Efficacy and safety of combinations of mirabegron and solifenacin in patients with overactive bladder: a systematic review and meta-analysis

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Abstract: Purpose: To investigate therapeutic efficacy enhancement capabilities of solifenacin and mirabegron combination in comparison to solifenacin monotherapy along with investigating the safety and tolerability of this combination. Methods: We searched electronic databases including EMBASE, MEDLINE, and EBM Reviews to identify studies that explored the outcomes of combination therapy of solifenacin and mirabegron in overactive bladder (OAB). The meta-analysis was performed by Review Manager 5.3 software. Results: In terms of efficacy, the results demonstrated that combination group presented significantly more mean volume voided (MVV) per micturition (MD=11.23; 95% CI: 7.21 to 15.25; P < 0.00001), less episodes of urgency incontinence (UI) (MD=-0.99; 95% CI: -1.17 to -0.80; P < 0.00001), less micturitions (MD=-0.45; 95% CI: -0.66 to -0.25; P < 0.0001), less urgency episodes (MD =-0.56;95% CI: -0.83 to-0.29; P < 0.0001), lower Patient Perception of Bladder Condition (PPBC) scores (MD=-0.49; 95% CI: -0.51 to -0.47; P < 0.00001), and more zero-incontinence (OR=1.44; 95% CI: 1.24 to 1.67; P < 0.00001), which overtly improved the total health-related quality of life (HRQoL) scores (MD=5.39; 95% CI: 3.38 to 7.41; P < 0.00001) for OAB patients. As for safety, there was no significant difference between the two groups in terms of treatment-emergent adverse events (TEAEs), such as dry mouth, urinary tract infection (UTI), urinary retention, and QT prolongation in electrocardiogram (ECG). Conclusions: Combination therapy of solifenacin and mirabegron provides satisfactory therapeutic effect without increasing the risk of side effects, which undoubtedly improves quality of life of OAB patients. Combining mirabegron 50 mg with solifenacin 5 mg is a recommended dose due to the balance achieved between efficacy and acceptable tolerability.

Keywords: Mirabegron, solifenacin, combination therapy, overactive bladder, meta-analysis

Introduction

OAB syndrome is a symptom complex defined as urinary urgency, in the absence of UTI or other obvious pathology [1, 2]. OAB symptoms are chronic and often bothersome, which can significantly impact quality of life (QoL), leading to pessimism, social isolation and depression [3, 4].

Antimuscarinics are the mainstay of oral pharmacotherapy for OAB, but persistence with treatment is limited by insufficient effectiveness and associated adverse events [5]. Until now, the problem of treatment for OAB still remains challenging. Thus, the introduction of totally new drug mirabegron, which is a b3-adrenoceptor agonist, has turned out to be much in demand among specialists engaged in OAB [6]. In clinical practice, most OAB patients are initiated on an antimuscarinic, which is escalated to a higher dose or switched to an alternative antimuscarinic or the b3-adrenoceptor agonist, mirabegron.

Some studies demonstrated that combination of mirabegron and antimuscarinic may improve efficacy without compromising tolerability, thus promoting treatment persistence [7-10]. However, some studies found the adverse events were increased during use of combination therapy [11-13]. Therefore, there is a clear need for a regularly updated and comprehensive systematic review of the effectiveness and safety
Combination therapy vs monotherapy in OAB

Materials and methods

Eligibility criteria, information sources and search strategy

We searched all the articles listed in the following databases: EMBASE, MEDLINE, and EBM Reviews. The first step was performed to identify all relevant trials using the following key words: "mirabegron; solifenacin; combination therapy; and overactive bladder". Then, we used lateral searching methods to check reference lists of relevant literatures to distinguish articles those not captured through our electronic search. Finally, all available randomized-controlled-trials (RCT) that include the safety and efficiency of combination of mirabegron and solifenacin for the treatment of OAB were included in the present study.

Inclusion criteria

The researches including key words were screened by us from 1996 to July, 2018, articles were eligible if they were randomized and placebo-controlled, using combination of mirabegron and solifenacin for OAB. Where there were duplications in congress abstracts or published journals, the data was rechecked to verify equivalence, and the most up-to-date or complete studies were eligible.

Exclusion criteria

Studies were excluded according to the following criteria: (1) the study type was a letter, comment, or case report; (2) there was a lack of a comparative placebo-controlled group and quantitative data; (3) patients were diagnosed with other diseases and undergoing several different treatments. Literatures were also excluded in which it did not address study questions, for different baseline, for different criterion of results, for different groups setting and research for animals after the abstracts and Full-texts were screened. The screen procedure is presented in Figure 1.

Quality assessment

The quality of the literatures included in the present analysis was assessed by two authors (LP XZ) according to the Cochrane Collaboration Reviewers’ Handbook. The quality standards consisted of the following domains: generation of randomization sequences, allocation concealment, blinding, incomplete outcome data, freedom from selective reporting, and freedom from other biases. Uncertainties were settled by discussion between the authors (LP XZ HS DYL). The quality evaluation of each paper is shown in Table 1.

Figure 1. The screen procedure for articles eligible.
## Table 1. The details of included studies

<table>
<thead>
<tr>
<th>Author year</th>
<th>Study design</th>
<th>Experimental group</th>
<th>Controlled group</th>
<th>Sample size</th>
<th>Duration</th>
<th>Quality assessment</th>
<th>Included population</th>
<th>Results</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrams 2014</td>
<td>RCT</td>
<td>S5+M50</td>
<td>S5</td>
<td>153</td>
<td>156</td>
<td>12 weeks</td>
<td>Male and female patients aged ≥18 years with OAB for ≥3 months.</td>
<td>Combination therapy with solifenacin/mirabegron significantly improved MVV, micturition frequency, and urgency compared with solifenacin 5 mg monotherapy</td>
<td>MVV, UI, micturition, urgency, PPBC scores, HRQoL scores, zero-incontinence, TEAEs, UTI, dry mouth, constipation, and QT prolongation in ECG</td>
</tr>
<tr>
<td>Drake 2016</td>
<td>RCT</td>
<td>S5+M50</td>
<td>S5</td>
<td>707</td>
<td>705</td>
<td>12 weeks</td>
<td>Patients aged ≥18 yr with OAB symptoms for ≥3 mo.</td>
<td>S5+M50 was superior to solifenacin 5 mg, with significant improvements in daily incontinence, micturition, and urgency noted in a 3-d diary</td>
<td>MVV, UI, micturition, urgency, PPBC scores, zero-incontinence, TEAEs, UTI, UR, dry mouth, constipation, and QT prolongation in ECG</td>
</tr>
<tr>
<td>Herschorn 2017</td>
<td>RCT</td>
<td>S5+M50</td>
<td>S5</td>
<td>883</td>
<td>434</td>
<td>12 weeks</td>
<td>Patients aged ≥18 yr with wet OAB for ≥3 mo.</td>
<td>The combined S5 + M50 group was statistically significantly superior to S5 at EoT for UI episodes, urgency episodes and nocturia, with effect sizes that appeared to be additive</td>
<td>MVV, UI, micturition, PPBC scores, HRQoL scores, zero-incontinence, TEAEs, UTI, UR, dry mouth, constipation, and QT prolongation in ECG</td>
</tr>
</tbody>
</table>

OAB, overactive bladder; S, solifenacin; M, mirabegron; RCT, randomized controlled trial; MVV, mean volume voided; UI, urgency incontinence; TEAEs, treatment-emergent adverse events; UTI, urinary tract infection; ECG, electrocardiogram.
Outcome measures

The efficacy of combination therapy was assessed in improvements in the number of urgency episodes, MVV, the episodes of UI, micturition episodes, PPBC scores, total HRQoL scores and the number of patients with zero-incontinence. Safety endpoints included TEAEs like UTI, urinary retention (UR), dry mouth, constipation, and QT prolongation in ECG.

Statistical analysis

We used the RevMan 5.3 software to perform our meta-analysis. Statistical heterogeneity was calculated by the I² test, with significance set at P < 0.05. Dichotomous data was presented as odds ratio (OR), and continuous parameters were shown as weighted mean difference with 95% confidence intervals (CIs). We utilized either the fixed-effect method or the random-effect method for this meta-analysis, depending on the presence or absence of significant heterogeneity. The fixed-effect method was used for combining results when statistically significant heterogeneity is absent; when heterogeneity is of presence, the random-effect method was worked. In addition, a sensitivity analysis was executed if low-quality trials were involved.

Results

Description of study

A total of 2411 articles were initially identified from the database and manual searches. 2137 papers are not RCTs. After deleting duplications, papers without mentioning study questions were excluded, 40 articles remain. After reviewing the full text of the remaining articles, literatures for different criterion of results, for different groups setting, and for animals were wiped out, eventually three RCTs [7, 9, 10] involving 3038 patients were included in our analyses. The detail characters of each study were shown in Table 1.

Efficiency

MVV, UI, micturition and urgency episodes

Three RCTs with a total of 3033 participants (1726 in the combination therapy group and 1307 in the solifenacin 5 mg group) were identified, as for MVV per micturition (Figure 2A), the fixed-effects estimate of the MD was 11.23, and the 95% CI was 7.21 to 15.25 (P < 0.00001), and there was no publication bias on MVV according to our analysis; analysis on data of UI per 24 hours (Figure 2B), the fixed-effects estimate of the MD was -0.99, and the 95% CI was -1.17 to -0.80 (P < 0.00001); when it comes to micturition per 24 hours (Figure 2C), the fixed-effects estimate of the MD was -0.45, and the 95% CI was -0.66 to -0.25 (P < 0.0001). Two RCTs with a cohort of 1726 participants (878 in the combination group and 884 in the solifenacin group) included urgency episodes data (Figure 2D), the fixed-effects estimate of the MD was -0.56, and the 95% CI was -0.83 to -0.29 (P < 0.0001). The results above illustrated that combination group presented significant increase in MVV, more decrease in episodes of UI as well as in mean number of micturition per 24 hours, and successfully reduced the mean number of urgency episodes per 24 hours.

PPBC score, number of responders for zero incontinence and total HRQoL score

As is shown in Figure 3, analysis on PPBC scores (Figure 3A), the fixed-effects estimate of the MD was -0.49, and the 95% CI was -0.51 to -0.47 (P < 0.00001); bases on the data about zero incontinence (Figure 3B), fixed-effects estimate of the OR was 1.44, and the 95% CI was 1.24 to 1.67 (P < 0.00001). As for total HRQoL score (Figure 3C), the fixed-effects estimate of the MD was 5.39, and the 95% CI was 3.38 to 7.41 (P < 0.00001). These results presented that combination therapy group showed significant decrease in PPBC score, meanwhile overtly increase in number of responders for zero incontinence as well as in total HRQoL score.

Safety

TEAEs, UR and QT prolongation of ECG

As for TEAEs, compared with monotherapy, Figure 4A showed that the OR was 1.08, and the 95% CI was 0.89 to 1.30 (P=0.44). Two RCTs included data on UR (Figure 4B), the OR was 1.74, and the 95% CI was 0.55 to 5.45 (P=0.34). In Figure 4C, the plot analyzing on QT prolongation of ECG showed that estimate of the OR was 1.39, and the 95% CI was 0.35 to
Combination therapy vs monotherapy in OAB

Figure 2. Forest plots showing changes in the MVV (A), mean number of episodes of UI (B), mean numbers of micturition per 24 hours (C), and mean number of urgency episodes per 24 hours (D). MD, mean difference; IV, inverse variance; CI, confidence interval; df, degrees of freedom; SD, standard deviation; MVV, mean volume voided; UI, urgency incontinence.
Combination therapy vs monotherapy in OAB

A  Patient Perception of Bladder Condition (PPBC) score

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>combination therapy</th>
<th>solifenacin monotherapy</th>
<th>Mean Difference</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean SD Total</td>
<td>Mean SD Total</td>
<td>IV Fixed 95% CI</td>
<td>Year</td>
</tr>
<tr>
<td>Abrams et al.2014</td>
<td>-1.8 0.1 153</td>
<td>-1.3 0.1 156</td>
<td>-0.50 [-0.52, -0.48]</td>
<td>2014</td>
</tr>
<tr>
<td>Drake et al.2016</td>
<td>-1.5 1.21 725</td>
<td>-1.2 1.37 728</td>
<td>-0.30 [-0.43, -0.17]</td>
<td>2016</td>
</tr>
<tr>
<td>Herschorn et al.2017</td>
<td>-1.7 1.43 848</td>
<td>-1.3 1.01 423</td>
<td>-0.40 [-0.54, -0.28]</td>
<td>2017</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1726 100.0%</td>
<td>1307 100.0%</td>
<td>-0.49 [-0.51, -0.47]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 10.27, df = 2 (P = 0.006); I² = 81%
Test for overall effect: Z = 44.42 (P < 0.00001)

B  Number of responders for zero incontinence

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>combination therapy</th>
<th>solifenacin monotherapy</th>
<th>Odds Ratio</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events Total</td>
<td>Events Total</td>
<td>M-H Fixed 95% CI</td>
<td>Year</td>
</tr>
<tr>
<td>Abrams et al.2014</td>
<td>90 153</td>
<td>70 156</td>
<td>1.76 [1.12, 2.75]</td>
<td>2014</td>
</tr>
<tr>
<td>Herschorn et al.2017</td>
<td>426 848</td>
<td>177 423</td>
<td>1.40 [1.11, 1.78]</td>
<td>2017</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>1726 100.0%</td>
<td>1307 100.0%</td>
<td>1.44 [1.24, 1.67]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 0.85, df = 2 (P = 0.66); I² = 0%
Test for overall effect: Z = 4.80 (P < 0.00001)

C  Total HRQoL score

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>combination therapy</th>
<th>solifenacin monotherapy</th>
<th>Mean Difference</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean SD Total</td>
<td>Mean SD Total</td>
<td>IV Fixed 95% CI</td>
<td>Year</td>
</tr>
<tr>
<td>Herschorn et al.2017</td>
<td>27.5 20.3 795</td>
<td>22.7 19.87 399</td>
<td>4.80 [2.39, 7.21]</td>
<td>2017</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>941 100.0%</td>
<td>549 100.0%</td>
<td>5.39 [3.38, 7.41]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 0.79, df = 1 (P = 0.37); I² = 0%
Test for overall effect: Z = 5.24 (P < 0.00001)

Figure 3. Forest plots showing changes in PPBC scores (A), number of responders for zero -incontinence (B), and total HRQoL scores (C). MD, mean difference; M-H, Mantel-Haenszel; CI, confidence interval; df, degrees of freedom. SD, standard deviation. PPBC, Patient Perception of Bladder Condition; HRQoL, healthy related quality of life.
Combination therapy vs monotherapy in OAB

Figure 4. Forest plots showing changes in TEAEs (A), UR (B), and QT prolongation of ECG (C). M-H, Mantel-Haenszel; CI, confidence interval; df, degrees of freedom. TEAEs, treatment-emergent adverse events; UR, urinary retention; ECG, electrocardiogram.
Combination therapy vs monotherapy in OAB

5.50 (P=0.64). The results suggested that the combination therapy group was similar to solifenacin-only group in terms of the incidence of TEAEs, QT prolongation of ECG.

Dry mouth, constipation and UTI

For dry mouth (Figure 5A), the pooled estimate of the OR was 1.09, and the 95% CI was 0.81 to 1.46 (P=0.58); analysis on data of constipation data (Figure 5B), the OR was 1.69, and the 95% CI was 1.11 to 2.59 (P=0.02); based on the urinary tract infection (Figure 5C), the pooled estimate of the OR was 1.01, and the 95% CI was 0.73 to 1.64 (P=0.65). No significant differences were presented between the combination group and the solifenacin monotherapy group in terms of dry mouth and UTI.

Discussion

This meta-analysis was in an effort to identify whether solifenacin and mirabegron combination therapy enhances efficacy compared with solifenacin monotherapy, as well as to identify the safety and tolerability of this combination.

Our results demonstrate that the combination group significantly improves the OAB symptoms of MVV per micturition, episodes of UI, micturition, and urgency episodes. This study also presents that combination therapy group showed significant decrease in PPBC scores, increases in number of responders for zero incontinence and total HRQoL score compared with solifenacin monotherapy. There was no significant difference between the two groups in terms of dry mouth, UR, UTI, and QT prolongation in ECG. In this study, we investigate the patient-reported outcomes (PROs), because the International Continence Society recommends the evaluation of PROs in OAB trials [14]. Responder analyses represent an additional tool for translating changes in subjective or objective measures into a clinically meaningful binary outcome.

This study suggests that the combination therapy group was similar to solifenacin monotherapy group in terms of the incidence of TEAEs. The incidence of preselected TEAEs relevant to patients, including UR, and cardiovascular (CV) safety. Muscarinic receptors play a role in mediating heart rate and vasodilation [15, 16], and in vitro, the b3-adrenoceptor subtype induces effects in human atrial and ventricular tissue [17]; therefore, potential CV effects with solifenacin or mirabegron could increase, particularly in older patients characterized by higher rates of concomitant CV morbidity [18]. In this study, the result showed that no palpable differences were found between the combination group and the solifenacin monotherapy group in view of the symptom of QT prolongation of ECG. Many studies showed that there were no differences in the incidence of CV-related TEAEs and changes in vital signs were of no clinical significance and were consistent with monotherapy and other combination trials [8-12, 19]. However, good clinical practice advocates regular blood pressure monitoring in older patients where CV risk may be cumulative. Other adverse effects such us dry mouth, constipation, and UTI were similar in two groups in this present study.

In the present study, solifenacin 5 mg and mirabegron 50 mg was analyzed, but it should be kept in mind that solifenacin and mirabegron can be recommended at different dosages. The therapy with solifenacin and add-on mirabegron may be effective even at a low dose, i.e. solifenacin 2.5 mg plus mirabegron 25 mg [20]. The SYMPHONY study reported that combined therapy had greater efficacy than solifenacin 5 mg alone on the change from baseline to end of treatment in the MVV/micturition, frequency of micturition/24 h, and urgency episodes [7, 12]. Solifenacin 5 mg combined with mirabegron 25 mg or 50 mg appeared optimal in terms of the benefit/risk profile in that study [21]. The SYNERGY study found that the effect size in the combined Solifenacin 5 mg plus Mirabegron 50 mg group was larger and more pronounced than in the combined Solifenacin 5 mg plus Mirabegron 25 mg group, with no obvious differences in safety profile [10]. Based on these studies, Solifenacin 5 mg plus Mirabegron 50 mg was the recommended daily dose and the most widely used dose in clinical practice in the general OAB population. For elderly patients and those with heart disease, severe renal impairment or moderate hepatic impairment, low dose could be initiated. In conclusion, combination therapy of solifenacin and mirabegron demonstrated greater increase in the MVV, decrease in episodes of UI, superior efficacy in reducing the mean numbers of micturition per 24 hours, and lesser mean number of urgency
Combination therapy vs monotherapy in OAB

### A  Dry mouth

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Events</th>
<th>Total</th>
<th>Events</th>
<th>Total</th>
<th>Weight</th>
<th>M-H. Fixed, 95% CI Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrams et al. 2014</td>
<td>18</td>
<td>153</td>
<td>20</td>
<td>156</td>
<td>20.1%</td>
<td>0.91 [0.46, 1.79] 2014</td>
</tr>
<tr>
<td>Drake et al. 2016</td>
<td>43</td>
<td>725</td>
<td>41</td>
<td>728</td>
<td>44.3%</td>
<td>1.06 [0.68, 1.64] 2016</td>
</tr>
<tr>
<td>Herschorn et al. 2017</td>
<td>61</td>
<td>848</td>
<td>25</td>
<td>423</td>
<td>35.6%</td>
<td>1.23 [0.76, 2.00] 2017</td>
</tr>
</tbody>
</table>

Total (95% CI) 1726 1307 100.0% 1.09 [0.81, 1.46]

Total events 122 86
Heterogeneity: Chi² = 0.56, df = 2 (P = 0.76); I² = 0%
Test for overall effect: Z = 0.58 (P = 0.56)

### B  Constipation

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Events</th>
<th>Total</th>
<th>Events</th>
<th>Total</th>
<th>Weight</th>
<th>M-H. Fixed, 95% CI Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrams et al. 2014</td>
<td>6</td>
<td>153</td>
<td>6</td>
<td>156</td>
<td>16.6%</td>
<td>1.02 [0.32, 3.24] 2014</td>
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<tr>
<td>Drake et al. 2016</td>
<td>33</td>
<td>725</td>
<td>22</td>
<td>728</td>
<td>61.0%</td>
<td>1.53 [0.88, 2.65] 2016</td>
</tr>
<tr>
<td>Herschorn et al. 2017</td>
<td>31</td>
<td>848</td>
<td>6</td>
<td>423</td>
<td>22.4%</td>
<td>2.64 [1.09, 6.37] 2017</td>
</tr>
</tbody>
</table>

Total (95% CI) 1726 1307 100.0% 1.69 [1.11, 2.59]

Total events 70 34
Heterogeneity: Chi² = 1.84, df = 2 (P = 0.40); I² = 0%
Test for overall effect: Z = 2.43 (P = 0.02)

### C  Urinary Tract Infection (UTI)

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Events</th>
<th>Total</th>
<th>Events</th>
<th>Total</th>
<th>Weight</th>
<th>M-H. Fixed, 95% CI Year</th>
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</thead>
<tbody>
<tr>
<td>Abrams et al. 2014</td>
<td>6</td>
<td>153</td>
<td>4</td>
<td>156</td>
<td>8.3%</td>
<td>1.55 [0.43, 5.61] 2014</td>
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<tr>
<td>Drake et al. 2016</td>
<td>17</td>
<td>725</td>
<td>16</td>
<td>728</td>
<td>33.9%</td>
<td>1.07 [0.54, 2.13] 2016</td>
</tr>
<tr>
<td>Herschorn et al. 2017</td>
<td>44</td>
<td>848</td>
<td>21</td>
<td>423</td>
<td>57.8%</td>
<td>1.05 [0.61, 1.79] 2017</td>
</tr>
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</table>

Total (95% CI) 1726 1307 100.0% 1.10 [0.73, 1.64]

Total events 67 41
Heterogeneity: Chi² = 0.31, df = 2 (P = 0.86); I² = 0%
Test for overall effect: Z = 0.45 (P = 0.65)

**Figure 5.** Forest plots showing changes in dry mouth (A), constipation (B), UTI (C). M-H, Mantel-Haenszel; CI, confidence interval; df, degrees of freedom. UTI, urinary tract infection.
episodes per 24 hours without increasing bothersome adverse effects, compared with solifenacin monotherapy. Combining mirabegron 50 mg with solifenacin 5 mg is a recommended dose due to the balance achieved between efficacy and acceptable tolerability.

Acknowledgements

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Disclosure of conflict of interest

None.

Abbreviations

OAB, overactive bladder; S, solifenacin; M, mirabegron; RCT, randomized-controlled-trials; MVV, mean volume voided per micturition; UI, urgency incontinence; UTI, urinary tract infection; UR, urinary retention; PPBC, Patient Perception of Bladder Condition; PVR, postvoid residual; ECG, electrocardiogram; OR, odds ratio; CI, confidence interval; MD, mean difference; CV, cardiovascular; PROs, patient-reported outcomes; QoL, Quality of life; HRQoL, Health-related quality of life.

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References


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