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REVIEWER'S REPORT

Manuscript No.: IJAR- 50375 Date: 21/02/2025

Title: "Efficacy and Safety of Mirabegron Plus Vitamin D3 vs. Mirabegron Alone in the Treatment of Adult Patients of Overactive Bladder: A Randomized Controlled Trial"

Recommendation:
✓ Accept as it is .....
Accept after minor revision.....
Accept after major revision .....
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		✓		
Techn. Quality		✓		
Clarity		✓		
Significance		✓		

Reviewer Name: Dr. S. K. Nath **Date:** 22/02/2025

Reviewer's Comment for Publication:
This study makes a valuable contribution to the understanding of OAB management, particularly in highlighting the potential benefits of Vitamin D3 supplementation as an adjunct therapy. Despite certain limitations, especially regarding sample size and study design, the findings offer promising directions for future research.

Reviewer's Comment / Report

Strengths of the Study

1. **Clear Objective and Relevance:** The paper presents a clear aim: to evaluate whether Vitamin D3 supplementation enhances the therapeutic efficacy of Mirabegron in treating overactive bladder (OAB). Given the rising interest in non-pharmacological adjuncts for OAB, this research is timely and relevant.

2. **Robust Methodology:** The randomized controlled trial (RCT) design strengthens the validity of the findings. The use of validated tools such as the Urgency Severity Score (USS), Overactive Bladder Symptoms Severity Score (OABSS), and a 3-Day Voiding Diary provides reliable and comprehensive outcome measures. Clear inclusion and exclusion criteria ensure a well-defined study population.

3. **Statistical Analysis:** The study employs appropriate statistical tests, showing clear differentiation between baseline and post-treatment effects across different groups. The post-hoc analysis adds depth to the findings by examining intergroup differences.

4. **Clinical Relevance:** The results provide practical insights for clinicians managing OAB, highlighting the potential of Vitamin D3 supplementation in patients with deficiency or insufficiency.

5. **Safety Monitoring:** The paper clearly states that no new side effects were observed, reinforcing the safety of both monotherapy and combination therapy.

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Weaknesses and Areas for Improvement

1. **Sample Size Limitations:** The final sample size of 99 participants, after accounting for dropouts, is relatively small for a clinical trial, limiting the generalizability of the findings. The paper acknowledges the influence of social stigma in rural India on patient recruitment but doesn't offer strategies for overcoming this in future studies.

2. **Lack of Blinding:** The open-label design introduces potential biases, particularly in subjective assessments such as self-reported urgency and voiding diaries. A double-blind design would enhance credibility.

3. **Vitamin D Dosage Clarification:** The exact dosage of 1500 μg weekly could be better justified, particularly in comparison to previous studies using different dosages or schedules.

4. **Short Duration of Follow-Up:** The study only spans 12 weeks, which might not be sufficient to observe long-term effects or relapses. A longer follow-up period would be more informative.

5. **Limited Diversity in Population:** Being conducted in a rural tertiary care hospital in India, the study lacks demographic diversity, making it harder to generalize findings to broader populations.

6. **Mechanistic Insights:** While the study hints at the possible mechanisms of Vitamin D in OAB symptom relief (calcium homeostasis and detrusor muscle hyperactivity), it lacks direct biochemical or physiological data to support these claims.

Suggestions for Future Research

1. **Larger, Multi-Centric Trials:** Conducting similar studies across different regions and including more participants would enhance generalizability.

2. **Double-Blind, Placebo-Controlled Design:** To minimize subjective bias, a double-blind trial with a placebo group for Vitamin D3 supplementation should be considered.

3. **Mechanistic Studies:** Incorporating biochemical assays, such as intracellular calcium measurements or bladder muscle biopsies, could provide deeper mechanistic insights.

4. **Long-Term Follow-Up:** Studies extending beyond 12 weeks could evaluate the sustainability of symptom improvement and any delayed side effects.

5. **Psychological and Quality of Life Measures:**
Including validated psychological or quality of life scales could provide a more comprehensive understanding of how OAB and its treatment affect daily functioning.