European Journal of Obstetrics and Gynecology 325 (2026) 115321



Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.journals.elsevier.com/european-journal-of-obstetrics-and-gynecology-and-reproductive-biology



Review article



Comparing the safety and efficacy of vibegron, mirabegron and tolterodine in patients with overactive bladder: a systematic review and network meta-analysis

R. Mohamed-Ahmed [a,b,1,*], A. Rantell [b,2], D. Robinson [a,b,3]

[a] King's College London, United Kingdom
[b] Department of Urogynaecology, King's College Hospital, London SE5 9RS, United Kingdom

ARTICLE INFO

Keywords:
Vibegron
Mirabegron
Tolterodine
Overactive bladder
Network meta-anaylsis
Systematic review

ABSTRACT

Introduction: Overactive bladder (OAB) is defined as 'urinary urgency with or without urinary urgency incontinence (UUI), usually associated with urinary frequency and/or nocturia, in the absence of urinary tract infection'. OAB is known to be a common disorder with a significant impact on quality of life.
First line treatments include weight loss in those with a BMI > 30, bladder retraining and fluid advice. Pharmacotherapy treatment includes antimuscarinics and mirabegron, a beta 3 agonist.
The National Institute of Clinical Excellence (NICE), has recently incorporated the use of a newer beta 3 agonist, vibegron, into its recommendations for the management of overactive bladder (OAB). There are no head-to-head studies which directly compare the efficacy of vibegron with mirabegron, an older beta 3 agonist.
Aim: This network meta-analysis aims to compare the safety and efficacy of vibegron when compared to mirabegron and tolterodine, more longstanding treatments for OAB.
Method: A systematic review was conducted to identify phase III randomised controlled trials, for patients with idiopathic OAB, which compared mirabegron and/or vibegron and/or tolterodine. The primary outcome was the change from baseline in episodes of urinary urgency (UU). The secondary outcomes assessed were:

- Change from baseline in UUI.
- Change from baseline in urinary frequency over 24 h.
- Change from baseline in maximum voided volume per void (mL).
- Adverse effects, including hypertension, dry mouth and constipation.

The study was registered on PROSPERO (CRD 420250636077) and analysis was performed using MetaInsight.
Results: Of the 2,647 identified articles, five studies were deemed suitable to include in the network meta-analysis.
Results for the primary outcome included 5,317 patients and demonstrated a greater improvement in UU episodes in the vibegron group, when compared to placebo, tolterodine and mirabegron.
Vibegron also ranked favourably in reduction in episodes of UUI and improvement in maximum voided volume per void. Whereas mirabegron had the greater improvement in reduction in episodes of urinary frequency.
Adverse events: The incidence of any adverse event was highest in the vibegron group. Tolterodine had the highest rate of hypertension and dry mouth. Constipation was highest in the vibegron group. However, it is important to note the large heterogeneity in definitions of adverse events as well as discrepancy in their reporting.
Conclusions: Vibegron appears to rank more favourably for improvement in episodes of UU, UUI and maximum voided volume per void, when compared to mirabegron and tolterodine. Mirabegron ranks more favourably for improvement in episodes of urinary frequency over 24 h.

* Corresponding author.
E-mail addresses: r.mohamed-ahmed@nhs.net (R. Mohamed-Ahmed), angela.rantell@nhs.net (A. Rantell), dudley.robinson@nhs.net (D. Robinson).
[1] ORCID: 0000-0002-6739-5014.
[2] ORCID: 0000-0002-9123-5352.
[3] ORCID: 0000-0002-4879-6672.

https://doi.org/10.1016/j.ejogrb.2026.115321
Received 13 March 2026; Received in revised form 13 July 2026; Accepted 14 July 2026
Available online 21 July 2026
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Mirabegron is least likely to be associated with hypertension, although reporting of adverse events is non-standardised and therefore may not be comparable.
This network meta-analysis does not account for other factors which may influence drug therapy choice i.e. contraindications, difficulties with swallowing and available treatment options.

Introduction

Overactive bladder (OAB) is defined by the International Continence Society as "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection or other obvious pathology" (1). It is a highly prevalent condition, affecting an estimated 11–16% of the adult population globally, with a significant negative impact on health-related quality of life, mental wellbeing, sleep and daily activities (2, 3). The pathophysiology of OAB is multifactorial and not fully understood, but is thought to involve detrusor overactivity, afferent pathway hypersensitivity and central nervous system dysregulation (4).

The management of OAB follows a step wise approach, beginning with conservative first-line strategies such as lifestyle modifications, fluid management, weight loss in those with a raised body mass index (BMI), bladder training and pelvic floor muscle training (5). When these measures are insufficient, pharmacotherapy forms the cornerstone of second-line treatment. For decades, antimuscarinics such as oxybutynin, tolterodine and solifenacin, have been the mainstay, working by blocking muscarinic receptors in the detrusor muscle to inhibit involuntary contractions (4). However, their use is often limited by anticholinergic side effects, including dry mouth, constipation, blurred vision, and cognitive effects, which contribute to high discontinuation rates (6).

The introduction of mirabegron, the first beta-3 adrenergic agonist approved for OAB, into treatment pathways in the United Kingdom in 2013 marked a significant therapeutic advance. By selectively activating beta-3 receptors in the detrusor, mirabegron promotes bladder relaxation and increases storage capacity without the typical anticholinergic side effects, offering an alternative for patients intolerant to antimuscarinics or in whom their use may be contraindicated (7). More recently, another beta-3 agonist, vibegron, has been developed and first approved for use in Japan in 2018. Vibegron exhibits high selectivity for the beta-3 receptor and a pharmacokinetic profile that allows for once-daily dosing without titration or need for dose altering in those with hepatic or renal dysfunction (8).

The National Institute for Health and Care Excellence (NICE) in the UK has incorporated vibegron into its treatment pathway for OAB since 2024, recognising it as an option after inadequate response to, or intolerance of, antimuscarinics (9). While placebo-controlled trials have established the efficacy of vibegron (10), there is a notable absence of head-to-head randomised controlled trials directly comparing it with mirabegron. Consequently, clinicians lack robust comparative evidence to inform decision-making between these two licensed medications.

Network meta-analyses (NMA) are a statistical technique that allow for the indirect comparison of multiple interventions by synthesising data across a network of randomised controlled trials (RCTs), even in the absence of direct trials (11). This method provides a hierarchy of treatments based on both efficacy and safety.

The objective of this systematic review and network meta-analysis is to compare the efficacy and safety of vibegron, mirabegron and tolterodine in the treatment of idiopathic OAB.

Materials & methods

Study design and registration

This study was conducted as a systematic review and network meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Network Meta-Analyses (12). The protocol was prospectively registered on the International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD 420250636077.

Eligibility criteria

Population: Adult patients (≥18 years) diagnosed with idiopathic overactive bladder, as defined by study authors, with symptoms for ≥ 3 months.

Interventions and Comparators: Phase III RCTs comparing the following interventions were eligible: vibegron 75 mg once daily, mirabegron 50 mg once daily, tolterodine 4 mg daily and/or placebo. Studies involving combination therapies or non-standard doses were excluded.

Outcomes:

Primary Efficacy Outcome: Change from baseline to study endpoint (12 weeks) in the mean number of urinary urgency (UU) episodes per 24 h.

Secondary Efficacy Outcomes:

1. Change from baseline in the mean number of urgency urinary incontinence (UUI) episodes per 24 h.
2. Change from baseline in the mean number of micturitions (urinary frequency) per 24 h.
3. Change from baseline in maximum voided volume per void (MVV, in mL).

Safety Outcomes:
Incidence of:

1. Any adverse event (AE).
2. Hypertension (as a treatment-emergent adverse event).
3. Dry mouth.
4. Constipation.

Study Design: Only Phase III, parallel-group, RCTs were included. Conference abstracts, non-randomised studies, trials in neurogenic or paediatric populations and unpublished data were excluded.

Search strategy

A comprehensive literature search was performed from database inception to May 2025 on the following electronic databases: MEDLINE (via PubMed), Embase, Cochrane Central Register of Controlled Trials (CENTRAL) and ClinicalTrials.gov. The search strategy combined Medical Subject Headings (MeSH) and free-text terms related to "overactive bladder," "vibegron," "mirabegron," "tolterodine," and "randomised controlled trial". The search was restricted to studies in the English language. The full search strategy for PubMed is provided in Supplementary Appendix A. Reference lists of relevant reviews and included studies were manually scanned for additional eligible trials.

Study selection and data extraction

Two independent reviewers screened titles and abstracts, followed by a full-text review of potentially eligible articles. Discrepancies were resolved through discussion with a third reviewer. Data were extracted using a standardised piloted form. Extracted information included: study

characteristics (first author, year, design, duration), participant demographics, intervention details (drug, dose, regimen) and outcome data (baseline values, endpoint values or change scores, number of events for safety outcomes). For continuous outcomes, the mean change from baseline, standard deviation (SD) and sample size were extracted. When only standard error (SE) or confidence intervals were reported, SDs were calculated using standard formulas.

Risk of bias assessment

The risk of bias for individual RCTs was assessed independently by two reviewers using the Cochrane Collaboration's Risk of Bias tool (RoB 2) for randomised trials (13). The tool evaluates bias across five domains: randomisation process, deviations from intended interventions, missing outcome data, measurement of the outcome and selection of the reported result. Judgments were categorised as "low risk", "some concerns" or "high risk'. This information is displayed in Table 1.

Statistical analysis and network meta-analysis

The network meta-analysis was analysed using the web-based tool MetaInsight (v3.0), which utilises the netmeta package in R (14). For continuous outcomes (UU, UUI, frequency, MVV), the analysis was based on the mean difference (MD) in change from baseline between treatments, along with its 95% confidence interval (CI). For dichotomous safety outcomes, the odds ratio (OR) with 95% CI was calculated. Random effects models were utilised for analysis, in order to allow for potential variations across trial designs.

The analysis assumed consistency between direct and indirect evidence within the closed treatment network. The geometry of the treatment network was illustrated using network plots, where nodes represent treatments and edges represent direct comparisons from head-to-head trials. The number of trials for that comparison is displayed on the network plot.

Global heterogeneity was assessed by visually inspecting the network and calculating the I^2 statistic for the entire network. The ranking of treatments for each outcome was estimated using surface under the cumulative ranking curve (SUCRA) values, where a SUCRA value of 100% indicates the treatment is always the best and 0% indicates it is always the worst (15, 16).

Results

Study selection and characteristics

The systematic literature search identified 2,647 records. After title/abstract screening and full-text review, five Phase III RCTs met all eligibility criteria and were included in the network meta-analysis (10, 17–20). The PRISMA flow diagram is presented in Fig. 1.

The five included studies enrolled a total of 5,317 participants with idiopathic OAB. The network of treatments included placebo (PBO), vibegron 75 mg (VIB), mirabegron 50 mg (MIR), and tolterodine 4 mg (TOL). The network geometry for the primary outcome is shown in Fig. 2. All studies were multi-centre, double-blind and had a 12-week treatment period. Key characteristics of the included studies are summarised in Table 2.

Risk of bias assessment

Overall, the included studies were judged to have a low risk of bias. All studies described adequate random sequence generation, allocation concealment and treatment blinding. Outcome data were largely complete and outcome measurement was standardised using patient-completed bladder diaries. The selection of reported results was deemed free from bias as primary and secondary outcomes were pre-specified in trial registries or protocols. A risk of bias assessment for each study is provided in Table 1.

Efficacy outcomes

Primary outcome: urinary urgency (UU) episodes

The network included data from 5,317 patients for this outcome. All active treatments were superior to placebo. Vibegron ranked more favourably when assessing reduction in UU episodes. The estimated mean differences (MD) versus placebo were: VIB: −0.66 (95% CI: −1.10 to −0.22); MIR: −0.52 (95% CI: −0.76 to −0.27) and TOL: −0.38 (95% CI: −0.50 to −0.16). The pairwise meta-analysis, as presented in Table 3, ranks the treatment options from best to worst, along the leading diagonal. The estimates above the leading diagonal are the estimates of treatment effect obtained from pairwise meta-analyses, whereas the estimates below the diagonal are from the network meta-analysis. The forest plot is presented in Fig. 3.

Secondary outcomes

- *Urgency Urinary Incontinence (UUI):* Similar to the primary outcome, vibegron ranked first for reducing UUI episodes, showing a statistically significant greater improvement compared to both mirabegron and tolterodine (Fig. 4).
- *Maximum Voided Volume (MVV):* Vibegron was associated with the greatest increase in MVV per void, significantly outperforming both mirabegron and tolterodine, which in turn were both superior to placebo (Fig. 5).
- Urinary Frequency (Micturitions/24 h): For this outcome, the ranking differed. Mirabegron showed the greatest reduction in 24-hour urinary frequency, achieving a statistically significant greater improvement compared to vibegron and a numerical, though not always statistically significant, advantage over tolterodine (Fig. 6).

The SUCRA rankings for all efficacy outcomes are summarised in Fig. 7, visually confirming the differential efficacy profiles.

Safety outcomes

The incidence of adverse events across the network is presented as odds ratios in Table 4.

Table 1
Risk of Bias.

Study	Domain 1: Randomisation Process	Domain 2: Deviations from Intended Interventions	Domain 3: Missing Outcome Data	Domain 4: Measurement of Outcome	Domain 5: Selection of Reported Result	Overall RoB
Staskin 2020	Low	Low	Low	Low	Low	**Low**
Staskin 2021	Some concerns	Low	Some concerns	Low	Some concerns	**Some concerns**
Kuo 2015	Low	Low	Some concerns	Low	Low	**Low**
Khullar 2013	Low	Low	Some concerns	Low	Low	**Low**
Yamaguchi 2014	Low	Low	Low	Low	Low	**Low**

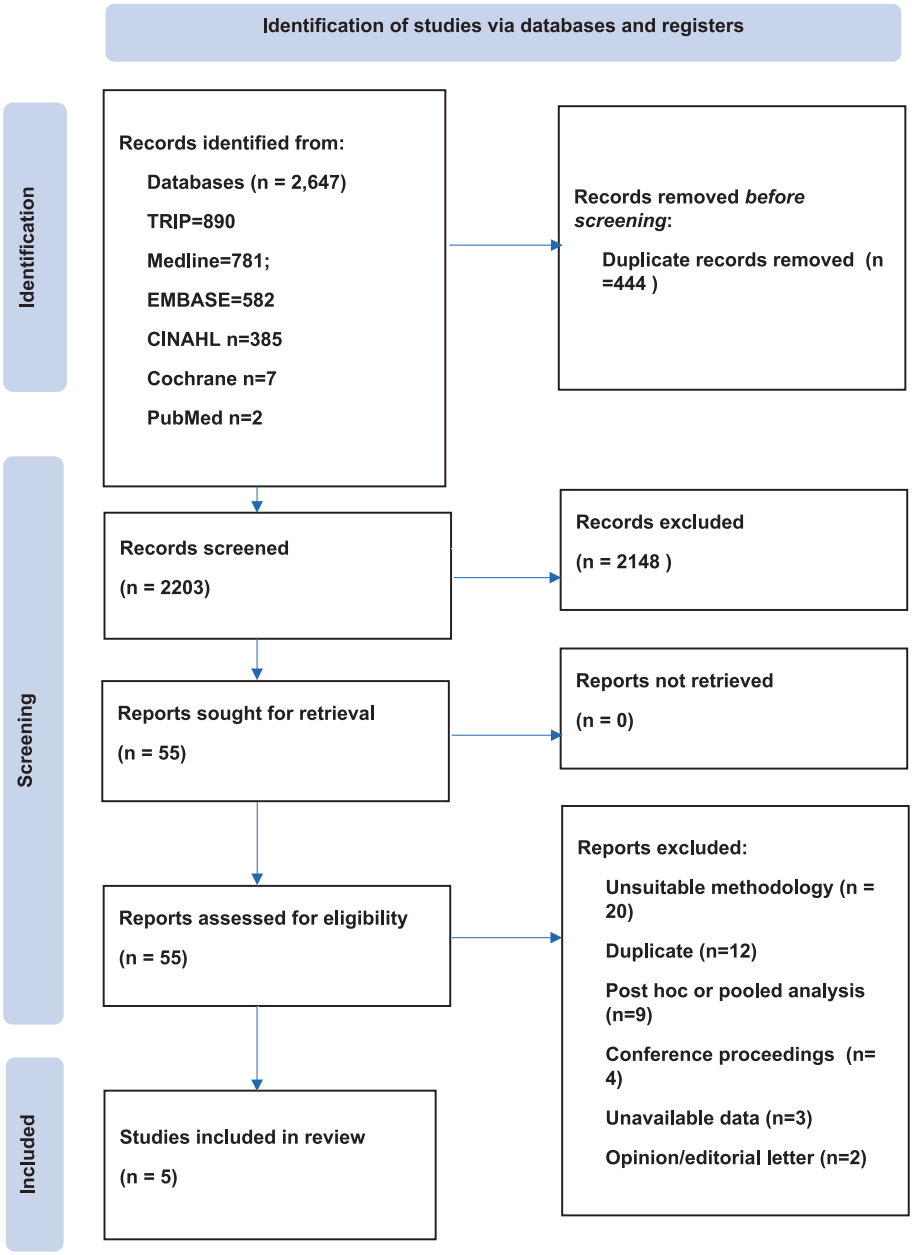


Fig. 1. PRISMA Flow Diagram of Study Selection.

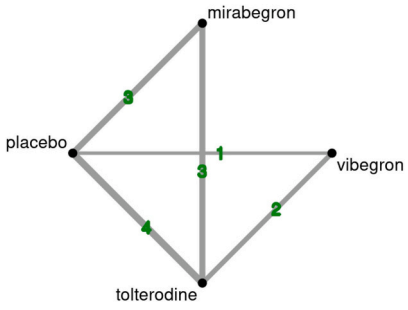


Fig. 2. Network Plot of Eligible Studies to Compare Efficacy Outcomes.

- *Any Adverse Event:* The odds of experiencing any AE were highest with vibegron (OR 1.51, 95% CI 1.08 to 2.10) and tolterodine (OR 1.36, 95% CI 1.09 to 1.70). Mirabegron had the lowest odds, which were not significantly different from placebo (OR 0.89, 95% CI 0.69 to 1.15).
- *Hypertension:* No treatment showed a statistically significant increase in hypertension compared to placebo, though point estimates were highest for tolterodine (OR 1.44, 95% CI 0.77–4.70) and lowest for mirabegron (OR 0.90, 95% CI 0.39–3.07).
- *Dry Mouth:* As expected, the antimuscarinic tolterodine had a markedly higher risk of dry mouth (OR 3.91, 95% CI 2.00–8.18). The risk with vibegron and mirabegron was not significantly increased (OR 1.20 and 1.08 respectively).
- *Constipation:* None of the treatments showed a statistically significant increase in constipation risk compared to placebo, though vibegron had the highest point estimate (OR 1.48, 95% CI 0.69–3.19).

It is important to note that there was considerable heterogeneity in the definitions and methods of reporting adverse events across the included trials (i.e. hypertension defined by AE report vs. predefined blood pressure threshold). This limits the direct comparability of safety

Table 2
Characteristics of Included Randomised Controlled Trials.

Author	Year of Publication	Study Design	Participants	Interventions	Comparators	Outcomes
Staskin et al	2021	Double −blind RCT	n = 506 (78.2% female) Mean age = 61 Diagnosis on bladder diary: Wet OAB: >/= 8 micturitions/day with >/=1 UUI episode per day Dry OAB: >/= 8 micturitions/day with >/=3 UU episodes per day Symptom duration: >12 weeks	Vibegron 75 mg once daily	Tolterodine eR 4 mg once daily	Primary outcome: Incidence of treatment-emergent adverse events Secondary outcomes: 1. Change from baseline of average daily micturitions 2. Episodes in UUI 3. Episodes of urinary urgency 4. Episodes of urinary incontinence
Staskin et al	2020	Double-blind RCT	n = 1,518 (85.2% female) Mean age = 62 Diagnosis on bladder diary: Wet OAB: >/= 8 micturitions/day with >/=1 UUI episode per day Dry OAB: >/= 8 micturitions/day with >/=3 UU episodes per day Symptom duration: >12 weeks	Vibegron 75 mg once daily or tolterodine ER 4 mg once daily	Placebo	Primary outcomes: Secondary outcomes: 1. Change from baseline in daily micturitions 2. Change from baseline in daily number of UUI episodes 1. Change from baseline in episodes of urinary urgency 2. Change in average voided volume per void in mL 3. Proportion of wet OAB with >/=75% reduction in average daily number of UUI episodes
Kuo et al	2015	Double-blind RCT	n = 1,126 (67% female) Mean age = 54.5 Diagnosis on bladder diary: >/= 8 micturitions/day with >/=1 UUI or UU episode per day Symptom duration: >12 weeks	Mirabegron 50 mg once daily Tolterodine ER 4 mg once daily	Placebo	Primary outcome: Change from baseline in mean number of micturitions/24 h Secondary outcomes: 1. Change from baseline in mean number of urgency episodes 2. Change from baseline in mean number of UUI episodes 3. Change from baseline in mean number of urinary incontinence episodes 4. Change from baseline in mean number of nocturia episodes 5. Change from baseline in mean number of mean volume voided/ micturition
Khullar et al	2013	Double-blind RCT	n = 1,978 (72.5% female) Mean age = 59.1 Diagnosis on bladder diary: >/= 8 micturitions/day with >/=3 UU episodes per day Symptom duration: >12 weeks	Mirabegron 50 mg once daily Mirabegron 100 mg once daily Tolterodine ER 4 mg once daily	Placebo	Primary outcomes: Secondary outcomes: 1. Change from baseline in mean number of incontinence episodes 2. Change from baseline in mean number of micturitions per 24 h 1. Change from baseline in mean volume voided per void in mL
Yamaguchi et al	2014	Double-blind RCT	n = 1,139 (83.7% female) Mean age = 58.3 Diagnosis on bladder diary: >/= 8 micturitions/day with >/=1 UUI episode per day or >/=3 UU episodes per day Symptom duration: >24 weeks	Mirabegron 50 mg once daily Tolterodine ER 4 mg once daily	Placebo	Primary outcome: Change from baseline in mean number of micturitions/24hr Secondary outcomes: 1. Change from baseline in mean number of urgency episodes/24 h 2. Change from baseline in mean number of urinary incontinence episodes/24 h 3. Change from baseline in mean number of UUI episodes/24 h 4. Change from baseline in mean number of nocturia episodes 5. Change from baseline in mean number of mean volume voided/ void

results and is a key limitation of this analysis. These findings should therefore be considered as descriptive rather than definitive.

Discussion

This systematic review and network *meta*-analysis, incorporating data from over 5,000 patients across five high-quality RCTs, provides a comprehensive indirect comparison of the newer beta-3 agonist vibegron with the established agents mirabegron and tolterodine for the treatment of idiopathic OAB. Although previous network *meta*-analyses on this has been conducted, this is the only one using a single anticholinergic comparator, rather than anticholinergics in general, and rather than just comparing to placebo (21, 22).

There has only been one open label, parallel group RCT, comparing mirabegron 50 mg once daily with vibegron 50 mg once daily, with 52 patients in each arm (23). Their results showed no significant differences in OAB symptoms scores at the end of treatment (12 weeks) when compared to baseline. It is important to note the sub-therapeutic dose of vibegron in this study as well as the small sample size which was not powered prior to study commencement.

Table 3
Pairwise Meta-analysis Relative Treatment Effects for Primary Outcome (Urinary Urgency Episodes).

VIBEGRON	−0.00 [-0.60; 0.60]	−0.20 [-0.84; 0.44]	−0.70 [-1.19; −0.21]
−0.09 [-0.48; 0.31]	**MIRABEGRON**	−0.17 [-0.42; 0.09]	−0.50 [-0.74; −0.26]
−0.25 [-0.66; 0.17]	−0.16 [-0.40; 0.08]	**TOLTERODINE**	−0.37 [-0.59; −0.15]
−0.62 [-1.01; −0.24]	−0.54 [-0.76; −0.31]	−0.38 [-0.59; −0.16]	**PLACEBO**

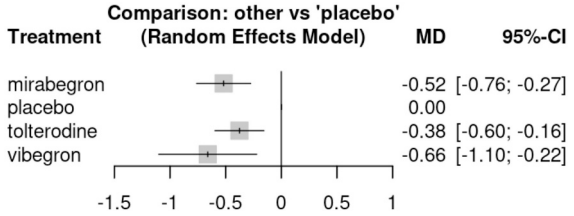


Fig. 3. Forest Plot for Mean Difference in Change from Baseline in Urinary Urgency.

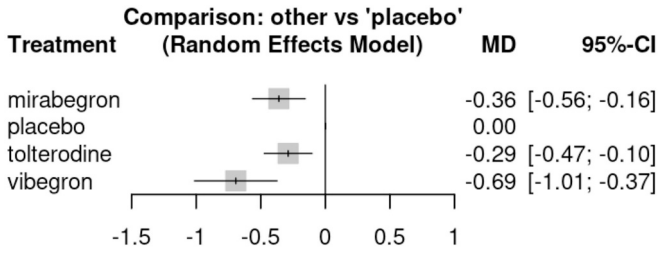


Fig. 4. Forest Plot for Mean Difference in Change from Baseline in Urgency Urinary Incontinence.

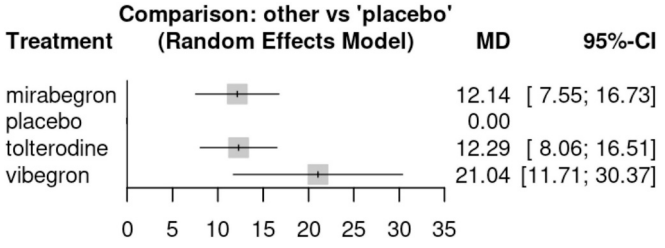


Fig. 5. Forest Plot for Mean Difference in Change from Baseline in Maximum Voided Volume per Void in mL.

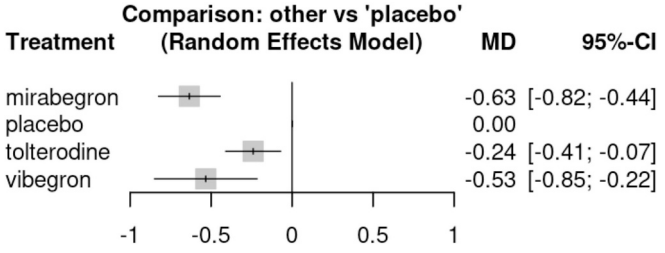


Fig. 6. Forest Plot for Mean Difference in Change from Baseline in Episodes of Urinary Frequency in 24 h.

Our key finding is that while all three drugs are effective, they exhibit distinct efficacy profiles. Vibegron ranked favourably in improving symptoms directly related to urgency, such as, reducing episodes of urinary urgency and urgency incontinence, and in increasing bladder storage capacity. This suggests vibegron may be particularly advantageous for patients whose predominant complaint is bothersome urgency and incontinence. The pharmacological basis for this observed effect may relate to vibegrons high receptor selectivity and pharmacokinetic properties (8). Previous NMAs demonstrate similar findings, with vibegron demonstrating a higher efficacy for long term reduction of total episodes of urinary incontinence (22).

Mirabegron showed the greatest efficacy in reducing the total number of daily micturitions and may therefore be more beneficial in those with bothersome urinary frequency. Tolterodine, the representative antimuscarinic, was effective across outcomes but did not rank first for any specific efficacy endpoints in this analysis.

The safety analysis revealed important differences. Mirabegron was associated with the most favourable tolerability profile, with odds of any adverse event comparable to placebo and the lowest point estimate for hypertension. This supports its established role as a well-tolerated option, especially for patients concerned about anticholinergic side effects (24). The higher odds of any adverse event with vibegron, driven largely by non-serious events, warrant attention but must be interpreted cautiously due to heterogeneity in reporting.

As anticipated, tolterodine carried a significantly higher risk of dry mouth, a well-recognised side effect of anticholinergics and a contributor to treatment discontinuation (25). The data on constipation and hypertension were inconclusive, with wide confidence intervals that preclude definitive conclusions. Comparative data demonstrated higher persistence and adherence to vibegron when compared to mirabegron and antimuscarinics, which is likely to be secondary to tolerability and a lower side effect profile (26).

Limitations

This analysis has several limitations. First, the number of included studies (n = 5) is modest, though the total patient population is substantial. This can influence the statistical power of an NMA. We also acknowledge that the second Staskin et al trial from 2021 uses the placebo subgroup from the EMPOWUR study to run an extension study. Although this subgroup are treatment naïve, there is a potential of bias introduced secondary to this. Second, the short-term follow-up of the trials limits conclusions about long-term comparative efficacy and safety. Third, there is significant heterogeneity in the reporting and definition of adverse events across the trials which thereby complicates the safety comparison; standardised reporting of adverse outcome in future RCTs is necessary. Fourth, the analysis did not account for potential effect modifiers such as patient age, gender, OAB subtype (dry vs. wet) or prior treatment history, which could influence outcomes. Finally, a network *meta*-analysis is not a substitute to data obtained from large, direct head-to-head RCTs.

Future research

Future studies should prioritise direct, long-term, active-comparator RCTs between vibegron and mirabegron. The efficacy of vibegron as part of combination therapy should also be investigated. Research should also explore predictors of response to different drug classes to allow for personalisation of treatment and individualised care. Further investigation into the real-world effectiveness, adherence and healthcare costs associated with these newer agents is also required.

Conclusion

This network meta-analysis demonstrates that vibegron, mirabegron and tolterodine have differing efficacy and safety profiles in the treatment of overactive bladder. These results can also reassure clinicians that vibegron is an effective introduction into treatment algorithms.

Within this NMA, vibegron ranked favourably in reducing episodes

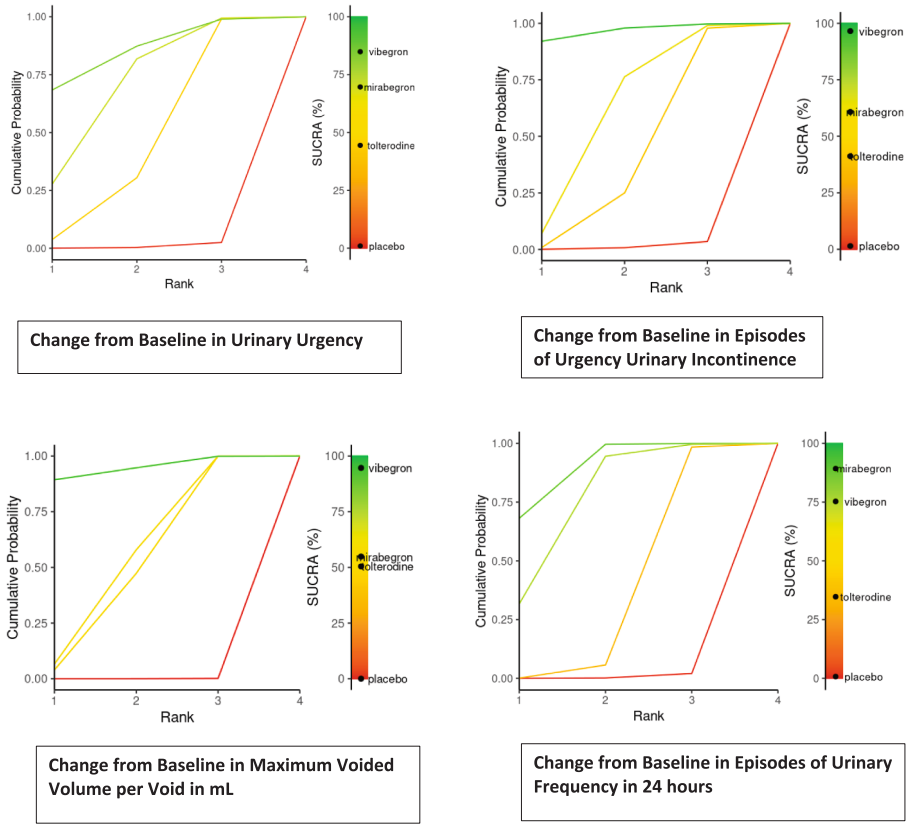


Fig. 7. SUCRA Rankings for Efficacy Outcomes.

Table 4
Table for Safety Outcomes (Odds Ratios).

	Vibegron OR [95% CI]	Mirabegron OR [95% CI]	Tolterodine OR [95% CI]
Any adverse event	**1.51 [1.08, 2.10]**	0.89 [0.69, 1.15]	1.36 [1.09, 1.70]
Hypertension	1.20 [0.46, 4.7]	0.90 [0.39, 3.07]	**1.44 [0.77, 4.7]**
Dry mouth	1.20 [0.39, 3.97]	1.08 [0.49, 2.47]	**3.91 [2.00, 8.18]**
Constipation	**1.48 [0.69, 3.19]**	1.14 [0.66, 1.99]	1.21 [0.74, 1.99]

of urinary urgency and incontinence-related outcomes, mirabegron for reducing urinary frequency and offering the best tolerability, while tolterodine is effective but associated with a higher risk of dry mouth. These findings, combined with consideration of patient preferences, comorbidities and cost, can help clinicians optimise individualised treatment strategies for patients suffering from OAB.

CRediT authorship contribution statement

R. Mohamed-Ahmed: Writing – original draft, Formal analysis, Data curation. **A. Rantell:** Writing – review & editing, Supervision. **D. Robinson:** Writing – review & editing, Supervision, Conceptualization.

Funding

This research did not require any funding.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Dudley Robinson reports a relationship with AbbVie Inc that includes speaking and lecture fees. The other authors have no relevant disclosures.

Acknowledgments

The authors thank Kate Clifford and the library services at King's College Hospital, London, for their support with the literature search.

Data availability

Data are available on request.

Ethical approval

Ethical approval was not required.

Patient consent

Not applicable.

Permission to reproduce material from other sources

Not applicable.

Clinical trial registration

Not applicable.

Appendix A:

Supplementary Appendix A (Search Strategy) is available for review on request.

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