INTRODUCTION

The incidence of LUTS/BPH and ED increase parallel with age, physicians need to be in a position to effectively treat both these conditions simultaneously. Moreover treatment of one condition can improve the other.

Recent large scale epidemiological studies have reported a statistically significant association between the two conditions, independent of age and cardiovascular co-morbidities (McVary K.et al, BJUI. 2006;97 Suppl 2:23-8.)

A growing body of evidence suggests the efficacy of phosphodiesterase (PDE) inhibitors alone and in combination with alpha-adrenergic blockers in managing lower urinary tract symptoms related to BPH. Although clinical benefit of PDE inhibitors has been shown, urodynamic data regarding the effect of these drugs is sparse. This study was designed to assess the efficacy of tamsulosin, tadalafl or a combination of the two in improving LUTS and urodynamic parameters in patients with BPH.

MATERIALS AND METHODS

We conducted a prospective, randomized open label trial on 45 men with symptomatic BPH

Inclusion Criteria

Men 45 years of age or more with LUTS/BPH

Exclusion Criteria

Contraindications to investigational drugs.

Patients with known allergy to drugs under study.

Bladder outlet obstruction due to cancer, calculi or stricture.

Previous prostate surgery.

Any neurological disease affecting storage and voiding functions.

Prostatic diseases like prostatitis and prostate cancer.

An episode of acute urinary retention within 4 weeks of the study initiation.

Pre-existing uncontrolled diabetes or hypertension.

Indication for surgical management of BPH

Selected patients were randomly assigned to three treatment groups.

GROUP A: Tamsulosin 0.4mg once daily

GROUP B: Tadalafl 10mg once daily

GROUP C: Tamsulosin 0.4mg + Tadalafl 10mg combination once a day

Computer generated random number table was used for allocation of treatment group

Patients were assessed at the start of the study and at the end of 3 months. Outcome was measured in terms of change in IPSS, QOL, IIEF and urodynamic parameters including change in Qmax, Pdet Qmax, BOOI, BCI and PVR.

Results

The three groups were comparable. The mean age was 61.82±6.79 years with mean duration of LUTS was 2.51±1.57 years. A statistically significant change in IPSS score (7.93±4.06 (p = .001) in Group A, 7.00±2.95 (p = .000) in Group B and 7.93±4.06 (p = .000) in Group C) was observed. However, there was no significant difference on intergroup comparison (p = .628). Significant improvement in the Qmax Index in Group A (p = .000) and B (p = .000) was noted. The similar findings of no added benefit of combination therapy was also reflected in the field of QOL as the percentage improvement in QOL Index was 56.84%, 34.76% and 17.4% in Group A, B and C respectively. Off course the baseline QOL index was lower in the combination group.

61.54% (n=2) of the symptomatic BPH patients had associated ED. However, majority of them had either mild or ED or mild to moderate (n=11) sexual dysfunction as measured by IIEF 5 scale. Our aim was not to prove that sildenafil failed to achieve higher ED score amongst patients with higher IPSS score.

Statistically significant improvement of ED was noted only in patients who received Tadalafil (Group B and C).

The maximum benefit of combination therapy was noted for IIEF improvement. The percent improvement in IIEF was 1.84%, 16.09% and 15.38% in Group A, B and C respectively. Uniflow Omax was improved by 2.2 points amongst patients who were on tamsulosin. Tadalafil Omax improvement was by a maximum of 5.67 points (p<0.01).

Despite the improvement in Omax, improvement in PVR was most, the maximum improvement with combination therapy was noted in Group C. However, maximum benefit is obtained from tamsulosin and not from PDE5 inhibitors alone.

Statistically significant improvement in the Qmax Index in Group A (p= .000) and B (p= .000) was noted.

Materials and methods

45 symptomatic BPH patients were prospectively randomized to receive tamsulosin (Group A), tadalafil (Group B) or a combination (Group C). Patients were assessed at the start of the study and at the end of 3 months. Outcome was measured in terms of change in IPSS, QOL, IIEF and urodynamic parameters including change in Qmax, Pdet Qmax, BOOI and PVR.

RESULTS

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CONCLUSION

Does symptomatic improvement in IPSS & IIEF Scores correlates with objective changes in urodynamic parameters amongst patients with symptomatic BPH following tamsulosin/tadalafil monotherapy or combination of both?: A Prospective Study.

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ABSTRACT

Does symptomatic improvement in IPSS & IIEF Scores correlates with objective changes in urodynamic parameters amongst patients with symptomatic BPH following tamsulosin/tadalafil monotherapy or combination of both?: A Prospective Study.

Statistically significant improvement of ED was noted only in patients who received Tadalafil (Group B and C).

The mean change in Omax, Pdet Qmax and PVR were insignificant and similar in all the three groups. The bladder outlet obstruction index (BOOI) and bladder contractility index (BCI) failed to show any significant change following therapy (Table 2).

Adverse events (headache and body aches) were noted more frequently in Group B although none discontinued treatment.

Tamsulosin and tadalafil significantly improved LUTS secondary to BPH. However, combination therapy did not give added benefit. The improvement in erectile function with tamsulosin was insignificant. Therefore, for patients with symptomatic BPH with bothersome ED, monotherapy with tadalafil may be considered rather than as a combination with tamsulosin. Interestingly to note that the subjective improvement in LUTS was not reflected objectively in urodynamic parameters.

Table 1.  Demographic profile of the study population.

Table 2.  Change in clinical and urodynamic parameters with treatment in the study groups.