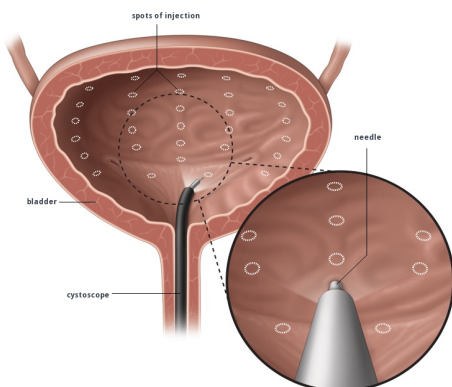


February 2016 Update #22

## Botox for Overactive Bladder

Since September this year intravesical Botox injections have been listed on the PBS as an authority script for overactive bladder with the following criteria:

1. The condition must be due to idiopathic overactive bladder
2. The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents
3. The patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botox
4. The patient must be willing and able to self-catheterise
5. The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment
6. The patient must be aged 18 years or older
7. Patient must be treated by a **urogynaecologist** or urologist

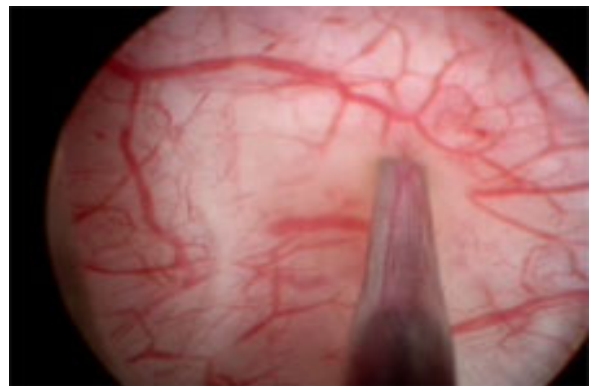


### Botox Action

Botox contains a protein complex purified from the bacterium *Clostridium botulinum*. A component of this complex, Botulinum Toxin Type A is the important active ingredient. Type A is one of the seven distinct botulinum toxins produced by different strains of the bacterium. Botox blocks the transmission of overactive nerve impulses to the targeted muscle by selectively preventing the release of the neurotransmitter acetylcholine (ACh) at the neuromuscular junction, temporarily preventing muscle contraction. This is primarily a local effect.

Botox is contraindicated in pregnancy, amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome.

Intradetrusor injection of Botox is also contraindicated in patients with urinary retention and in patients with post-void residual (PVR) urine volume >200 mL, who are not routinely performing clean intermittent self-catheterization (CIC).



### Botox Studies

In clinical trials, 6.5% of patients (36/552) initiated clean intermittent catheterization for urinary retention following treatment with Botox 100 Units as compared to 0.4% of patients (2/542) treated with placebo. The median duration of catheterization for patients treated with Botox was 63 days (minimum 1 day to maximum 214 days) as compared to a median duration 11 days (minimum 3 days to maximum 18 days) for patients receiving placebo.

Patients with diabetes mellitus treated with Botox were more likely to develop urinary retention than non-diabetics. In clinical trials, 12.3% of patients (10/81) with diabetes developed urinary retention following treatment with Botox vs. 0% patients (0/69) treated with placebo. In patients without diabetes, 6.3% of patients (33/526) developed urinary retention following treatment with Botox vs. 0.6% of patients (3/516) treated with placebo.

Chartier-Kastler in 2015 studied 829 patients over 3.5 years who received multiple doses of intravesical botox injections. There was a significant improvement in 70%. The median time to request retreatment was <6 months (34.2%), 6-12 months (37.2%), and greater than 12 months (28.5%). There was a 5.7% incidence of side effects, with the most common being UTI.