Defining Efficacy in the Treatment of Overactive Bladder Syndrome

Sagar Shah, MD, Victor W. Nitti, MD

Department of Urology, New York University School of Medicine, New York, NY

Patients seek treatment for overactive bladder syndrome (OAB) due to poor quality of life, and perceived improvement in quality of life (QOL) from medical therapy is multifactorial. Many feel that efficacy/success of medical therapy for OAB should not be linked to improvements in 1 or 2 endpoints, but instead should be linked to patient expectation and QOL improvement. Ideally, once patient-centered goals are defined, outcomes should be correlated with relief of symptom(s), patient satisfaction, and goal attainment expectations as a result of treatment.
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Overactive bladder syndrome (OAB) as defined by the International Continence Society (ICS) consists of the presence of urinary urgency, with or without urge incontinence, usually with frequency and nocturia.[1] The prevalence rates in both men and women in the United States is estimated at approximately 17%.[1] The total cost of OAB for the year 2000 has been estimated at $12.6 billion.[2] This cost is made up of diagnostic, treatment, routine care, consequence, and indirect costs from loss of productivity. Due to prevalence and cost of this condition, there are significant resources being utilized to develop treatments that improve patient quality of life (QOL) and reduce the financial burden to society.

OAB is a medical problem largely due to its negative impact on daily QOL. The subjective impact of urinary frequency and urgency (with/without urge

incontinence) on psychosocial and physical well-being is an important aspect of caring for this group of patients. The severity and degree of bother associated with the symptoms of OAB can directly influence a person's mobility, degree of social isolation, impairment in work-related activities, disruption of sleep, impairment of domestic and sexual life, and result in depression.[3] Patients may also develop extreme coping strategies including self-imposed fluid restrictions, avoidance of social events and travel, and dependence on protective undergarments. OAB not only affects the lives of patients, but also the lives of their caretakers and their QOL. Thus, many patients and their caretakers seek out treatments that will help provide improvement in these aspects of their lives. Unfortunately, relatively few data are available on the effect of current treatments on patient QOL.

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Most clinical trials evaluating the efficacy of medications and other treatments related to OAB define success as efficacy based on improvements in primary and secondary clinical endpoints. Generally, these clinical endpoints include reduction in incontinence episodes, micturition frequency, urgency measures, and nocturia. The potential problem with this is that clinically significant changes in these parameters compared with placebo may not result in meaningful change in QOL for the patient or the caretaker and may result in discontinuation of medication. Failure to achieve meaningful changes in quality may be related to the fact that a particular symptom is not adequately changed or an adverse event impacts negatively on QOL. A strong argument for this is the poor rate of medication persistence seen in managed care patients with OAB that are significantly lower than reported discontinuation rates from clinical trials.[4-7] Persistence rates for OAB drugs range from 8% to 29% in studies with at least 1 year of follow-up.[4,5,7-9] When comparing extended-release (ER) formulations with immediate-release (IR) formulations, no significant difference was seen in persistence rates after multivariate analysis.[6] In a study evaluating patient reasoning for OAB medication discontinuation, only one-third of patients cited a single reason for discontinuation, with most citing multiple reasons with a mean of 2.3 reasons.[10] The more common reasons included: 46.2%, "didn't work as expected"; 21.1%, "side effects"; 17.2%, cost; and 11.2%, "another medication/medical condition required me to stop." Patient adherence with prescribed therapy is affected by perceived benefit, pill burden, complexity of dosing schedule, memory lapses, and adverse events.[11]

With patients seeking treatment for OAB due to poor QOL and perceived improvement in QOL from medical therapy being multifactorial, it is clear why many believe that efficacy/success of OAB medication probably should not be linked to improvements in 1 or 2 endpoints, but instead should be linked to patient expectation and QOL improvement. Ideally, once patient-centered goals such as the ability to perform certain tasks are defined, outcomes should be correlated with relief of symptom(s), patient satisfaction, and goal attainment expectations as a result of treatment. We need to establish more clear-cut evidence of how a myriad of factors affect treatment response.

QOL Outcomes in OAB Treatment

Despite improvements in objective measures, changes in health-related quality of life (HRQOL) are not necessarily always seen with OAB medical therapy.[12] With QOL the main reason patients seek treatment for OAB, utilization of QOL measures to evaluate treatment benefit seems more appropriate. The ICS recommends that therapeutic interventions aimed at improving the symptoms of OAB should also be assessed for their effects on HRQOL measures.[13]

Recently many reports have come out evaluating treatment effects of various OAB medications on QOL measures. One tool utilized for this has been the King's Health Questionnaire (KHQ). The KHQ is used as a rapid, validated tool to assess urinary incontinence and other OAB symptoms. It consists of 21 questions in 8 different QOL domains, a domain assessing urinary coping strategies, and a separate scale measuring the severity of urinary symptoms. Weighted summary scores for each domain range from 0 to 100, with higher scores representing worse impairment. A change in each QOL domain of 5 points or more and a change of 3 points or more in the symptom severity scale is a meaningful result. Using pooled data from placebo-controlled, randomized drug trials, changes in KHQ parameters have been assessed for trospium ER, fesoterodine, solifenacin, and darifenacin.[14-17] Data for darifenacin came from phase III extension trials. Changes in KHQ parameters after treatment with transdermal oxybutynin, IR tolterodine, and IR oxybutynin have come from open-label trials.[18,19] In general, after treatment with these OAB medications (Table 1), meaningful changes from baseline

Table 1
Changes in King's Health Questionnaire Scores After Therapy

Domain	Solifenacin 5 mg*	Solifenacin 10 mg*	Tolterodine ER 4 mg†	Tolterodine 2 mg‡	Oxybutynin 2.5/5 mg‡	Darifenacin 7.5/15 mg‡	Fesoterodine 4 mg†	Fesoterodine 8 mg§	Oxybutynin Transdermal‡
General health	−4.3	−4.0	−1.9	−0.45	0.58	0.15	−2.9	−2.6	−1.2
Incontinence impact	−24.7	−27.3	−22.7	−10.38	−8.62	−19.42	−7.8	−9.6	−13.5
Role limitations	−20.6	−22.7	−21.5	−11.44	−9.07	−21.30	−18.5	−21.4	−13.3
Physical limitations	−17.7	−20.3	−18.8	−8.23	−8.01	−17.79	−17.2	−19.6	−11.7
Social limitation	−11.3	−11.7	−13.2	−6.16	−6.77	−10.62	−11.6	−13.8	−6.7
Personal relationships	−8.7	−9.3	−10.0	−2.78	−5.0	−5.41	−7.8	−9.6	−6
Emotions	−16.0	−17.7	−14.2	−4.57	−6.51	−11.75	−12.4	−15.3	−8.8
Sleep/energy	−13.8	−14.4	−12.7	−5.98	−6.15	−8.10	−10.7	−12.3	−11.2
Severity(coping) measure	−10.5	−13.2	−12.4	−6.16	−5.48	−8.77	−11.3	−13.7	−8.6

ER, extended release.
*$P < .001$ compared with placebo.
†$P < .01$ compared with placebo.
‡$P < .001$ compared with baseline.
§$P < .05$ compared with placebo.

were seen in all domains except for general health, and in some cases in the personal relationships and emotions domain.[15-17]

Other QOL questionnaires including the Overactive Bladder Questionnaire (OAB-q) and Patient Perception of Bladder Condition (PPBC) have been utilized to evaluate effects on QOL by OAB medication therapy. The OAB-q is a validated 33-item, self-administered symptom bother and HRQOL questionnaire.[20] This tool is designed to assess the effect of OAB symptoms (frequency and urgency) in both continent and incontinent male and female subjects with OAB. The HRQOL scale consists of 25 items forming 4 subscales (coping, concern/worry, social interaction, sleep). Subscale and total scores were transferred onto a 0 to 100 scale, with higher scores indicating better HRQOL. An additional 8 items form the symptom bother scale. Higher scores on the symptom bother scale indicate increasing symptom bother. A threshold of 10 points has been suggested to represent a minimally important difference on the OAB-q.[21] In an open-label study utilizing darifenacin, significant changes were seen in PPBC from baseline after treatment (4.6 to 3.1; $P < .0001$).[22] In this same group, 72% of patients had a decline in PPBC score, with 23% reporting no change and 4.1% reporting an increased (worse) score after treatment. Despite this statistically significant improvement in PPBC in the group overall, only 85.6% of patients deemed themselves to be satisfied with treatment. In an open-label study of solifenacin, a similar decline in PPBC was seen (4.4 to 2.9) after treatment with the medication.[23] In an open trial with fesoterodine, significant changes were also seen in PPBC, OAB-q symptom bother, and OAB-q HRQOL from baseline.[24]

Despite these studies demonstrating significant changes in QOL measures following treatment with various OAB medications, patient persistence with OAB medications in a population of managed care patients ranged from 9% to 13.2% over a 1-year period depending on formulation, with no significant differences between IR or ER formulation.[10] This suggests that these changes in QOL are not clinically significant despite being statistically significant or that other factors are involved in determining patient satisfaction and persistence with therapy. This helps to put forth an argument that QOL measures alone are also not ideal measures of treatment benefit and efficacy.

Defining Success/Efficacy

Objective measures currently used to assess outcomes of OAB treatments do not always translate into improvement in QOL and resultant patient satisfaction with treatment. Statistically significant changes in QOL measures in trials may also not translate into patient satisfaction and persistence with medical therapy. Patient satisfaction is determined by subjective personal evaluation of treatments, health services, and health care providers. Satisfaction is complicated and is affected by objective clinical improvement, side effects, accessibility and convenience, availability of resources, continuity of care, availability of information on the disease, information giving, pleasantness of surroundings, and quality/competence of health care providers.[25] Patients' understanding of their comorbidities and potential treatment side effects also carries an unknown but finite influence on satisfaction. The role of expectations in satisfaction cannot be minimized. A patient's high expectations may remain unsatisfied even after "successful" treatment because expectations for treatment benefit were not aligned with what could reasonably be expected in regard to objective improvement. The role of expectations can be accounted for and controlled by ensuring that expectations are measured at the time of treatment initiation. Thus, determination of satisfaction involves a comprehensive evaluation of several dimensions of care based on patient expectations as well as provider and treatment performance. In chronic diseases like OAB, where a patient must live with treatment long term, patient satisfaction may be the only distinguishing outcome between treatments.[26] High levels of satisfaction have been positively associated with good health status, fewer medical encounters, and shorter hospital stays.[27] Evidence also suggests that patient satisfaction may be more sensitive to change than QOL in clinical trials in chronic diseases.[28]

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For a condition like OAB, which significantly impairs QOL and where different patients will desire different outcomes from their treatment based on priorities, satisfaction is a particularly useful outcomes measure. There are generic and condition-specific questionnaires that can be utilized to assess satisfaction with OAB treatment.

The generic Benefit, Satisfaction, and Willingness (BSW) questionnaire is composed of 3 items designed to assess treatment benefit, patient satisfaction with treatment, and patient willingness to continue treatment. This questionnaire has been validated using data from a 12-week, placebo-controlled trial of tolterodine in patients with OAB.[29] In this study,

correlations were seen between patient-reported treatment satisfaction and improvement in QOL questionnaires (OAB-q and KHQ) and objective micturition variables.

Another potential questionnaire that may be useful in assessing satisfaction in OAB patients is the Treatment Satisfaction Questionnaire for Medication (TSQM). TSQM is not specific for OAB treatments, but can be used as a general measure of treatment satisfaction with medication for many illnesses. The first version contains 4 scales: side effects (4 items), effectiveness (3 items), convenience (3 items), and global satisfaction (3 items). It has been shown to be psychometrically sound and a valid measure of patients' satisfaction with medication.[30] A second version exists and is slightly shorter, but psychometric tests have shown that it performs equivalently when predicting measures of concurrent validity.[31]

The condition-specific Overactive Bladder Treatment Satisfaction Questionnaire (OAB-S) is a 5-domain questionnaire that evaluates expectations of control, impact on daily living with OAB, OAB control, fulfillment of OAB medication tolerability, and satisfaction with OAB control. Internal reliability coefficients were good (Cronbach's alpha, 0.76-0.96) and test reliability has also been established (reliability coefficient, 0.72-0.87).[31,32] OAB-S is available in more than 16 languages.[33] When comparing OAB-S with TSQM, OAB-S was found to have better test reliability, discriminating patients by severity level and in terms of detecting change in satisfaction levels in OAB sufferers.[34]

Another potentially useful way to assess outcomes of OAB treatment is goal attainment; it represents an individualized approach to a specific patient and is centered on patient expectations. Goal attainment scaling (GAS) has been widely used to assess drug trials for the treatment of Alzheimer's disease.[35,36] GAS has been found to be more responsive to change than measures commonly used in evaluating effectiveness of specialized intervention.[37] The Self-Assessment Goal Achievement (SAGA) questionnaire has been developed for use in the OAB arena.[38] After interviewing patients with lower urinary tract symptoms and OAB, researchers identified 9 symptoms to be the most bothersome. These symptoms were then incorporated into Part 1 of SAGA as a fixed assessment of 9 symptom goals. In the second part, patients can record any other goals they have related to their symptoms, which is in line with traditional GAS. At follow-up, patients rate the level of goal achievement. Further testing of reliability and validity of SAGA is needed prior to recommendation for use in clinical trials.

Patient satisfaction is more sensitive to change than QOL measures in clinical trials of other diseases.[28] High levels of satisfaction are also associated with good health status and fewer medical encounters.[39] Patient satisfaction with OAB treatment has also been shown to be associated with compliance with medical therapy.[40] Future studies that utilize the questionnaires evaluating satisfaction with OAB therapy based on goals may help us to parse which OAB treatments are more efficacious from a satisfaction standpoint. This would allow us to individualize therapy and increase satisfaction and persistence with therapy, resulting in reduced costs for provider visits, less loss of productivity, and decreased use of sanitary garments.

Efficacy and Effect on Quality of Life: Oxybutynin Gel

In evaluating effects on QOL, a number of factors need to be considered in addition to efficacy. Adverse events (particularly dry mouth and constipation), perceived benefit, pill burden, complexity of dosing schedule, memory lapses, and adverse events all affect patient satisfaction and adherence to medications. With objective clinical improvements being similar for currently available OAB medications, it is likely that adverse events, pill burden, and complexity of scheduling will drive satisfaction. In this regard, transdermal medications offer an advantage in certain patients as they may result in improved satisfaction due to no increase in pill burden, fewer adverse events due to avoidance of first-pass metabolism, ease of use, and simplicity of scheduling.[40,41] Transdermal oxybutynin formulations have shown the lowest incidence of antimuscarinic side effects of the drugs for OAB. Transdermal patches have been shown to be preferred by caregivers over capsules in the treatment of Alzheimer's due to satisfaction with ease of administration and less interference with daily life.[42] This may also be the case with OAB therapy, but further investigation is needed. The newest formulation of oxybutynin, transdermal gel, has been shown to be effective for the treatment of OAB with very low side effects. In the pivotal trial, Staskin and colleagues showed statistically significant improvements in key parameters of urgency, urinary incontinence, and

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urinary frequency versus placebo.[43] The mean number of urge incontinence episodes decreased significantly in patients treated with the topical gel formulation than in those given placebo (−3.0 vs −2.5 per day; $P <$ .0001) and mean urinary frequency decreased (−2.7 per day; $P = .0017$). In addition, voided volume increased (21.0 mL; $P = .0018$) significantly in the oxybutynin gel versus placebo (−2.0 per day and 3.8 mL, respectively). Antimuscarinic side effects were low, with treatment related dry mouth at 6.9% and constipation at 1.3%.[43] Application site reactions were infrequently observed in the oxybutynin gel group in only 5.4% of patients and this led to study withdrawal in only 0.8%.[43] Skin reactions seem to be significantly less than those reported for oxybutynin transdermal patch, where erythema and and itchiness were reported in 8.3% and 14% of patients.[40] Oxybutynin topical gel is associated with fewer application-site reactions, which is expected to result in greater satisfaction with therapy than with the oxybutynin patch or oral medications.[43]

Recently, Sand and colleagues[44] showed that treatment with oxybutynin transdermal gel translated into improvements in QOL in women. In a subanalysis of the phase III trial, which included 704 women aged 18 years and older (mean, 59 years) diagnosed with OAB and urinary incontinence, the Incontinence Impact Questionnaire (IIQ) and KHQ were used to assess QOL. Differences in efficacy and QOL between placebo and treatment groups were compared via analysis of covariance. Starting with week 4 of treatment, patients using oxybutynin transdermal gel showed significantly more improvement than patients in the placebo group, as measured by IIQ (total score, −73.3 vs −47.8; $P = .0001$) and KHQ.

Going Forward

A more wideapread utilization of satisfaction-based questionnaires to evaluate the success of OAB therapy needs to be performed to help us identify more specific determinants of satisfaction and adherence. This could allow improvement in current therapies as well as the development of medications with qualities that result in improved satisfaction and not just statistically significant changes in objective parameters that do not necessarily translate into an effective medication from a patient standpoint. ■

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Main Points

- Overactive bladder syndrome (OAB) is a medical problem largely due to its negative impact on daily quality of life (QOL).
- Most clinical trials evaluating the efficacy of medications and other treatments related to OAB define success based on improvements in primary and secondary clinical endpoints; these clinical endpoints are reduction in incontinence episodes, micturition frequency, urgency measures, and nocturia. Clinically significant changes in these parameters compared with placebo may not result in meaningful change in QOL for the patient or the caretaker and may result in discontinuation of medication.
- The International Continence Society recommends that therapeutic interventions aimed at improving the symptoms of OAB should also be assessed for their effects on health-related quality-of-life (HRQOL) measures.
- With objective clinical improvements being similar for currently available OAB medications, it is likely that adverse events, pill burden, and complexity of scheduling will drive patient satisfaction.
- Oxybutynin topical gel is associated with fewer application-site reactions, which is expected to result in greater satisfaction with therapy.

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