FPIN's Help Desk Answers

OnabotulinumtoxinA Injections for Urge Incontinence

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Clinical Question

Are onabotulinumtoxinA (Botox) injections effective for treatment of urge incontinence in women?

Evidence-Based Answer

Detrusor muscle injections of onabotulinumtoxinA can be used to decrease the number of episodes of urinary incontinence in women for whom treatment with anticholinergic agents has been ineffective. (Strength of Recommendation: B, based on two randomized controlled trials [RCTs].) Compared with oral anticholinergics, detrusor muscle injections of onabotulinumtoxinA decrease urge incontinence episodes and have a higher rate of complete symptom resolution. Compared with anticholinergics, onabotulinumtoxinA injections cause less dry mouth but more urinary tract infections and urinary retention.

Evidence Summary

A 2013 multicenter, double-blind RCT compared onabotulinumtoxinA with placebo in 548 women 44 to 75 years of age with idiopathic overactive bladder for which anticholinergic therapy was ineffective.[1] Patients were randomized to detrusor muscle injections of 100 U onabotulinumtoxinA vs. placebo injections of normal saline with 12-week follow-up. Primary outcomes included episodes of urinary incontinence per day and patient perception of treatment benefit as measured by the Treatment Benefit Scale, which includes responses of greatly improved, improved, not changed, or worsened. OnabotulinumtoxinA injections decreased daily episodes of urinary incontinence by 2.9 vs. 1.0 for placebo ($P < .001$). Approximately 63% of patients reported a treatment response of greatly improved or improved after the injections vs. 27% in the control group ($P < .001$).

A 2013 multicenter, double-blind RCT compared the effectiveness of detrusor muscle injections of 100 U onabotulinumtoxinA vs. placebo injections of normal saline in 492 women 48 to 74 years of age with idiopathic overactive bladder for which anticholinergic therapy was ineffective.[2] Primary outcomes after 24 weeks of follow-up included the number of urge incontinence episodes per day and treatment response on the Treatment Benefit Scale. OnabotulinumtoxinA decreased the number of urge incontinence episodes per day more than placebo (−2.6 vs. −0.8; $P < .001$) and resulted in more patients with a positive treatment response (61% vs. 29%; $P < .001$).

Another 2012 multicenter, double-blind RCT compared detrusor muscle injections of 100 U onabotulinumtoxinA with anticholinergic medication in 247 patients 45 to 70 years of age with idiopathic urge incontinence.[3] Patients were randomized to detrusor muscle injections of saline

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plus 5 mg of solifenacin (Vesicare) per day or detrusor muscle injections of 100 U of onabotulinumtoxinA with daily oral placebo for six months. The primary outcome was the number of incontinence episodes per day; secondary outcomes included complete symptom resolution and 75% reduction in incontinence episodes. The anticholinergic and onabotulinumtoxinA groups had similar decreases in urge incontinence (3.1 vs. 3.3 episodes, respectively; $P = .81$). Complete symptom resolution was more common in the onabotulinumtoxinA group (27% vs. 13%; $P = .003$). The proportion of patients with 75% reduction in urge incontinence was similar between groups (54% vs. 40%; $P = .06$). Anticholinergic agents had a higher incidence of dry mouth (46% vs. 31%; $P = .02$) but lower incidences of catheter use for urinary retention (0% vs. 5%; $P = .01$) and urinary tract infections (13% vs. 33%; $P < .001$).

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