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Original Research Article

Role of mirabegron in the management of overactive bladder: a knowledge, attitude, and practice survey among Indian healthcare professionals

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ABSTRACT

Background: Overactive bladder (OAB) is identified by urinary urgency, with or without urgency urinary incontinence, typically accompanied by increased daytime urinary frequency and nocturia, in the absence of proven infection or other evident pathology.
Methods: A cross-sectional, observational, questionnaire-based knowledge, attitude, and practice (KAP) survey was conducted across India from January 2022 to July 2023 to understand OAB therapy through 14 multiple–choice questions containing questionnaire shared with 1, 029 healthcare professionals (HCPs), including urologists, surgeons, nephrologists, and consulting physicians.
Results: The HCPs see 10-20% of patients daily in clinical practice, wherein 5-10% are females. Patients usually consult general practitioners first and then other specialists. Although anticholinergics are commonly used in the management of OAB, HCPs reported that side effects (57%) and the high cost of therapy (43%) were mainly responsible for discontinuing anticholinergics. Mirabegron was preferred by 67% of HCPs in the treatment of these patients. Mirabegron is also preferred as a first-line treatment by all HCPs in this survey. It is prescribed for 6-12 months, has a response rate of >75% in clinical practice, and offers a more favourable side-effect profile compared to anticholinergics. In cases where patients do not respond to anticholinergics or experience treatment failure, a combination therapy of mirabegron and solifenacin is preferred.
Conclusions: The survey highlights the use of mirabegron as a first-line treatment for OAB, its better side-effect profile, and its role in combination therapy with solifenacin for patients unresponsive to anticholinergics, ultimately improving the quality of life of patients.

Keywords: Overactive bladder, Mirabegron, Antimuscarinic, KAP survey, β-3 agonist

INTRODUCTION

Overactive bladder (OAB) syndrome is a chronic condition that affects both men and women and has a significant impact on the quality of life.[1] The prevalence of OAB in Asia is reported to be between 1.9% to 53.1%.[2,3] Although OAB also affects children and young adults, it is common in those aged >40 years and the prevalence seems to increase with age.[2]

The globally accepted definition of OAB from the International Consultation on Incontinence Research

Society (ICI-RS), 2014 is: "OAB is identified by urinary urgency, with or without urgency urinary incontinence, typically accompanied by increased daytime urinary frequency and nocturia, in the absence of proven infection or other evident pathology". Patients often experience various combinations of these symptoms, each with varying levels of severity.[1]

Various factors may contribute to OAB, with the primary cause differing from person to person. Despite ongoing research, the exact cause of OAB remains unclear. However, four theories have been proposed to elucidate its pathophysiology and all these theories attempt to detrusor overactivity.[1,4]

Non-pharmacologic and pharmacologic approaches are implemented in the management of OAB.[4,5] Lifestyle modifications such as weight loss and exercise, dietary and fluid intake changes, bowel regulation, and smoking cessation are recommended for management.[4] Behavioural therapy for OAB includes bladder training, bladder control strategies, pelvic floor muscle training, and fluid management.[5]

Pharmacotherapy mainly involves the use of anticholinergic/antimuscarinic drugs and β3 agonist therapy.[4,5]Anticholinergic drugs, such as oxybutynin, darifenacin, solifenacin, tolterodine, fesoterodine, trospium, flavoxate, propantheline, and propiverine, are commonly used.[1,4,6] However, they have been linked to side effects like dry mouth, constipation, blurred vision, and somnolence.[4]

The second drug category that is used is β3-agonists.[1,6] Mirabegron, the first β3-agonist available since 2013, has shown promising results in alleviating OAB symptoms.[1,6,7] It is recommended as an alternative to anticholinergic therapy. It has comparable efficacy to anticholinergics but lower side effects, especially dryness of mouth.[1] Studies show higher adherence to mirabegron and superior results when combined with anticholinergics. It is safe for elderly patients.[1]

Considering the impact that OAB has on the quality of life, it is important to understand the perspective of the healthcare professional (HCPs) towards its management. As mirabegron and its combination have secured an important place in the management of OAB, it is important to understand its use, the perception of HCPs towards its initiation, and the patient groups that benefit in the clinical practice.

KAP surveys assess the beliefs and perceptions of a population regarding a specific topic, as well as how they implement those into practice.[8] The objective of the present study was to assess the understanding, opinions, and clinical approaches of Indian HCPs regarding OAB and its management, including mirabegron and its combination, in real-world settings or day-to-day outpatient department (OPD) clinics, ruling out standardized regulations of a clinical trial.

METHODS

Survey design and setting

This was a cross-sectional, observational, questionnaire-based KAP survey across India from January 2022 to July 2023. The flow of the study was: the sharing of the questionnaire to participants i.e., HCPs who gave consent, followed by filling of the questionnaire based on experience, collection of questionnaires, compilation, analysis, and presentation of data.

Survey participants

The total number of survey participants was 1, 029. The participants were registered medical practitioners, including urologists, consulting surgeons, nephrologists, and consulting physicians, with recognized qualifications, working in OPDs of privately run hospitals/clinics in a tertiary care setting and using mirabegron and its combination.

Survey instruments

The questionnaire was a specially designed, self-completion, and structured questionnaire, which included 14 multiple-choice questions. It was used to assess the attitude, perception/practices toward the use of mirabegron in treating OAB. These included 3 knowledge, 2 attitudes/perceptions, and 9 practice-based questions.

Knowledge-based questions were as follows

What percentage of OAB patients do you see daily in your clinical practice? What percentage of female OAB patients do you see daily in your clinical practice? Have your female patients consulted with any other specialty before approaching a specialist?

Attitude-based questions were as follows

Are you satisfied with the current treatment available for OAB? What would be the order preference for the first consultant of female OAB patients towards a specialty?

Practice-based questions were as follows

How long do you prescribe mirabegron to OAB patients? What percentage of your patients discontinued the anticholinergic therapy? What are the reasons behind the discontinuation of anticholinergic therapy? What are the treatment options you consider for patients who do not respond to anticholinergic therapy or are not suitable for anticholinergic therapy? Have you ever used mirabegron as a first-line therapy for your OAB patients? If yes, then how many percentages of patients of OAB respond to

mirabegron as a first-line therapy? What factors do you consider while prescribing mirabegron? Which are the factors do you consider to begin with mirabegron and solifenacin combination therapy? Which step-down option do you prefer for long-term maintenance therapy in your OAB patients who are already on mirabegron and solifenacin combination therapy?

Ethical consideration

This was a survey through which no patient-related data was captured and therefore ethics committee approval was not necessary and hence not obtained. As this was not a clinical trial, no clinical trial registration was required.

Statistical analysis

Categorical values were summarized by using frequencies and percentages. A comparison of variables representing categorical data was assessed. Many participants responded to more than one option for some questions if desired and suitable. The denominator for calculating the proportion for a particular question was the total number of participants who replied to a particular question. Data has been summarized and presented in tables and graphs.

RESULTS

Baseline demographics

The questionnaires were distributed among 1, 029 HCPs participating from different zones across India. These included HCPs from Central (6.70%), East (25.85%), North (25.36%), South (21.77%), and West (20.31%) zones. All HCPs completed the survey.

Knowledge about OAB

Of the surveyed HCPs in their clinical practice, more than half of HCPs (55%) observed 10-20% of OAB patients daily. Nearly half of them (47%) observe 5-10% of female OAB patients daily. Furthermore, the majority of them reported that their female patients consulted with other specialties before visiting a proper specialist (Table 1).

Attitude or perception about the management of OAB

In terms of the preference of female patients for specialties for the first consultation, most patients visit a general practitioner first, and then a consulting physician before visiting a specialist such as a surgeon or a urologist (Figure 1).

The majority of HCPs (67%) expressed satisfaction with the currently available treatment for OAB (Table 1).

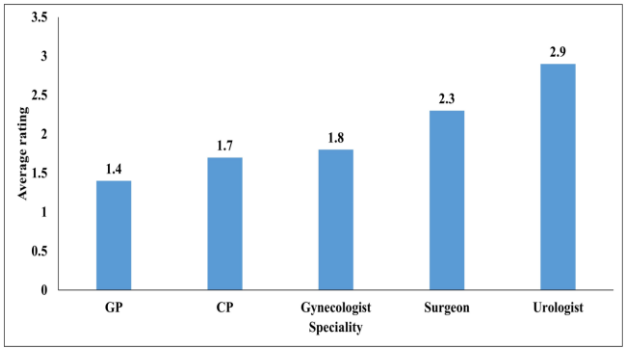

Figure 1: Order preference for the first consultation by female OAB patients toward a specialty.
CP: Consulting physician; GP: general practitioner

Practice assessment for mirabegron

Among the surveyed HCPs, most HCPs (43%) reported prescribing mirabegron for 6-12 months to their OAB patients, while some (31%) reported prescribing it for 3–6 months (Table 2).

Over half of HCPs (56%) reported that <25% of their patients discontinued anticholinergic therapy. Some others (40%) reported that patients between 25% and 50% discontinued anticholinergic therapy (Table 2). The most common reason for discontinuing anticholinergics was side effects, followed by the high cost of therapy (Table 2).

Mirabegron is the most preferred treatment option considered for patients who do not respond to anticholinergic therapy or are not suitable for anticholinergic therapy (Table 2).

All HCPs mentioned using mirabegron as the first line of treatment for OAB (Table 2). Most HCPs (42%) reported that >75% of patients respond to mirabegron when used as first-line treatment, while some (32%) reported that >50% to 75% of patients respond to mirabegron when used as first-line treatment (Table 2).

The preferred step-down option for long-term maintenance therapy in OAB patients who are already on mirabegron and solifenacin combination therapy is continuing with a reduced dose of the combination (Table 2).

The main factor considered while prescribing mirabegron is its safety, followed by its use in long-term maintenance and in patients not responding to anticholinergics (Table 3).

Lastly, the factors considered for initiating mirabegron and solifenacin combination therapy included treatment failure with anticholinergics/β-3 agonist, no response with anticholinergics/β-3 agonist, and poor adherence to anticholinergics (Table 3).

Table 1: Knowledge among HCPs about OAB and their attitude or perception towards its management.

S. no.	Response statements	Percentage of HCPs
1	Percentage of OAB patients seen in clinical practice daily	
	5	7
	5-10	16
	10-20	55
	>20	22
2	Percentage of female OAB patients seen daily in clinical practice	
	5	11
	5-10	47
	10-20	28
	>20	14
3	Opinion on female patients consulting any other specialty before approaching a specialist	
	Yes	94
	No	6
4	Satisfaction with the current treatment available for OAB	
	Yes	67
	No	33

Table 2: Practice for the use of mirabegron.

S. no.	Questions	Percentage of HCPs
1	Duration for which mirabegron is prescribed to OAB patients (months)	
	1-3	24
	3-6	31
	6-12	43
	>12	2
2	Patients discontinuing anticholinergic therapy (%)	
	<25	56
	25-50	40
	>50-70	3
	>70	1
3	Reasons for discontinuation of anticholinergic therapy	
	Side effects	57
	High cost	43
	Limited efficacy	7
4	Treatment options considered for patients who do not respond to anticholinergic therapy or are not suitable for anticholinergic therapy	
	Mirabegron	67
	Wait-and-watch approach	30
	Bladder injections	8
	Surgery	2
	Nerve stimulation	2
5	Used mirabegron as a first-line therapy for OAB patients	
	Yes	100
	No	0
6	Percentages of OAB patients responding to mirabegron as a first-line therapy	
	<25	2
	25-50	6
	50-75	32
	>75	42
7	Preferred step-down option for long-term maintenance therapy in OAB patients who are already on mirabegron and solifenacin combination therapy	
	Continued with a reduced dose of the combination	53
	Mirabegron monotherapy	38
	Solifenacin monotherapy	23

Table 3: Factors considered in practice while prescribing mirabegron or its combination.

S. no.	Questions	Rating
1	Factors considered while prescribing mirabegron	
	Safety profile	4.5
	Long-term maintenance therapy	4.3
	Non-responding to anticholinergics	4.2
	Naive patients	3.8
	Relatively younger patients with OAB	3.7
	Treatment failure with anticholinergics	3.6
	Comorbid conditions with OAB	3.6
	Poor adherence to anticholinergics	3.5
	Elderly conditions with OAB	2.5
2	Factors considered for initiating mirabegron and solifenacin combination therapy	
	Treatment failure with anticholinergics/β-3 agonist	4.5
	Non-responding to anticholinergics/β-3 agonist	4.3
	Poor adherence to anticholinergics	3.9
	Safety profile	3.9
	Severe OAB symptoms	3.2
	Elderly patients with OAB	3.2
	Comorbid condition with OAB	2.8

Rated on a scale of 0 to 5 (0: least important, 5 most important); OAB: overactive bladder

DISCUSSION

We administered a KAP survey to understand the knowledge, perception, and approaches for OAB in India. This survey provided valuable information on various aspects of OAB management, including in terms of patients examined daily, treatment satisfaction, duration of mirabegron therapy, drawbacks of anticholinergic treatments, and demographic data on the use of mirabegron-solifenacin combination therapy. Overall, the survey enabled us to gain a comprehensive understanding of the practical real-world aspects of OAB treatment in India.

Knowledge about OAB

According to the findings of the present survey, 10–20% of patients with OAB were seen in daily practice. This data is consistent with the results of an Indian study which reports the overall prevalence of OAB to be 15.5%.[3] Furthermore, the present survey suggests that 5–10% of female patients with OAB are seen daily in clinical practice. This finding is also supported by literature wherein the prevalence of overall OAB in women is reported from 5% to 25% for women aged 15 to 64 years.[9] According to an Indian study, it is around 8.6% in a similar age group.[3]

Attitude or perception about the management of OAB

This survey highlighted that the females usually consult a GP first, followed by a CP, and then the specialists. Furthermore, it also reflected that 67% of HCPs were satisfied with the currently available treatment for OAB.

Practice assessment for mirabegron

Survey data shows that mirabegron is generally prescribed for 6-12 months in OAB patients. The findings from clinical trials also indicate that mirabegron is clinically effective and maintains high adherence rates for up to 12 months. Moreover, its distinct mechanism of action suggests a more favorable tolerability profile compared to anticholinergic agents, potentially enhancing persistence in long-term treatment.[10]

The findings of this study reveal that discontinuation rates for anticholinergic therapy were up to 50% and the main reasons reported were side effects and the high cost of therapy. Although anticholinergics have historically been used in the treatment of OAB, their application is limited due to low tolerability and the onset of side effects associated with anticholinergic activity.[11] Furthermore, literature reports that healthcare providers are discontinuing anticholinergics due to the evidence linking their usage to increased risks of cognitive decline and other side effects.[11] One of the studies reported that 51.3% of patients permanently discontinued anticholinergic therapy, highlighting the need for new therapies and strategies to increase persistence and adherence to improve outcomes in OAB.[12]

Mirabegron is the preferred treatment option for patients not responding to anticholinergic therapy as per the findings of this study. According to the literature reports, mirabegron has comparable effectiveness to the majority of anticholinergics and is associated with a reduced occurrence of dry mouth, a primary adverse effect associated with anticholinergics.[4] In one study, mirabegron was found to be effective in treating OAB in

patients who discontinued anticholinergic therapy due to inefficacy.[13,14]

This survey also highlighted that mirabegron is universally utilized as a first-line therapy by all the participating HCPs and more than 75% of patients responded to it. A study by Shin and Choo evaluated the effectiveness and persistence of mirabegron as a first-line treatment for OAB in 196 patients. The study found significant improvements in daily frequency, nocturia, urgency episodes, and urgency urinary incontinence in the mirabegron monotherapy group ($p<0.05$). The persistence rate was 68.0% at 3 months, 54.4% at 6 months, and 39.4% at 12 months.[15] Furthermore, mirabegron is feasible as a first-line medication for OAB patients, and doses starting from 25 mg/day are as effective as 50 mg/day.[16]

According to the survey findings, safety profile and long-term maintenance therapy are considered crucial factors when prescribing mirabegron. Literature also supports this finding as the incidence of anticholinergic side effects, frequently reported as the most troublesome by patients, is significantly reduced with mirabegron, indicating improved adherence and longer treatment duration with mirabegron.[17] Moreover, the use of mirabegron in patients with OAB is associated with a lower risk of new-onset dementia compared with the use of anticholinergics.[14]

The present survey suggests that factors like no response to anticholinergics and treatment failures with anticholinergics are considered when initiating combination therapy with mirabegron and solifenacin. Mirabegron and solifenacin have different mechanisms of action, and their concurrent use does not affect their pharmacokinetics.[18] The findings from the Symphony trial indicated that combination therapy with solifenacin/mirabegron (solifenacin 2.5, 5, or 10 mg plus mirabegron 25 or 50 mg) significantly improved mean volume voided per micturition, micturition frequency, and urgency compared with solifenacin 5 mg monotherapy. All combinations were well tolerated.[18]

Another study, the BESIDE trial, reported that the combination was superior to solifenacin 5 mg and resulted in significant improvements in daily incontinence ($p=0.001$), daily micturition ($p<0.001$), and incontinence noted in a 3-d diary ($p=0.014$). The combination was superior to solifenacin 10 mg for improving daily micturition but non-inferior to solifenacin 10 mg for key secondary endpoints. All treatments were well tolerated.[19] Furthermore, as per the responder analysis and patient-reported outcomes from the BESIDE study, significantly more patients on combination achieved clinically meaningful improvements in incontinence and micturition frequency, which were accompanied by similar improvements in patient perception of bladder condition, symptom bother, and health-related quality of life.[20]

The EAU guidelines recommend considering dose escalation or offering an alternative anticholinergic formulation, mirabegron, or a combination if an anticholinergic treatment proves ineffective.[14] Lastly, the Canadian Urological Association guidelines recommend a combination treatment with solifenacin and mirabegron for patients who remain incontinent after the initial treatment with anticholinergic therapy.[21]

The present study benefits from a large, diverse sample of 1,029 healthcare professionals across various specialties and settings, utilizing a structured questionnaire to comprehensively assess knowledge, attitudes, and clinical practices. Conducted over 18 months, it provides real-world insights into current treatment strategies and challenges, improving understanding of the clinical practice. However, there are some limitations as well.

The limitations include potential selection bias among participants, reliance on self-reported data which may be subject to recall bias, and absence of clinical outcomes data to validate reported practices effectively.

CONCLUSION

The present survey highlights the knowledge and perception of HCPs on OAB. It also highlights the practices of using mirabegron in routine clinical practice. The survey points towards the utilization of mirabegron as a first-line agent in the management of OAB over anticholinergics. It can be started in doses as low as 25 mg/day showing comparable effectiveness to higher doses of 50 mg/day. Moreover, it has a better side-effect profile than anticholinergics and the response rate in clinical practice is good. The mirabegron and solifenacin combination is preferred in patients who do not respond to anticholinergics or have treatment failure. It is effective, well-tolerated, and improves their quality of life.

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Conflict of interest: Dr. Dinesh Patil and Dr. Vikram Sahu are full-time employees of Alembic Pharmaceuticals Ltd, which actively markets Mirabegron
Ethical approval: Not required

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