# **TOOLS FOR PRACTICE #393 | July 7, 2025**



# **Avoiding the void? Mirabegron for overactive bladder**

**CLINICAL QUESTION** 

What are the benefits and harms of mirabegron for patients with overactive bladder (OAB)?

## **BOTTOM LINE**

Versus placebo, mirabegron reduces voids by 3-5 per week and incontinence episodes by 3 per week with similar adverse effects at 12 weeks. Compared to anticholinergics, mirabegron has similar efficacy. Fewer patients on mirabegron experience dry mouth (~3% versus 8%) or tachycardia (~1% versus 2%) at 12-52 weeks. Mirabegron costs ~\$30/month more than lower-cost anticholinergics.

# **EVIDENCE**

- 7 systematic reviews [8-14 randomized controlled trials (RCTs), 5500-10,774 non-neurogenic OAB patients].<sup>1-7</sup> Results statistically different unless indicated.
- Versus placebo (at 12 weeks):
  - Voids: Reduced by 3-5/week versus placebo<sup>1,3,4</sup> (example: Baseline 80 voids/week to 62-68 for mirabegron versus 66-73 for placebo).<sup>8-10</sup>

- o Incontinence episodes: Reduced by 3/week versus placebo<sup>1,3,4</sup> (example: Baseline 14-24 episodes/week to 6-12 for mirabegron versus 9-14 for placebo).<sup>8-10</sup>
- Adverse events:
  - Hypertension, urinary tract infection (UTI), dry mouth, constipation: no difference.<sup>1,3,6,7</sup>
  - Nasopharyngitis: Inconsistent; increased in 2/3 reviews [2.5-6.4% versus 1.6-3.2% (placebo)].<sup>1,3,6</sup>
- Versus anticholinergics (at 12-52 weeks):
  - Voids/week: No difference.<sup>2,4</sup>
  - o Incontinence episodes/week: No difference. <sup>2,4</sup>
  - Adverse events:
    - Dry mouth:<sup>2,5</sup> 3.1-3.6% versus 7.6-9% (anticholinergics), number needed to treat (NNT)=20.
    - Tachycardia (reported in 1 review):<sup>5</sup> 1.5% versus 2.3%, (anticholinergics), NNT=125.
    - Hypertension, UTI, constipation, withdrawals due to adverse events: No difference.<sup>2,5,7</sup>
- Limitations: Short duration for serious adverse events (examples: cardiovascular, falls); most RCTs industry funded; mean age usually 55-60, minimizing generalizability to older adults.

### **CONTEXT**

- Non-invasive therapies:
  - o Guidelines recommend interventions like bladder training, pelvic floor muscle therapy, weight loss if appropriate, and caffeine reduction.<sup>11,12</sup>
  - Efficacy similar for non-invasive therapies versus anticholinergics;<sup>13</sup> no comparisons exist for non-invasive therapies versus mirabegron.
  - Guidelines recommend anticholinergics or mirabegron after non-invasive therapies.<sup>11,14</sup>
- Anticholinergic within-class comparisons:
  - o Similar efficacy: 15 58% reporting cure/improvement versus 42% (placebo), NNT=7.
  - Similar adverse events with few exceptions [example: oxybutynin versus tolterodine:<sup>16</sup> Dry mouth number needed to harm (NNH)=6; withdrawal NNH=17].
  - Extended release (ER) and immediate release formulations similar in efficacy and tolerability, except less dry mouth with ER (NNT=12).<sup>16,17</sup>
- Cost (30 days):<sup>18</sup> Solifenacin 5-10mg daily \$10; Tolterodine LA 2-4mg daily \$16; Mirabegron 25-50mg daily \$46.

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