Efficacy and Safety of Add-on Treatment with Mirabegron for Benign Prostatic Hyperplasia Patients with Persistent Storage Symptoms after Alpha- blocker therapy.

Thesis submitted for partial fulfillment of the Master degree in Urology

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SUMMARY

Benign prostatic hyperplasia (BPH) is the most common benign disease in men with various lower urinary tract symptoms (LUTS) and the fourth most common disease among men aged 50 years and older. Alpha-1adrenoceptor blocker (A1B) is the most commonly used pharmacological agent to treat LUTS in men with BPH. However, even after treatment with A1B, storage or OAB symptoms may persist. Around 50%-75% of elderly male patients of BPE with LUTS appear to have predominant/coexisting OABS. Traditionally antimuscarinic drugs were the main stay of therapy for 'BPE induced OABS' although accompanied by bothersome adverse events such as dry mouth, constipation and urinary retention leading to significant drug discontinuity. Mirabegron is a newer selective beta-3 agonist that has been tried in combination with α -1 blockers for alleviating 'BPE induced NN-OABS' that act by relaxing the bladder detrusor in the storage phase thereby increasing its storage capacity and ameliorating OABS. Furthermore, patients treated with mirabegron have been shown to have higher persistence and adherence rates than patients receiving anti muscarinic. Moreover that, mirabegron has also been shown to act as a competitive antagonist of α 1adrenoceptors in the urethra leading to urethral smooth muscle relaxation.

Our prospective study included 50 male patients with persistant storage LUTS, after they had been taking a regular daily dose of α 1-adrenergic receptor blockers for 4 weeks, All patients were received mirabegron 50 mg once daily for 8 weeks. All patients were evaluated before and two months after add-on mirabegron 50 mg daily. The mean age of our patients is 60.22 ± 7.06 yrs. The median of PSA test results is 1.4(0.925). The median prostate volume of patients is 57.50(21.25) ml.

The aim of our work was to evaluate the efficacy and safety of adding mirabegron for benign prostatic hyperplasia patients complaining of persistent storage symptoms after alpha-blocker therapy.

- All patients underwent detailed clinical evaluation in the form of :
 - 1. Complete history and physical examination
 - 2. Urinary symptoms related to OAB were evaluated with OABSS
 - 3. Urinary symptoms related to BPH were evaluated with IPSS
 - 4. Quality of life assessment by (QOL) score .
- All patients underwent investigation in the form of :

Lap : Urine culture and sensitivity, prostate specific antigen (PSA).

Rad: Ultrasound abdomen and pelvis with post-voided residual urine volume (PVR) and prostate volume (PV) measurement..

Our results revealed that mirabegron improve the OABSS, IPSS, IPSSs and IPSSv. Moreover that voided volume (VV) and Maximum urinary flow rate (Qmax) also IPSS quality of life (Q.OL) improved with drug intake.

Only 5 patients representing 10% of patients (95% CI: 2%, 18%) had side effects after mirabegron medication. All cases of mild degree and self-limited side effect, more over that no patient discontinues treatment. there for we think that ABS with Mirabegron add-on therapy was effective, safe and well tolerated. and promising option for patients with BPH related OAB.