Hypothesis / aims of study
This study compares the cost-effectiveness of onabotulinumtoxin A (Botox) and anticholinergic medications for the management of urgency urinary incontinence (UUI).

Study design, materials and methods
We evaluated the cost-effectiveness of Botox as compared to anticholinergic medications for women who participated in a 6-month double-blind, double-placebo-controlled, randomized trial, known as the ABC trial. The ABC trial compared daily oral anticholinergic medication plus one saline injection (placebo) to one injection of 100 U of Botox plus daily oral placebo. We estimated the societal costs for each treatment arm by summing the treatment costs, patient costs to manage UUI (e.g., laundry, incontinence pads), and healthcare utilization reported by patients during the 6 months of the trial (e.g., ER visits, doctors’ visits for complications from treatment or UUI, and medications to treat UTI). We valued all medical and non-medical utilization using a variety of pricing sources, including physician fee schedules for healthcare utilization, the Red Book for prescription drug costs, wholesale prices for patients’ utilization of incontinence products, and published estimates when other data sources were not available. We also valued the days of work and household productivity lost because of UUI for the trial participants and report these estimates separately from the cost-effectiveness.

Study outcomes included the proportion of participants with complete resolution of UUI over the course of the trial, and the proportion that experienced a >75% reduction in UUI episodes as documented in monthly 3-day diaries compared to baseline. Quality-adjusted life-years (QALYs) are calculated by applying preference weights to select measures from the overactive bladder questionnaire completed at baseline through 6 months. We also estimated and compared average costs for treatment, UUI care, and other direct medical costs per group through 9 months, the median time of effective UUI control for Botox patients. Cost analyses assumed that Botox patients incurred no additional costs between months 6 and 9 while the AC group incurred an additional 3 months of medication costs.

Results
Data were analysed for 231 participants (112 Botox and 119 anticholinergic medication). Over the 6-month period of the trial, the cumulative mean direct societal cost estimates were $1270 and $1340 for the Botox and the anticholinergic groups respectively, with anticholinergic medication costs incurred at the beginning of each month. Botox recipients were significantly more likely than anticholinergic group to experience complete resolution of UUI (27% vs. 13%; p-value of 0.003). Though not significant, they were also more likely to achieve >75% reduction in UUI episodes (54% vs. 40%), (p-value of 0.06). Differences in QALY gains between the treatment groups were small, as both groups enjoyed considerable improvement in quality of life. Adjusting the 6-month trial results to a 12 month measure, the Botox and anticholinergic groups averaged 0.706 and 0.702 QALYs, respectively.

Because costs and QALYs are similar between the two arms, we conducted additional sensitivity analyses to assess the cost-effectiveness of Botox over 9 months. Mean direct societal costs of Botox exceeded the mean costs of anticholinergic medications through 4 months of treatment, but fell below those of anticholinergic patients between months 5 and 9 (Figure) because Botox patients have no additional treatment costs, whereas anticholinergic patients have monthly medications costs.

Interpretation of results
Results from the cost-effectiveness evaluation of the ABC trial indicate that onabotulinum-toxin A has similar cost and effectiveness outcomes to anticholinergic medications in the first 6 months of treatment of women with urgency urinary incontinence. If costs and outcomes are considered through 9 months, Botox may be preferred to anticholinergic medications, resulting in similar QALY gains at a lower cost.

Concluding message
In light of the lower cost over time and higher percentage of patients with complete symptom resolution, Botox may be favored over anticholinergic medications as a treatment for urgency urinary incontinence.
Disclosures

**Funding:** National Institutes of Health: NICHD

**Clinical Trial:** Yes

**Registration Number:** ClinicalTrials.gov: NCT01166438

**RCT:** Yes

**Subjects:** HUMAN

**Ethics Committee:** University of Pittsburgh Institutional Review Board: PRO09060114

**Helsinki:** Yes

**Informed Consent:** Yes