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REAL WORLD EVIDENCE: EFFECTIVENESS OF ALFUZOSIN IN BENIGN PROSTATIC HYPERPLASIA

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ABSTRACT

Background/Objectives: To evaluate the effectiveness and safety of Alfuzosin - An uroselective Alpha blocker in patients with Benign Prostatic Hyperplasia. **Materials and Methods:** A prospective, open labelled study among thirty patients with Benign Prostatic Hyperplasia (BPH) where the symptoms of Benign Prostatic Hyperplasia (BPH) were accessed and graded as per standard questionnaire i.e International Prostatic Symptomatic Score(IPSS). A standard performa was made to capture the general physical examination, vital signs i.e blood pressure, heart rate, systemic examination such as cardiovascular system and abdomen examination including digital per rectal examination. Laboratory investigations included random blood sugar, prostate specific antigen and urine analysis. The ultrasonography investigations were done to measure the size of prostate and to assess the post void residual urine. The uroflow meter analysis was done as an OPD procedure. The patient was advised to come up for follow visit at first and third months. **Results:** In our study, patients on Alfuzosin 10 mg once daily showed a significant improvement in post void residual urine, uroflow rates and symptomatic score(IPSS). The improvement in the above parameters was found to be statistically significant from first month onwards and the improvement persisted till end of the study. The drug is safe and well tolerated. **Interpretation/conclusion:** Alfuzosin has been found to be a safe option in medical management of Benign Prostatic Hyperplasia.

KEYWORDS: Alfuzosin; Benign prostatic hyperplasia; Post void residual urine.

INTRODUCTION

Benign prostatic hyperplasia (BPH) is one of the most common conditions affecting the elderly males,[1] since the geriatric population constitute a major pie and hence this result in a major impact in medical practice nowadays.[2] The enlargement of the prostate can produce voiding symptoms, which can lead to pathological changes in the urinary bladder and the kidney.

Management of BPH has also changed significantly with a considerable advance in the understanding of the demographics and natural history of the disease.[3]

The pharmacotherapy of BPH comprises of alpha-1 receptor antagonists, 5-alpha reductase inhibitors, phytotherapy, Gonadotropin releasing hormone analogues and androgen receptor blockers.

Among the alpha-1 receptor blockers, the newer alpha-1 blocker Alfuzosin has been claimed to be uroselective[4] and is nowadays being used in the place of specific alpha-1A receptor (bladder neck specific) antagonist Tamsulosin.

The present study has been designed to understand the efficacy and the safety profile of Alfuzosin in Benign Prostatic hyperplasia, this study has been undertaken as specific studies are lacking from Indian Perspective.

MATERIALS AND METHODS

This study was conducted from 1-10-2005 to 30-9-2006 in patients with BPH attending urology department, the study was conducted on both outpatients and inpatients of R.L Jalappa hospital and research centre, attached to Sri Devaraj Urs Medical College, Tamaka, Kolar.

During the study period the data was collected in a structured and validated Performa, the proforma containing detailed information on each patient was prepared according to the protocol designed for the study. Informed consent was taken from all the patients included in the study. Ethical clearance was obtained from the institutional ethics committee.

The patients fulfilling the following criteria were included in this study

Inclusion criteria

1. Patients greater than 45 years of age with clinical diagnosis of symptomatic BPH.
2. IPSS score more than four at the base line.
3. PSA value of less than10 nanograms/milli Liter.
4. Patients with maximum urinary flow rate of ≤12 mL/s but ≥ 4 mL/s for a voided volume of ≥ 120mL

Patients were excluded if they fulfil any one of the following criteria

1. Patients suspected to be having carcinoma of prostate.
2. PSA value > 10 nanograms/milliLiter
3. Neurogenic bladder cases.
4. Patients with upper motor lesions.
5. Patients with urethral strictures.
6. Patients with urinary bladder stones.
7. Patients who have undergone previous prostate surgery.
8. Patients with known hypersensitivity to alpha-1 blockers.

The data included hospital number, ID & age of the patient, dates of visiting the OPD and the dates of admission and history of presenting illness. The proforma also enlisted general physical examination, vital signs like blood pressure, heart rate, systemic examination like cardiovascular system and abdomen examination including digital per rectal examination.

Laboratory investigations included random blood glucose, prostate specific antigen and urine analysis.

The ultrasonography investigations were done to measure the size of the prostate and post void residual urine.

The uroflow meter analysis was done as an OPD procedure.

The assessment of the symptoms was done by using International Prostatic Symptom Score (IPSS) at baseline, first month and third month to assess the symptomatic improvement. The uroflowmeter analysis, ultrasonography of the size of the prostate and the post void residual urine was done at the base line, first month, and on the third month of the follow up to assess the clinical improvements.

Alfuzosin 10 mg once a day was prescribed and patients were advised to come for the follow up on the first month and the third month of treatment. The data obtained were analysed by using student t test and repeated measure ANOVA has been used to find the significance of the study parameters between onset, first month and third month in each group.

RESULTS

The mean age of patient in the treatment group was 64.13 years.

The International Prostatic Symptomatic Score in Alfuzosin treatment reduced significantly. At baseline it was 26.60 and reduced to 9.10 at third months.

IPSS	Mean	SD
Baseline	26.60	4.87
First month	17.03	3.66
Third month	9.10	2.22
% change	65.8 %	

Comparison of PSA (ng/ml) score between two groups

There is no change in the PSA values in the treatment group until the end of the study. The PSA remains unaltered in each and every time point.

Comparison of PVRU (ml) score

The effects of Alfuzosin treatment on the post void residual urine is shown in the below table, there were significant reductions from baseline to the end of third month in the treatment groups ($p<0.001$).

Comparison of Prostate Ultra sound (cc) score

There is no significant change in the size of the prostate in both the tamsulosin and alfuzosin groups.

Comparison of URO flow (ml/s) score

The changes in Qmax during the active treatment are shown in figure below there was a significant increase in Qmax relative to baseline in the treatment group at each vist ($p<0.001$). The maximum increase in the Qmax was obtained at third month.

URO flow (ml)	Mean	SD
Baseline	6.40	2.01
First Month	14.63	3.86
Third month	22.80	4.58
Percent change	256.25%	

DISCUSSION

Benign prostatic hyperplasia is one of the most common conditions affecting elderly males with a resultant impact on the medical practice as the elderly constitute an increasing population not only in India but also throughout the world.[2] A decade back, surgery and watchful-waiting were the only accepted management options for BPH. Now there has been a drastic decline in the surgery as medication has become the most frequently used treatment for BPH that has been a major change in urological clinical practice.

Alpha-1 blockers have become the major drugs for BPH among which Alfuzosin has been claimed to be uroselective Alpha-1 blocker.

In our study, we have analysed the efficacy of Alfuzosin 10mg once daily on IPSS, PSA, PVRU, size of the prostate, uroflow analysis and per rectal examination.

The improvement of prostatic symptomatic score of alfuzosin was seen from first month and attained the maximum at third month. The mean reduction in total symptom score at third month was 9.10(65.8%) in alfuzosin group.[5] Perhaps a study of longer duration of six months or more may show definite difference in improvement in the effect of one drug over the other.

In analysing the PSA values, in our study where the follow-up was up to 12 weeks has shown no statistical change. In the study conducted by Park CH et al, which involved 211 patients treated with tamsulosin, also shows no significant change in the PSA values up to 52 weeks.[1]

In the present study with Alfuzosin the post void residual urine showed a significant reduction from the baseline till the third month($p<0.001$), in concurrence with the study of Rosette JJ[8] et al involving 101 patients on alfuzosin and 86 patients on tamsulosin.

In the present study, it was also observed that post void residual urine in the alfuzosin group was lower at the end of third month.

In the uroflowmetry analysis, there was a significant increase in Qmax relative to baseline in in the treatment arm at each time ($p<0.001$).i.e. Baseline to first month and from first month to third month. The maximum increase in the Qmax was obtained at third month, As per the meta-analysis of two European randomized, double blind, multicentric studies with tamsulosin for 12 weeks, a significant improvement in Qmax from baseline has been reporte,[6] and similar findings have been found in the present study also.[7]

As for the size of the prostate is concerned, in our study there was no significant change in the size of the prostate in both the groups which was also similar to a study done by Rossette JJ.[8] The study drug has not altered the prostatic size because the enlargement of the prostate depends on the tissue androgen namely dihydrotestosterone which is converted from testosterone by 5-Alpha reductase. In our study, alfuzosin was well tolerated, and the treatment emergent adverse events were not serious enough to warrant withdrawal from the study. A study conducted by Roehrborn C et al also states similar findings.[4]

In the present study side effects were low and compliance was good with study drug.

Retrograde ejaculation was not complained by any of our patients in the study, however most of the patients were elderly coming from a low socio-economic status with a rural background that also followed good old Indian traditions like staying in a joint family how much ever the couples believed in the indulgence of the sexual activity is uncertain.

With the limited study period in the present study, it may be that Alfuzosin can be used as better option for medical management of BPH.

CONCLUSION

The results of the present study show that alfuzosin 10 mg once daily in the treatment of BPH produce improvement in urinary flow rates, symptoms and post void residual urine and it was well tolerated, thus maintaining the improvement in the lower urinary tract symptoms.

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