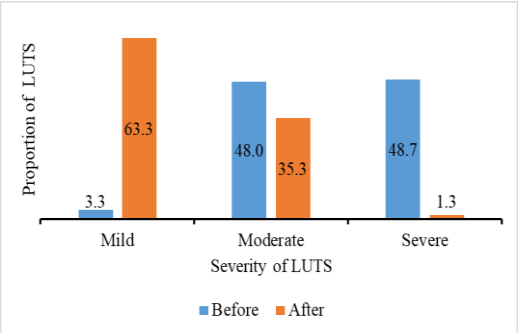

Figure 1 Bar chart showing proportion of patients in the three LUTS severity scales before and after medical treatment at three months.

With regards to symptom severity score, IPSSS, for Lower Urinary Tract Symptoms, majority of patients had moderate and severe LUTS at 48% and 48.7% respectively and only 3.3% had mild LUTS at start of therapy. After only three months of therapy, there was a 60% increase in patients reporting mild LUTS, and a decrease of 2.7% and 47.4% among patients reporting severe and moderate LUTS respectively.

Medical therapy for LUTS patients was largely Tamsulosin based, alone or in combination with finasteride. But some few patients received Prostacare based therapies, alone or in combination with finasteride, and finasteride alone. Fig 2

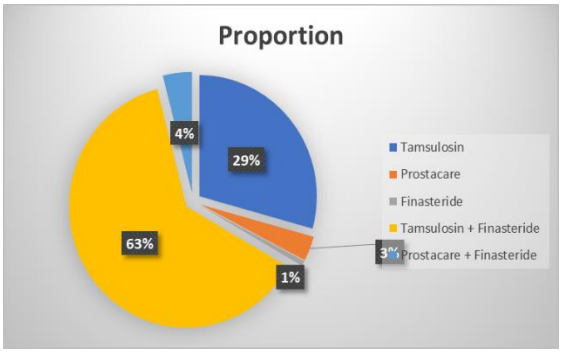

Figure 2 Pie chart showing medication offered to patients with LUTS as proportion for the 150 patients

3.1. General HRQL using BPH impact index (BII) score for BPO patients

Figure 3 show mean scores of BII (BPH impact index score) at baseline and at third month of therapy for BPO patients. Patients receiving combination therapy had higher mean baseline BII than those treated with monotherapy. All medical treatment showed a relevant improvement in BII score ($p<0.001$) at third month of therapy. The smallest improvement of BII from baseline was observed in the Prostacare group, with a mean change 4.4 points while the largest change in BII was in tamsulosin + finasteride, with mean change 6.9 points (Figure 3)

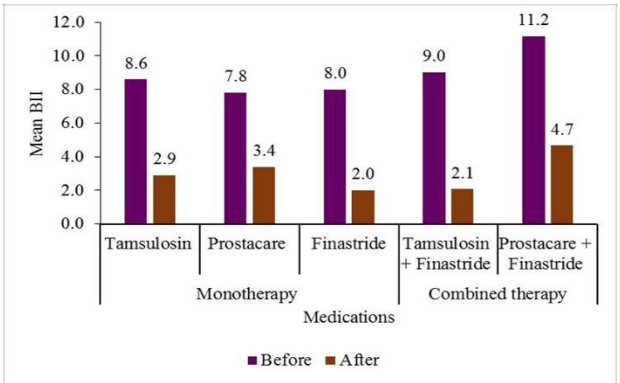

Figure 3 Baseline and end of study mean BII by treatment groups

The overall incidences of adverse effects (AE) with use of medications was reported by 15.3% of all patients. The four adverse events were almost reported equally being more in the Tamsulosin plus finasteride combination therapy than in all the other therapies. (Table 1).

Table 1 Adverse effects of various medical therapies (N=23)

Side effects	Tamsulosin	Tamsulosin + Finasteride	Prostacare + Finasteride	Total
Dizziness	2	4	0	6
Erectile dysfunction	0	5	0	6
Loss of libido	0	4	1	5
Poor ejaculation	2	4	0	6

4. Discussion

This study has evaluated changes in symptoms and QoL among patients with BPO managed by medications based on what is currently practiced at a tertiary hospital in Tanzania. We observed the overall significant improvements LUTS and quality of life in patients who were on medical therapy for BPO. Majority of participants of this study had baseline moderate and severe symptoms. This finding was similar to a Ghanaian study where similar proportions of symptoms were dominant [13]. At third month of therapy six out ten men of the studied population had mild symptoms proving evidence of overall good outcome of available medical therapies.

In Our study majority of patients were given combination therapy of tamsulosin and finasteride or monotherapy of tamsulosin and few were given phytotherapeutic drug (S. repens) either alone or in combination. The reason for these clinicians' preferences of other drugs over pytotherapeutic drug was not established but could be lack of hospital treatment protocol. In the AUA BPH Guideline, phytothrapeutic medications are considered as a treatment option[14] and it has been recommend that general conclusion about S. repens should not be made and these products potency needs to be assessed individually as may differ depending on extraction procedure[15-17]. Also our study findings gives a clue that further research is needed on the available and approved S. repens drug product which is currently used in Tanzania.

There was marked improvement of both symptoms and QoL before and after therapy between the most prescribed monotherapy and combination therapy was nearly the same. These findings were different from other studies which have proved combination therapy to be superior to monotherapy[18-19]. The tendency to have equivalent symptom and QoL improvement between combination of tamsulosin and finasteride and tamsulosin alone was also observed in QUALIPROST study [12, 20-21]. These results could be explained by short duration of treatment in these two studies and differ from others in which significant differences was observed after long term therapy.

All of the medical treatments studied were associated with improvements in both symptoms and QoL using both IPS and BII score tools; this observed improvement was similar to that observed in previous studies of different drug therapies using similar tools [12, 22]. The trend of change of QoL with change in symptom was observed also in one study done in four European countries, where QoL was less affected in Germany than other countries and the study concluded that the change in QoL may also differ basing on geographical discrepancies and cultural habits or merely organizational differences [23].

In the current study the overall reported treatment side effect incidences were more in the combined therapy group. Tamsulosin +Finasteride was associated with high reported incidences of adverse side effects among users which was similar to another study comparing side effects in group of therapies which reported less adverse effects with use of monotherapy(19).Explanation for this observation could be due to combined effect of medications on a combination therapy group. The most reported side effects in the current study were dizziness, poor ejaculation and poor erectile function

5. Conclusion

Majority of patients receive a combination therapy of Tamsulosin and finasteride and monotherapy of tamsulosin for BPO. Pytothrerapeutic drug either alone or in combination were the least preferred by clinicians. In general, medical therapy for LUTS for BPE at MNH was associated with considerably significant improvements in QoL and symptoms. Tamsulosin and a combination of tamsulosin and finasteride had equivalent efficacy in improving both symptoms and QoL. Adverse effects were more reported to those who received a combination of tamsulosin and finasteride. The results of this study add evidence on current treatments for BPO at MNH and should help to further inform decision-making regarding treatment. A multi-center study with a follow up of not less than six months is recommended.

Study limitation

The limitation of our study was data were obtained with no randomization or blinding; patients were allocated to a specific management approach based on clinician judgment, which could lead to a selection bias also the relatively short follow-up period of three months when studying medications like 5 alpha-reductase inhibitors which have been proved to have maximum effect with use for six months.

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declare no conflict of interest.

Statement of informed consent

Permission to conduct the study was obtained from Muhimbili University of Health and Allied Sciences (MUHAS) and MNH management. Informed consent was obtained from patients. All patients' information including raw data was be kept confidential during and after study period.

Authors' contributions

HGK: designed the study, collected data, performed data analysis and wrote the report with a manuscript. OVN and NMK participated in the study design and manuscript preparation

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