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Cost-Effectiveness Analysis of Anticholinergics vs. Botox for Urgency Urinary Incontinence: Results from the ABC Randomized Trial

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Abstract

OBJECTIVES—To compare the cost-effectiveness of Botox and anticholinergic (AC) medications for the management of urgency urinary incontinence (UUI).

METHODS—Cost and effectiveness data were analyzed from participants in the Anticholinergic versus Botox Comparison (ABC) randomized trial of daily AC medication versus 100U intradetrusor Botox injection. Societal costs included treatment costs, patient costs, and medical and non-medical utilization during the 6-month trial. Quality-adjusted life-years (QALYs) were

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calculated based on questionnaire-derived utility measures and annualized based on data collected at baseline through 6 months. We also estimated average direct costs for each treatment through 9 months, the duration of time when approximately half the Botox participants maintained adequate symptom control.

RESULTS—Data were analyzed on the 231 women that completed 6-month follow-up in the ABC trial (119 AC and 112 Botox). The mean reduction in UUI episodes/day was not significantly different per group. The cumulative mean direct costs over the first 6 months were also similar, $1,339 for the AC group and $1,266 for the Botox group with AC costs exceeding Botox costs after 5 months. Both groups had considerable QALY gains. Annualizing the 6-month trial results to a 12-month measure, the AC and Botox groups averaged 0.702 and 0.707 QALYs, respectively. Estimates through 9 months favored Botox showing AC participants incurred higher cost per month of adequate symptoms control ($305) compared to Botox participants ($207).

CONCLUSION—Botox and AC medications have similar costs and effectiveness in the first 6 months of UUI treatment. If costs and outcomes are considered through 9 months, Botox may have significantly lower costs but similar UUI symptom control as AC.

INTRODUCTION

Urgency urinary incontinence is a common and debilitating condition affecting 6.1% of the adult US population.(1) Annual costs in the US are estimated at $66 billion in 2007 dollars.(2) While anticholinergics have been considered first-line therapy, a recent systematic review on treatment of overactive bladder (OAB) demonstrated suboptimal efficacy and adherence associated with six medications evaluated.(3) Inadequate efficacy, adverse events or intolerability, and cost have been frequently cited by patients as factors leading to discontinuation of anticholinergic medication.(4)

OnabotulinumtoxinA (Botox) is a newer therapy with proven efficacy in treating urgency urinary incontinence refractory to anticholinergic therapy.(5) However, prior to the 2012 Food and Drug Administration approval of Botox for this indication, patient costs for its off-label use thwarted its adoption as a common therapeutic alternative. Botox can result in temporary incomplete bladder emptying requiring intermittent catheterization.(6) Data directly comparing the cost and effectiveness of Botox with anticholinergic agents would provide insight into the optimal therapy for patients with urgency urinary incontinence.

A recent multicenter, randomized trial—the Anticholinergic versus Botox Comparison (ABC) trial—demonstrated similar efficacy between oral anticholinergic therapy and Botox in women without neurologic disease who had moderate to severe urgency urinary incontinence.(7) Women using these two therapies had similar reduction in the frequency of urgency urinary incontinence episodes over 6 months. However, women in the Botox group were more likely to report complete resolution of urgency urinary incontinence, and the two therapies had different side-effect profiles.(7) There were higher risks of transient urinary retention and urinary tract infections with Botox and more frequent occurrence of dry mouth with anticholinergic medications.(7)

Botox is a newer therapy with a different route of delivery, mechanism of action, and side-effect profile compared with anticholinergic medications. A better understanding of its cost-effectiveness will help inform decision-making regarding the optimal approach. Therefore, the objective of this planned secondary analysis of the ABC trial is to compare the cost-effectiveness of anticholinergic medications and Botox bladder injections for the management of urgency urinary incontinence.

METHODS

We received no industry support to conduct this clinical trial or the trial-based economic study. Each site's institutional review board approved the protocol. Each participant signed an IRB-approved consent form. The first participant was randomized on May 5, 2010. Due to an administrative oversight, the trial was not registered at clinicaltrials.gov until July 19, 2010. A total of 20 participants (8%) were randomized but no subject had reached the primary outcome prior to registration.

Women were randomized to receive oral anticholinergic medication plus one intradetrusor injection of saline or 100U intradetrusor injection of onabotulinumtoxinA (Botox®, Allergan, Irvine, CA) plus oral placebo pills. Participants completed the Patient Global Symptom Control(8) (PGSC) at 2, 4, and 6 months after randomization, that assessed whether current treatment was providing adequate control of urinary leakage. Responses ranged from 1 (*disagree strongly*) to 5 (*agree strongly*). Dose escalation was allowed for inadequate symptoms control (PGSC scores ≤ 3).

Women in the anticholinergic group initially received solifenacin 5 mg, with the option to increase to solifenacin 10 mg at 2 months or be changed to trospium XR 60 mg at 4 months if symptom control remained inadequate. Women in the oral placebo group were similarly "dose-escalated" according to PGSC scores, receiving different placebo capsules that were identical to the corresponding active treatment.

We chose anticholinergic medications with different mechanisms of action and once daily dosing while attempting to maximize efficacy and minimize side effects.(9–11) At 6 months, all oral study medications were discontinued (active and placebo); participants completed PGSC scores monthly until they no longer experienced adequate symptom control.

We limited the cost analysis to ABC trial participants who completed 6 months of follow-up to obtain accurate cost estimates over that period using actual costs through 6 months for our primary analysis. Additional analyses used actual costs through 6 months and estimated treatment costs and effectiveness from 6 to 9 months. The methods and primary results for the ABC trial have been published.(7, 9) In brief, participants in this randomized double-blind trial completed baseline measures that included a 3-day bladder diary and short forms of validated questionnaires including the Overactive Bladder Questionnaire (OABq-SF).(12, 13) The bladder diary was repeated monthly to obtain the primary outcome measure, change from baseline in mean number of urgency urinary incontinence episodes over 6 months, as was the OABq-SF. Three and 6 months after randomization, participants completed the

Patient Global Impression of Improvement (PGI-I) as well as the Short Form Health Survey (SF-12).(14)

Cost analyses were performed from the societal perspective based on actual treatment and not intention to treat. Costs were estimated using a resource costing method. We collected units of participants' medical and non-medical direct and indirect resources utilized or foregone using patient self-reports and trial medical records and applied unit costs to calculate total costs. All costs were estimated in 2012 U.S. dollars without discounting at 6 or 9 months. We estimated direct intervention costs by group assignment (anticholinergic or Botox therapy), applying assumptions about standard clinical care for each treatment to approximate real-world costs; thus, we did not include costs related to cystoscopy for the anticholinergic group nor did we assign costs related to placebo pills for the Botox group. Similarly, we assumed an initial office visit for all participants and one additional visit for patients in the anticholinergic therapy arm if they changed treatment from solifenacin to trospium.

For participants in the anticholinergic arm, we assigned medication costs only for pills taken. For participants in the Botox arm, we assumed one 2-week follow-up visit and the cost to assess a post-void residual for all participants and one 6-week follow-up visit for participants who reported self-catheterization at 2 weeks.

We prospectively collected the other medical and non-medical resource use, including any complications during the 6 months following randomization, such as UTI treatment and catheterization costs. We systematically queried participants about interval inpatient and outpatient care, physical therapy, laboratory tests, medications, home health care services, and nursing home stays related to urogynecologic diagnoses. We also identified the relevant codes for health care utilization reported by participants, such as current procedural terminology (CPT), healthcare common procedure coding system (HCPCS), and diagnosis-related group (DRG). We assigned the unit price of medical care based on the corresponding Medicare reimbursement rate as a proxy for cost and calculated medication costs using the average wholesale price in Drug Topics Red Book®.

At each visit, we also assessed routine non-medical care costs for incontinence supplies, including menstrual and incontinence pads, and incontinence-related costs for laundry or dry cleaning. We extrapolated the weekly utilization estimates to the time period between interviews. We multiplied self-reports of resources used by per-unit resource cost estimates from published sources(15, 16) and online retailers. We assessed transportation to care costs by valuing self-reports of the miles traveled for visits using the General Services Administration reimbursement rate per mile.

We also assessed indirect costs for both therapies as the productivity losses associated with incontinence, such as work loss days and reduced productivity at work and home. Participants' lost productivity was valued using hourly compensation data for women aged 35 or older from the Bureau of Labor Statistics and applying the methodology in Haddix, Teutsch, and Corso.(17)

To conduct cost-effectiveness and cost-utility analyses, we used multiple measures of intervention effectiveness, including reduction in the number of urgency urinary incontinence episodes per day, percentage of participants that experienced complete resolution of symptoms, and a health-related utility measure generated from the monthly OABq responses by applying the Yang et al.(18) algorithm. The OAB5-D is derived from 5 questions of the OABq (urge to urinate, urine loss, sleep impact, coping strategy, and concern with overactive bladder). We used these utility values to calculate quality-adjusted life-years (QALYs), assuming linear changes in patient utility between monthly assessments and calculating the area under the curve for the 6-month period. For the 22 participants with missing OABq responses, we used the prior month's OABq. We annualized QALYs to a 12-month measure. For costs and QALYs, we calculated p-values for the differences between groups using non-parametric bootstrap tests and 1,000 iterations from the trial data(19), testing the probability that the mean difference in costs or QALYs between treatments was zero. This methodology uses repeated draws from the trial data to generate a distribution of the difference in mean costs and adequate symptom control. We used an F-test to estimate whether differences between groups in mean episodes of urgency urinary incontinence were statistically significant. We also calculated differences between groups in the mean percentage of participants with adequate symptom control, using the Mantel-Haenszel test and accounting for randomization strata.[6]

We examined whether differences in direct or indirect costs between groups were driven by factors other than treatment using a generalized linear model with inverse Gaussian variance function and identity link, controlling for clinical site, age, baseline urgency urinary incontinence episodes, insurance status, race, and ethnicity. Similarly, we estimated a linear regression model for QALYs controlling for site, age, baseline urgency urinary incontinence episodes, baseline utility values, and prior anticholinergic use.

We calculated the average cost-effectiveness ratio for each treatment group over the 6-month trial period as the difference from baseline in mean cumulative costs, assuming zero costs at baseline, divided by the difference from baseline in mean QALYs over the trial period. We report these average costs per QALY gained over the 6 months of the trial by treatment group.

We conducted a sensitivity analysis over 6 months that used the SF-12 data to estimate health utility at baseline and for the full trial period. We used these SF-6D utility estimates based on a subset of six dimensions to estimate health utility and to calculate baseline and annualized trial period QALYs and compared results to QALY measures derived from the OABq.(20)

We also modeled costs and outcomes between the two groups through 9 months as this was the duration of time when approximately half of the Botox participants maintained adequate symptom control and was within the interval that a typical patient would request reinjection of Botox in clinical practice.(21) Because the OABq data were collected only during the trial period, they could not be used to estimate QALYs beyond 6 months. However, because PGSC scores were collected at months 2, 4, 6, and monthly through 12 months for all

patients who reported adequate symptom control on the most recent previous assessment, we used adequate symptom control as the effectiveness measure.

We calculated the mean number of months of adequate symptom control (i.e., PGSC scores of 4 or 5) by treatment group from 0 to 9 months. For Botox participants, we used actual reports of symptom control based on the PGSC instrument for months 6 through 9, which showed a gradual degradation of effect consistent with the typical course of therapy and used actual treatment costs through 6 months, but assumed no additional costs between 6 and 9 months. Conversely, for anticholinergic effectiveness, we used the actual PGSC scores from 0 to 6 months and assumed that anticholinergic patients would maintain the same level of symptom control between months 6 and 9 as reported at the 6-month time point. We used actual anticholinergic costs from 0 to 6 months and assumed monthly anticholinergic costs for months 6 through 9, because the anticholinergic group stopped medications at 6 months.

We used a nonparametric bootstrap procedure to calculate p-values for the difference in mean cumulative costs and months of adequate symptom control through 9 months. We estimated and compared cost per month of adequate symptom control by calculating estimated costs over 9 months divided by months of adequate symptom control for each group.

RESULTS

The baseline characteristics were similar between treatment groups for the 231 randomized women who completed the 6-month trial with the exception of baseline health utility values (Table 1). For the anticholinergic (Botox) group most women were white, with a mean age of 57 (59) years, and had medical insurance; they reported about 5 urgency urinary incontinence episodes per day, and 56% (59%) had previously used anticholinergic medications for urgency urinary incontinence. Baseline health utility scores (higher = better health) averaged 0.656 for the anticholinergic participants and 0.667 for the Botox participants (P=0.03).

Table 2 shows estimated per patient costs and effectiveness over 6 months. Direct medical and non-medical costs did not differ significantly between groups (P=0.06). Direct costs per person were $1,339 in the anticholinergic group and $1,266 for Botox. These unadjusted cost estimates were similar to adjusted costs that controlled for clinical site, age, baseline number of urgency urinary incontinence events, insurance status, race, and ethnicity, and therefore only unadjusted results are reported. We also estimated the difference in indirect costs over 6 months from urgency urinary incontinence or from the study treatment. Indirect costs were not significantly different between groups ($150 in the anticholinergic group versus $106 in the Botox group), (P=0.62).

Over 6 months, the mean reduction in urgency urinary incontinence episodes per day was not different between treatment groups (3.3 ± 0.26 for anticholinergic and 3.3 ± 0.28 for Botox, P=0.81). However, Botox recipients were significantly more likely to experience complete resolution of urgency urinary incontinence (27% vs. 13%; P=0.003).(7)

Compared with baseline health utility measures, women in both treatment groups enjoyed utility gains, with annualized QALY gains (6-month gain in utility scores × 2) of 0.046 for the anticholinergic group (bootstrapped $P<0.001$ testing difference from baseline=0) and 0.039 for the Botox group (bootstrapped $P=0.001$). The difference between the groups in QALY gains was not statistically significant ($P=0.19$). Annualizing the 6-month trial results demonstrated that the anticholinergic and Botox participants averaged 0.702 and 0.707 QALYs, respectively (data not shown).

Findings from a sensitivity analysis that used SF-12-derived QALYs and baseline utility measures were similar. We found no significant difference between the anticholinergic and Botox groups in terms of QALY changes from baseline, but both groups had QALY declines over the trial period (0.0422 for the anticholinergic group and 0.0261 for the Botox group; $P=0.31$), possibly reflecting a lack of sensitivity of a generic health utility index, such as the SF-6D, to reduced urinary incontinence.

For the anticholinergic group, the average cost per QALY gained was $58,098 (= cumulative 6 month direct costs of $1,339 ÷ 6-month QALY gain of 0.02305). The analogous measure for the Botox group was $64,262 per QALY gained (= cumulative 6 month direct costs of $1,266 ÷ 6-month QALY gain of 0.01970). These CERs suggest that each treatment, when evaluated individually, may be considered cost-effective.

We estimated the cost-effectiveness of anticholinergic and Botox through 9 months, the time point when roughly half (55%) of the Botox patients still had adequate symptom control representing a conservative time period for repeat injection. After month 5, Botox mean direct costs were lower than anticholinergic costs because Botox patients had no additional treatment costs, whereas anticholinergic patients continued to incur monthly medication costs to maintain efficacy (Figure 1). We used declining levels of adequate symptom control observed in the Botox group from 6–9 months and assumed that the anticholinergic group maintained their reported 6 month level of symptom control between months 6 and 9 (73%) (Figure 2). We estimated cumulative direct costs at 9 months for the anticholinergic group of $1,942 per participant to achieve 6.36 months of adequate symptom control ($305/month of adequate symptom control) compared with estimated cumulative direct costs for the Botox group of $1,266 per participant to achieve 6.13 months of adequate symptom control ($207/month of adequate symptom control), $p<0.0001$ (Table 3).

DISCUSSION

With the aging of the U.S. population and increased prevalence of urgency urinary incontinence with age, the demand for new treatment approaches is increasing. Many therapeutic options for urgency urinary incontinence have emerged, including new anticholinergic and beta adrenergic medications, neuromodulation, and recently approved intradetrusor Botox injections. Changes in health care financing and rising medical costs warrant a careful assessment of the comparative effectiveness and cost-effectiveness of new treatments prior to widespread adoption.

These data from a population of women with idiopathic urgency urinary incontinence suggest similar overall cost-effectiveness in the short term for Botox compared to anticholinergic therapy. These two therapies are nearly equivalent given similar direct costs and improvements in QALYs. However, Botox may be more cost-effective than anticholinergic medications because it has a potentially longer duration of effect, with minimal additional costs and greater likelihood of complete continence.

While an absolute cost-effectiveness threshold of $50,000 per QALY is commonly used, the World Health Organization threshold is tailored to different countries' gross domestic products (GDPs). The per-capita GDP for the United States was $49,965 in 2012.(22) Following the recommendations of the Commission on Macroeconomics and Health, CHOICE uses gross domestic product (GDP) as a readily available indicator to derive the following three categories of cost-effectiveness: highly cost-effective (less than GDP per capita); cost-effective (between one and three times GDP per capita); and not cost-effective (more than three times GDP per capita).(23) Based on these criteria, both treatments would be considered cost-effective.

Botox clearly costs more up front but has equivalent or better efficacy than anticholinergic therapy at 5 months, although efficacy gradually decreases over time. For patients who prefer to proceed with a "pay-as-you-go" approach, anticholinergic medications may be preferable to Botox. This assumes both adequate medication adherence and stable long-term efficacy. Further study of the long-term cost-effectiveness of Botox with multiple injections compared to long-term anticholinergic use is necessary to better understand optimal treatment strategies for urgency urinary incontinence.

Anticholinergic medications have poor adherence, with reported continuation rates as low as 30% at 3 months and 10% at 1 year, and high rates of side effects, particularly among the elderly.(24, 25) If real-life adherence with anticholinergic medications were lower than observed in this trial, the presumed associated reduction in efficacy could change the cost-effectiveness conclusions and favor Botox, which is not dependent on adherence beyond the initial injection.

Data support the two anticholinergic agents, solifenacin and trospium (used by 16.8% of subjects) chosen in the ABC trial as strong comparators to Botox(26–28), leading to a good foundation for this study. Limited data are available to accurately analyze the cost-effectiveness of Botox for treating urgency urinary incontinence. Wu et al.(29) assessed the cost-effectiveness of Botox compared with anticholinergic medications using a Markov decision model with a 2-year time horizon. They estimated that Botox (200U) was more expensive than anticholinergic therapy at $4,392 vs. $2,563, but with improved effectiveness at 1.63 vs. 1.50, respectively. With an incremental cost-effectiveness ratio of $14,377 per QALY, they concluded that Botox was cost-effective compared with anticholinergic medications. Their model was sensitive to medication adherence rates and to the utility values associated with urgency incontinence.

Our study has several strengths and limitations. Because these data were collected from a multicenter, randomized trial and because we used actual treatment costs and true rates of

effectiveness to calculate cost-effectiveness ratios, this study provides stronger evidence than estimates abstracted from studies with varying inclusion criteria and outcomes or from limited geographic regions. The ABC trial design approximated real-life dosing algorithms by allowing dose escalation and switching of medications as is often done in clinical practice. In addition, the study used solifenacin as the first-line therapeutic drug, a highly cost-effective anticholinergic choice.(26, 28) One limitation is the lack of actual cost data from 6 to 9 months; the assumption that Botox costs remain constant until the need for reinjection does not reflect additional costs between 6 and 9 months for pads and other therapies that may occur prior to the need for reinjection. Given that all subjects discontinued oral medication at 6 months, the assumption that anticholinergic costs continued to accumulate may be overestimated if adherence were lower than in the clinical trial but presumably efficacy would also decrease in such a situation. We attempted to balance this by assuming constant efficacy for 6 to 9 months based on the 6-month reported efficacy. In addition, using the OABq to derive a condition-specific health utility measure may not generate utility and QALY estimates that are comparable to values from generic health utility indices. In fact, the annualized QALY values in our study are lower than those calculated from SF-12 responses from the same individuals (0.702 versus 0.867 over trial period for anticholinergic; 0.707 versus 0.884 over trial period for Botox). However, given our interest in the differences in utility from baseline and between treatment groups, the OAB-5D utility measures provided estimates comparable to SF-6D-derived measures. Additionally, OAB-5D measures may capture health utility differences related to urinary incontinence that generic indexes do not detect. Finally, costs incurred in a clinical trial setting may not be generalizable to the broader urgency urinary incontinence patient population. To mitigate this impact, we excluded additional research-related visits and intervention costs, limiting analyses to clinically appropriate costs. Our data support the early evidence that Botox is at least as cost-effective as anticholinergic therapy and a reasonable therapeutic option for patients with urgency incontinence.

In conclusion, cost-effectiveness evaluations provide valuable information to help patients, physicians, and payers make appropriate choices. This analysis of commonly used medical therapy versus Botox bladder injections suggests that these treatments have similar costs and effectiveness over 6 months. Studies of the long-term cost effectiveness of Botox is warranted before considering Botox as second-line treatment after behavioral and exercise therapy.

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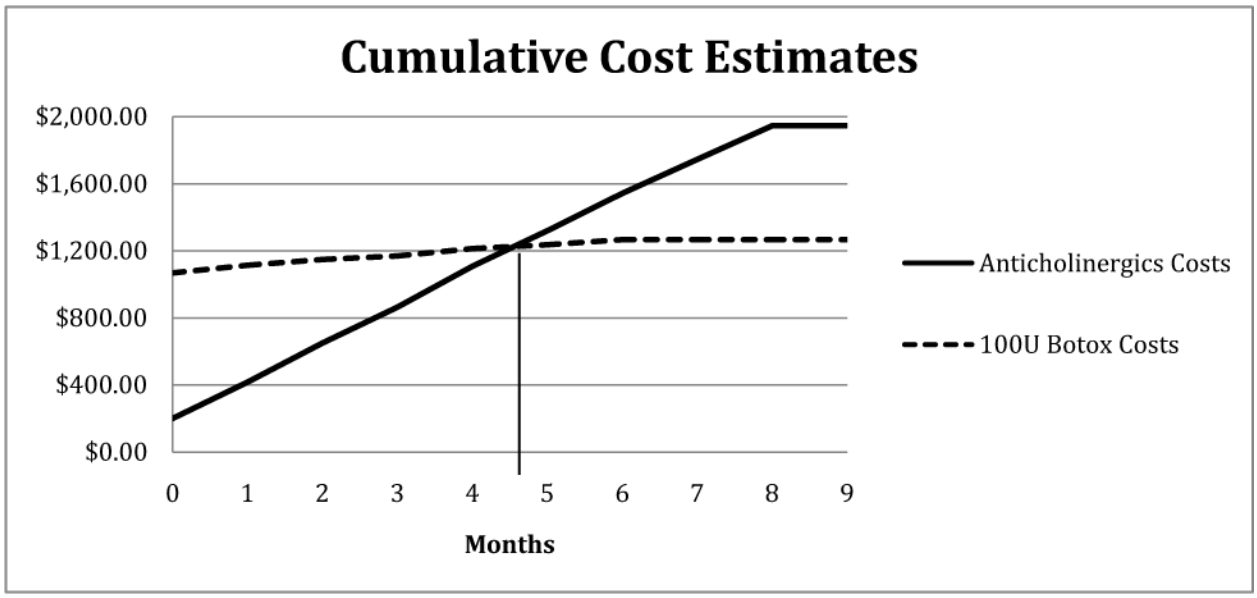

Figure 1.
Estimated cumulative costs for ABC study sample, by treatment group, through 9 months

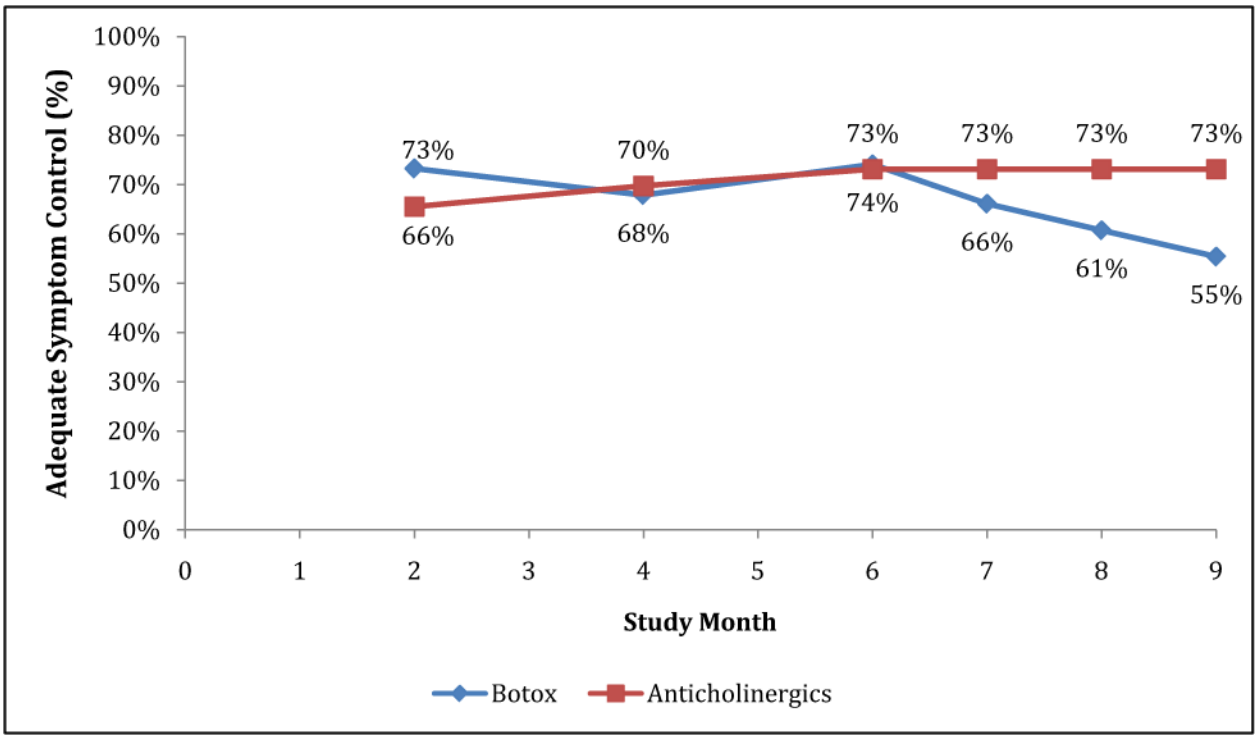

Figure 2. Percentage of ABC study sample with adequate symptom control, by treatment group, months 2 through 9

Note: Months 7 through 9 in the Botox group are actual observed values. Months 7 through 9 in the Anticholinergic group are assumed values based on maintaining efficacy present at the 6-month time period.

Table 1

Baseline Characteristics and Clinical Outcomes of Participants by Treatment Group [*]

Baseline Characteristic	Anticholinergic Group (N=119)	Botox Group (N=112)
Age—years	57.2 ± 11.5	58.9 ± 10.7
Hispanic ethnicity—no. (%) [†]	19 (16)	21 (19)
Race—no. (%) [†]		
White	92 (77)	88 (79)
Black	22 (19)	17 (15)
Other	5 (4)	7 (6)
Type of insurance—no. (%)		
Private only	57 (48)	58 (52)
Medicare or Medicaid only	15 (13)	9 (8)
Other	47 (39)	45 (40)
Working outside the home—no. (%)	64 (54)	51 (46)
Prior anticholinergic therapy—no. (%)	67 (56)	66 (59)
Episodes of urgency incontinence—no./day [‡]	5.1 ± 2.8	4.9 ± 2.6
Health utility [§]	0.656 ± 0.03	0.667 ± 0.05

[*] Plus-minus values are means ± SD. Except where noted, none of the baseline values differed significantly between the treatment groups.

[†] Race and ethnic group were self-reported.

[‡] Reported by patient in 3-day diary entries.

[§] Utility scores are on a scale of 0 (death) to 1 (optimum health). P-value for difference in mean baseline utility score (QALYs) between groups is 0.03. Utility scores (QALYs) were calculated by obtaining baseline scores on the OABq, then applying the Yang et al. (2009)OAB-5D utility scoring methodology to estimate baseline utility values.

Table 2

Estimated Costs and Outcomes by Treatment Group, 6-Month Trial Period *

Cost/Outcome Category	Anticholinergic Group (N=119)	Botox Group (N=112)	Difference between Groups (Anticholinergic-Botox)	P value
Costs over 6 Months				
Treatment Costs *	$1,226 ± 231	$1,072 ± 24	$154	<0.01
Routine Care Costs †	$59 ± 91	$63 ± 113	−$4	0.77
Complications Costs ‡	$54 ± 137	$131 ± 240	−$77	<0.01
Total Direct costs **	**$1,339 ± 276**	**$1,266 ± 272**	**$73**	**0.06**
Total Indirect costs §	$150 ± 850	$106 ± 428	$44	0.62
Outcomes				
Reduction in no. of urge incontinence episodes per day	3.3 ± 0.26	3.33 ± 0.28	0	0.91
Complete resolution of symptoms	13.5%	26.8%	−13.3%	0.003
Quality-adjusted life year (QALY) difference from baseline ‖	0.046	0.039	0.007	0.19

Note: P-value tests the whether the difference between groups is equal to zero. For costs and QALYs, we use a nonparametric bootstrap test, for reduction in urgency urinary incontinence episodes, we use an F-test, and for complete resolution of symptoms, we use a Mantel-Haenszel test.

* Treatment Costs include the costs for the medication (Botox injection or Anticholinergic pharmacy costs), procedure and physician follow-up visit costs, as well as travel costs associated with visits. Results are reported as means with standard deviations.

† Routine Care Costs include pad, diaper, and laundry costs associated with urgency urinary incontinence.

‡ Complications Costs include outpatient and inpatient visits for medical complications associated with treatment as well as travel costs for these visits.

** Estimates of the actual direct medical and non-medical costs were based on utilization of resources during the trial and reported by trial participants. Estimates include the cost of treatment, travel for visits, complications, and incontinence care-related products and expenditures.

§ Indirect costs include value of time lost from work, reduced on-the-job productivity, and household productivity losses, with each valued using earnings estimates from the Bureau of Labor Statistics.

‖ Quality adjusted life years (QALY) adjusted to 12-month measure for ease of interpretation. Calculated using participant responses to the OABq for months 0 through 6.

Table 3

Modeled Nine Month Costs by Cost Category and Treatment Group

Cost/Outcome Category	Anticholinergic Group (N=119)	Botox Group (N=112)	Difference between Groups (anticholinergic-Botox)	P value
Estimated Costs over 9 Months				
Treatment Costs *	$1,829 ± 345	$1,072 ± 24	$757	<0.01
Routine Care Costs †	$59 ± 91	$63 ± 113	−$4	0.77
Complications Costs ‡	$54 ± 137	$131 ± 240	−$77	<0.01
Total Direct Costs	$1,942 ± 370	$1,266 ± 272	$676	<0.01

Note: Results are reported as means with standard deviations.

* Treatment Costs include the costs for the medication (Botox injection or Anticholinergic pharmacy costs), procedure and physician follow-up visit costs, as well as travel costs associated with visits.

† Routine Care Costs include pad, diaper, and laundry costs associated with urgency urinary incontinence

‡ Complications costs include outpatient and inpatient visits for medical complications associated with treatment as well as travel costs for these visits.