

UTILIZATION OF THE SELF-ASSESSMENT GOAL ACHIEVEMENT QUESTIONNAIRE TO EVALUATE THE IMPORTANCE OF TREATMENT GOALS IN SUBJECTS WITH OVERACTIVE BLADDER SYMPTOMS

Hypothesis / aims of study

Unmet treatment expectations are important factors in the discontinuation of overactive bladder (OAB) medication [1]. Successful management of chronic conditions such as OAB may be contingent on patients having realistic treatment goals and on clinicians understanding what treatment goals are important to the patient. Despite this, little is known about the relative importance of treatment goal objectives and domains for patients with OAB. In this study, we asked patients with OAB symptoms to identify and rate the importance of their treatment goals before treatment using the recently developed Self-Assessment Goal Achievement (SAGA) questionnaire, and assessed the achievement of these goals following treatment.

Study design, materials and methods

Men and women aged ≥ 18 years were eligible to participate in this 12-week, prospective study if they reported OAB symptoms for ≥ 3 -months, had ≥ 8 micturitions/24 h and ≥ 3 urgency episodes/24 h recorded in a 3-day bladder diary, and reported at least "moderate" bladder-related problems on the Patient Perception of Bladder Condition. All subjects were treated with open-label fesoterodine 4 mg once daily for the first 4 weeks, with an option at week 4 to increase their dose to 8 mg once-daily or maintain 4-mg dosing for the remaining 8 weeks of treatment based upon discussion of treatment efficacy and tolerability with the investigator. Subjects completed the SAGA baseline module prior to or during the baseline visit and the SAGA follow-up module at week 12. The baseline SAGA module includes a list of 9 prespecified (fixed) treatment goals (**Figure 1**) and allows subjects to list up to 5 additional (open) treatment goals. On the baseline module, subjects rated the importance of all fixed and open goals using a 5-point scale (1 = not very important goal to 5 = very important, with an option to choose "not applicable" for fixed goals), ranked their 5 most important goals, and identified criteria for successful achievement of their most important goals. At week 12, subjects used the SAGA follow-up module to rate the degree to which they achieved each individual fixed and open goal as well as their degree of overall goal achievement using a 5-point scale (1 = did not achieve goal to 5 = greatly exceeded goal, with an option to choose "not applicable" for individual fixed goals).

Results

The SAGA baseline module was completed by 328 subjects, and the follow-up module was completed by 310 subjects. At baseline, the fixed goals most commonly rated as "very important" were "Reduce the sudden need to rush to the bathroom" (77%), "Reduce frequency to the bathroom through the day" (66%), and "Reduce frequency to the bathroom at night" (59%) (**Figure 1**). Among the 128 subjects who reported UUI at baseline, 104 (81%) rated "Reduce my urine leakage" as a "very important" goal (compared with 52% of subjects overall). The fixed goals most commonly rated as "not very important" at baseline were "Reduce the difficulty starting or maintaining a urinary stream" (25%), "Reduce the urine loss when I cough, laugh, exercise, or sneeze" (19%), and "Reduce the difficulties I have completely emptying my bladder" (14%) (**Figure 1**). Greater than 1300 different open treatment goals were listed by subjects on the baseline SAGA module, with 84% of subjects recording ≥ 3 open goals; these goals related to multiple physical and psychosocial aspects of subjects' lives (eg, reduced OAB symptoms; being able to play or go out with one's children/grandchildren; to be able to go shopping, walking, or out for the evening without leakage or frequently looking for a toilet). At week 12, 81% of subjects reported that they achieved the goal of "Reduce the sudden need to rush to the bathroom" (the goal most frequently rated as "very important" at baseline) at least "somewhat;" 87% of subjects reported that they achieved their overall goals at least "somewhat."

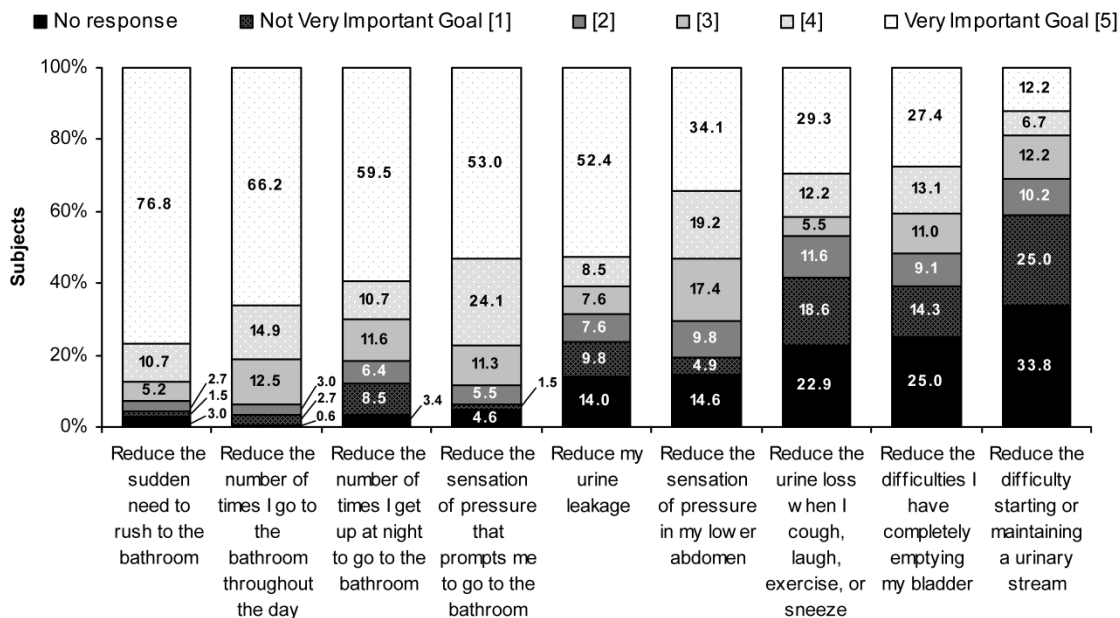
Interpretation of results

Individuals affected by OAB symptoms have multiple treatment goals that they wish to achieve. Many of the subjects in this study considered reducing urinary urgency and frequency as important treatment goals at baseline. However, there was considerable variability among individual subjects in types of open treatment goals reported at baseline. The majority of subjects reported partial or full achievement of their treatment goals after 12 weeks of open-label treatment with flexible-dose fesoterodine.

Concluding message

The SAGA questionnaire is a promising new tool to identify treatment goals in patients receiving pharmacologic treatment for OAB symptoms. SAGA questionnaire outcomes may be useful in the clinical setting for helping subjects' develop realistic treatment expectations, which may lead to improved treatment outcomes.

Figure 1. Subject-Reported SAGA Fixed Goals and Goal Importance at Baseline (N=328)



References

1. Benner et al. BJU Int. 2009 Nov 12. Epub ahead of print

Specify source of funding or grant	Pfizer Inc
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	Yes
Specify Name of Public Registry, Registration Number	Clinicaltrials.gov NCT00806494
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Multi-centre Research Ethics Committee for Wales
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes