ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at:www.ijmacr.com

Volume – 8, Issue – 3, May - 2025, Page No.: 103 – 108

Assessment of Mirabegron's Effectiveness and Tolerability in Treating Overactive Bladder in Women: A Prospective Study

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How to citation this article: Dr. Swathi Sapuru, Dr. Aditi Bansal, Dr Aditi Agarwal, Dr. Divyashree Choudhary, "Assessment of Mirabegron's Effectiveness and Tolerability in Treating Overactive Bladder in Women: A Prospective Study", IJMACR- May - 2025, Volume – 8, Issue - 3, P. No. 103 – 108.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Mirabegron, the first b3-adrenoceptor agonist specifically approved for addressing overactive bladder (OAB), a common and persistent collection of symptoms, has a substantial adverse effect on various facets of life quality, including social interactions, mental health, finances, and sexual function. Our research seeks to examine the effectiveness and safety of using mirabegron as a therapeutic choice for OAB. Furthermore, we aim to pinpoint any patient-specific traits that might indicate their likely response to the treatment.

Method: It was a prospective observational study conducted on 178 women (22 losses to follow up) with OAB, between June 2022 to May 2023. Patients were prescribed Mirabegron 50 mg once daily for 6 weeks. They were assessed at the initial appointment and at 6 weeks using validated questionnaires. The primary outcome measure was defined using the International Consultation of Incontinence Modular Questionnaire Female Lower Urinary Tract Symptoms long Form (ICIQ- FLUTS LF).

Results: 200 women were prescribed Mirabegron and 178 (89%) completed 6 weeks of drug therapy. Of those completing the course, There was significant symptom improvement based on the ICIQ-FLUTS long form scores from 20.13 to 9.00 ($p < 0.001$). Eight (8%) patients discontinued Mirabegron prematurely due to side-effects. Six (6%) did not attend follow up and Eight (8%) decided against taking the medication and did not use their prescription.

Conclusion: Mirabegron is a treatment option for patients with overactive bladder. Patients experience significant benefits from the therapy, and it is generally well-tolerated, as indicated by the small number of people who cease treatment because of side effects.

Keywords: Mirabegron, Overactive bladder

Introduction

The International Continence Society (ICS) characterizes Overactive Bladder Syndrome as a clinical condition involving lower urinary tract dysfunction. This syndrome manifests with symptoms such as urgency, which may or may not be accompanied by urge incontinence, and typically includes increased urinary frequency and nocturia. These symptoms occur in the absence of related metabolic issues, infections, or localized conditions. While urinary incontinence itself is not life-threatening, it significantly impacts the mental well-being of women and diminishes their quality of life. Despite being frequently underreported, epidemiological data indicates that the occurrence of OAB in women is around 16.9% and tends to increase with age. [2,3] Due to patients' reluctance to discuss their symptoms with healthcare providers, the physical and economic burden of OAB is likely underestimated, potentially affecting up to half of the female population. [4,5] Consequently, it is crucial to assess and manage this "silent" problem affecting numerous women who do not seek help. Overactive bladder is a debilitating condition that can substantially reduce quality of life, leading to diminished self-esteem, anxiety, depression, reduced work efficiency, and a higher incidence of sexual difficulties, often accompanied by personal distress and social isolation. The primary goal of treatment is to alleviate overactive bladder symptoms in women and thereby enhance their life quality. The main treatment approaches involve non-pharmacological and pharmacological interventions. Non-pharmacological clinical management includes general advice, behavioral therapies, and physical therapy. Conversely, the primary treatment strategy for overactive bladder syndrome is medication. Currently, anticholinergic drugs are the most commonly prescribed agents for managing this condition. However, some patients show a limited response to antimuscarinics or may experience side effects like dry mouth or constipation. As a result, a significant number of patients discontinue antimuscarinic treatment, with less than 25% continuing after one year. Recent advancements in understanding the underlying mechanisms of OAB have identified three subtypes of b-adrenoceptors (b1, b2, and b3) in the bladder muscle and lining. Mirabegron, a newly approved drug by the FDA, is the first b3-adrenoceptor agonist to be used clinically. It improves the bladder's capacity to hold urine without hindering its ability to contract during urination. [7] Mirabegron does not share the same adverse effects as anticholinergic medications and, therefore, may be better tolerated by some individuals who experience side effects with anticholinergics. Mirabegron exhibits high activity for b3-adrenoceptors and very low activity for b1 and b2 adrenoceptors. Stimulation of b3-adrenoceptors directly causes relaxation of the detrusor smooth muscle, a process mediated by increased intracellular levels of cyclic adenosine monophosphate.

Methodology

A prospective study was conducted at the Department of Obstetrics and Gynecology, SMS Medical College, Jaipur, from June 2022 to May 2023, involving 200 women with lower urinary tract symptoms who had either not responded to, or declined, conservative

treatment. Prior to commencing the study, ethical approval for drug use was obtained. All participants provided informed and written consent. The study then applied inclusion criteria, selecting women exhibiting overactive bladder symptoms, specifically: frequency (voiding more than 8 times daily), urgency (a sudden, compelling need to urinate), urge incontinence (involuntary urine leakage), and nocturia (2 or more episodes per night). Women were excluded if they had urinary tract infections, uncontrolled hypertension, cardiovascular disease, or were taking diuretics. Symptoms were evaluated using the long form of the International Consultation on Incontinence Modular Questionnaire Female Lower Urinary Tract Symptoms (ICIQ-FLUTS LF)[8], and categorized by frequency (F score), voiding (V score), and incontinence (I score). Participants were prescribed 50 mg of Mirabegron once daily for six weeks. Assessments were performed at the initial visit and again after six weeks using validated questionnaires. Post-treatment analysis was conducted, and outcomes were measured. The primary outcome measure was assessed using the ICIQ-FLUTS LF. Secondary outcomes included rates of discontinuation and adverse reactions. Statistical analysis of pre- and post-treatment data was performed using the Wilcoxon test, Kruskal-Wallis test, chi-square test, and a significance level of $p < 0.01$. Urgency episodes within a 24-hour period decreased significantly in the Mirabegron group ($p < 0.05$). Statistically significant improvements were also observed in incontinence episodes, urgency incontinence episodes, and nocturia episodes. Consistent with our findings, the DRAGON dose-ranging study by Chapple CR et al. (2013)[10] reported a dose-dependent reduction in the mean number of micturitions over 24 hours, with statistically significant differences between the placebo group and the 50mg, 100mg, and 200mg Mirabegron groups ($p < 0.05$). Additionally, the DRAGON study demonstrated statistically significant mean improvements from baseline to the final follow-up visit in mean voiding volume (MVV), incontinence episodes, UUI episodes, urgency episodes, level of urgency, and nocturia episodes. The ARIES study by Nitti VW et al. (2013)[11] also reported statistically significant improvements in MVV, level of urgency, number of UUI episodes, urgency episodes, and nocturia episodes in 24 hours from baseline to the final visit. Furthermore, the ARIES study showed statistically significant improvements in the number of incontinence episodes and micturitions in 24 hours from baseline to Week 4 for both Mirabegron groups compared with the placebo group (all $p < 0.05$), a finding also observed in our investigation. A similar comparative study, the CAPRICORN study by Herschorn S et al. (2013)[12], found that 50 mg Mirabegron, compared with placebo, resulted in significantly greater improvements at 4 weeks in the mean number of incontinence episodes in 24 hours ($p < 0.001$) and micturition in 24 hours. At these time points, 50 mg Mirabegron also demonstrated statistically significant improvements compared with placebo in mean level of urgency, number of UUI episodes in 24 hours, and urgency episodes. The success of drug therapy depends on both its side-effect profile and efficacy. Mirabegron exhibits a favorable side-effect profile, with only 8% of the total study population reporting any side effects and only 4% discontinuing therapy before the 6-week point due to side effects. Palpitations were the most frequently reported side effect (4%), a rate consistent with published literature. This study has certain limitations. Its design did not allow for comparisons of Mirabegron's response against placebo

or antimuscarinic therapy. The study cohort comprised a heterogeneous group of patients, and the drug study group size was small. The outcome was evaluated using the ICIQ-FLUTS. While this provides a global assessment of improvement, which we considered a more useful indicator than changes in individual quality of life, it provides valuable data on the proportion of patients likely to benefit from drug therapy.

Conclusion

This study gives valuable data on the proportions of patients that are likely to benefit from drug therapy. In conclusion, Mirabegron is an effective and well-tolerated treatment option for women with overactive bladder, demonstrating a low incidence of side effects and improving both symptoms and quality of life to a degree broadly comparable with other pharmacological therapies.

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Legend Tables

Table 1: Assessment of change in F Score overtime(n=178)

Time point	Total Score			Wilcoxon Test	
	Mean (SD)	Median(IQR)	Range	V	P Value
Pre-Treatment	20.13(6.93)	19.50(8.25)	6.00- 38.00	4005.0	<0.001
Post-Treatment	9.00(3.83)	9.00(6.00)	1.00- 19.00		
Absolute Change	-11.27 (3.54)	-11.00 (3.00)	-20.00--4.00		
Percent Change	-56.6%(9.0)	-57.1%(9.4)	-89%--36%		

Table 2: Assessment of change in V Score overtime(n=178)

Time point	F Score			Wilcoxon Test	
	Mean (SD)	Median(IQR)	Range	V	P Value
Pre-Treatment	8.06(3.10)	8.00(3.00)	2.00- 16.00	3916.0	<0.001
Post-Treatment	2.70(1.53)	2.00(1.00)	0.00- 8.00		
Absolute Change	-5.40 (2.14)	-5.00 (3.00)	-12.00-0.00		
Percent Change	-67.2%(15.5)	-69.2%(12.5)	-100%-0%		

Table 3: Assessment of change in I Score overtime (n =178)

Time point	V Score			Wilcoxon Test	
	Mean (SD)	Median(IQR)	Range	V	P Value
Pre-Treatment	2.70(2.09)	2.00(3.00)	0.00- 8.00	2628.5	<0.001
Post-Treatment	1.53(1.40)	1.00(2.00)	0.00- 5.00		
Absolute Change	-1.19 (1.04)	-1.00 (1.00)	-4.00-4.00		
Percent Change	-52.2%(24.4)	-50.0%(26.7)	-100%-0%		

Table 4: Assessment of change in Total Score overtime (n =178)

Time point	I Score			Wilcoxon Test	
	Mean(SD)	Median(IQR)	Range	V	P Value
Pre-Treatment	9.37(3.33)	9.00(4.00)	3.00- 18.00	4005.0	<0.001
Post-Treatment	4.78(2.04)	5.00(3.00)	1.00- 8.00		
Absolute Change	-4.67 (1.77)	-5.00 (2.00)	-10.00--1.00		
Percent Change	-50.2%(12.6)	-50.0%(13.4)	-83%--25%		

Table 5: Summary of Side Effects

Side Effects	Present	Absent
Any	16(8.0%)	184(92.0%)
Palpitation	8(4.0%)	192(96.0%)
Heart Burn	2(1.0%)	198(99.0%)
Headache	0(0.0%)	100(100.0%)
Abdominal Pain	6(3.0%)	196(97.0%)
Urinary Retention	2(1.0%)	198(99.0%)
Pruritis	0(0.0%)	100(100.0%)
Lethargy	0(0.0%)	100(100.0%)