ABSTRACT

Evaluating the impact of stress urinary incontinence (SUI) on quality of life (QOL) is of paramount importance, as reflected in the International Continence Society's characterization of the primary symptom as a "complaint." Emphasis on health-related QOL also is consistent with the World Health Organization definition of health, which includes the social and emotional impacts of a medical condition. QOL has been assessed and reported by means of several general and disease-specific questionnaires, and health-related QOL has become a standard outcome measure in randomized clinical trials. A variety of questionnaires have been recommended and evaluated for assessing the impact of incontinence on QOL, and new, more specific instruments are being developed. The emphasis on QOL in patients affected by SUI underscores the importance of considering all aspects of a patient's life before making treatment decisions and drawing conclusions about treatment success.


IMPACT OF STRESS URINARY INCONTINENCE ON QUALITY OF LIFE

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TERMINOLOGY

Although the terminology used to describe SUI and its consequences has changed, the language has long embraced the principles of QOL. In 1976, the ICS defined incontinence as "the involuntary loss of urine that is a social or hygienic problem." The term compassionate and effective management of stress urinary incontinence (SUI) requires careful examination of the condition's impact on a patient's quality of life (QOL). The critical role of QOL is embraced in the recent International Continence Society (ICS) revision of terminology for lower urinary tract dysfunction, which describes the primary symptom of SUI as a "complaint." The World Health Organization (WHO) has further emphasized the importance of QOL by including emotional and social well-being in the WHO definition of health.

QOL is measured and reported in numerous ways by use of both general and disease-specific assessment instruments. The concept of health-related QOL has emerged as a key outcome for clinical studies. The large number of studies examining health-related QOL points to the importance of assessing all facets of a patient's life, and the patient's perspectives on those facets, before arriving at conclusions about the effects of treatment.

Recent studies of treatment for SUI have incorporated various forms of QOL assessment and have made health-related QOL outcomes an integral part of efficacy evaluation. Studies of medical and surgical therapy have shown that effective intervention in SUI can significantly improve patient QOL. These investigations also have affirmed the importance of defining and evaluating QOL in ways that are meaningful to the patient.
“quality of life” did not appear in the definition, but describing a condition that constitutes a “social or hygienic problem” clearly speaks to the concept. The definition was retained in the new ICS definition of lower urinary tract dysfunction and accepted by the second International Consultation on Incontinence (ICI).1

Patients who present to physicians and exhibit treatment-desired behavior tend to have a “social or hygienic problem.” However, surveys to ascertain the prevalence of incontinence require a different definition. Toward that end, the ICS also defines urinary incontinence as “the complaint of any involuntary loss of urine.” By that definition, more than 50% of women older than 20 years of age have incontinent episodes, but most of them do not desire or seek treatment. The episodes may occur during a fit of coughing during allergy season but are absent for the remainder of the year.

With respect to SUI, the ICS and the second ICI have adopted 3 types of terminology, defining SUI in terms of a symptom, a sign, and a condition (Table).1 The symptom is the patient’s complaint of involuntary leakage of urine. The sign is the clinician’s observation of involuntary leakage from the urethra. The condition is a urodynamic diagnosis, and the term “genuine stress incontinence” has been changed to “urodynamic stress incontinence” to reflect this new terminology and to clarify its meaning.

The terminology of incontinence encompasses a spectrum of clinical circumstances that have important implications for accurate diagnosis and treatment. At one end of the spectrum is pure stress incontinence. A large group of patients have mixed incontinence, characterized by symptoms of both stress and urge incontinence. Other patients have only urge symptoms that lead to urine leakage; these patients may be best described as “overactive bladder—wet.”

### Incontinence and QOL

The second ICI, sponsored by WHO, produced a series of clinical management algorithms for urinary incontinence. The algorithms focus on the initial workup and management of patients who present with signs, symptoms, or complaints of incontinence. As part of the initial clinical assessment, the consultation recommended evaluation of the impact that incontinence has on the patient’s QOL.

The degree to which incontinence adversely affects a patient’s QOL is the driving force behind the patient’s decision to seek treatment. If the impact is somewhat minimal, it stands to reason that the patient will likely accept a more conservative approach to treatment. In contrast, if incontinence exacts a heavy toll on QOL, many patients may be open to more aggressive and invasive therapy. With respect to treatment alternatives, the impact of incontinence on QOL clearly influences choices and decisions.

QOL is a multidimensional phenomenon, and the individual patient’s perspective is of paramount importance. What we as clinicians think about the importance of a patient’s QOL is irrelevant compared with the patient’s perception. Some physicians may have difficulty working through the concept of the predominance of the patient’s wishes. Nonetheless, it is a fact we must accept in order to provide truly effective treatment. The patient relates QOL to family, the ability to work, the ability to continue routine activities inside and outside of the home, and in terms of overall functioning in the community.

### Assessing QOL

Numerous questionnaires have been developed for assessment of health-related QOL. Some address general health and well-being, whereas others are specific to certain conditions. Two recent publications describe some of the questionnaires that have been used to assess urinary symptoms, including questionnaires designed to evaluate the impact of urinary incontinence on QOL.3

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<th>Table. International Continence Society Definition of Stress Urinary Incontinence</th>
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<td><strong>SYMPTOM</strong></td>
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Data from Abrams et al.1
Questionnaires have been used extensively to assess lower urinary tract symptoms. Roles of questionnaires include recording of symptoms and assessment of QOL, and can elicit diagnostically useful information. Questionnaires have also been developed for epidemiologic studies and for outcomes measurement in clinical trials of therapeutic interventions.

Currently available QOL questionnaires follow 1 of 2 basic approaches to assessment. Generic questionnaires seek out information that permits construction of a general profile of physical and psychological health and well-being. The instruments achieve comparable results across a range of conditions and allow comparisons between populations with different diseases, such as patients with SUI and those with rheumatoid arthritis. Generic questionnaires do not measure the impact of a specific condition and, can therefore be rather insensitive, particularly in elderly patients, who often have comorbid conditions.

As their name suggests, disease-specific instruments target a specific condition or group of conditions. The questionnaires uniformly assess symptoms and their impact on patient lifestyle, making them potentially more sensitive. Because they are disease specific, these instruments do not detect effects on other health dimensions and do not allow for comparisons between differing disease groups.

No universally accepted questionnaire exists within the field of incontinence. The members of the second ICI sought to create universally accepted instruments by developing a series of questionnaires applicable to patients with incontinence. The ICI questionnaires (ICIQ) are currently in development.

The first of the questionnaires, the ICI short form (ICIQ-SF) has already been fully validated (Figure 1). The ICIQ-SF represents an attempt to capture and reflect patient perspective. For example, in the validation process for the questionnaire, it became obvious that physician views on severity of leakage differed from patient views. Questions are structured to capture as precisely as possible the patient’s evaluation of the condition and its impact on QOL (Figure 2). The patient may report that leakage is minimal or nonexistent; although the physician may disagree with the patient’s assessment, the patient’s perception is the most important consideration.

Eventually, the ICI will have validated long-form modules for urinary incontinence, other urinary symptoms, prolapse, bowel incontinence, and bowel

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**Figure 1. International Consultation on Incontinence Questionnaire (ICIQ-SF)**

**HOW OFTEN DO YOU LEAK URINE?**
- Never = 0
- About once per week or less often = 1
- 2 or 3 times per week = 2
- About once per day = 3
- Several times per day = 4
- All the time = 5

**HOW MUCH URINE DO YOU USUALLY LEAK?**
- None = 0
- Small amount = 2
- Moderate amount = 4
- Large amount = 6

**OVERALL, HOW MUCH DOES LEAKING URINE INTERFERE WITH YOUR EVERYDAY LIFE?**
- 0 = not at all, to 10 = a great deal

**WHEN DOES URINE LEAK?**
- Self-diagnosis items

Score = 0-21 (alpha 0.92).

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**Figure 2. Self-Diagnosis Items from the ICIQ-SF**

**WHEN DOES URINE LEAK? (PLEASE TICK ALL THAT APPLY TO YOU)**
- Leaks before you can get to the toilet
- Leaks when you cough or sneeze
- Leaks when you are asleep
- Leaks when you are physically active/exercising
- Leaks when you have finished urinating and are dressed
- Leaks after you feel a sudden desire to pass urine that is difficult to delay
- Leaks when you wash you hands or hear the sound of running water
- Leaks when you are opening or unlocking the door
- Leaks for no obvious reason
- Leaks all the time

ICIQ-SF = International Consultation on Incontinence Questionnaire.
symptoms. Generic modules will include QOL, sexual matters, and emotional issues. The modular approach will permit distinctions between the effects of a patient's general health on QOL and the effects of incontinence or urinary symptoms. The module dealing with sexual matters will be adapted to each incontinence condition and to male and female patients. Upon validation of the entire ICIQ series, QOL assessment will be adaptable to a wide range of patient groups and clinical circumstances.

**STRESS INCONTINENCE AND QOL**

Until recently, QOL assessment in the field of incontinence has focused primarily on urge incontinence. This focus has been driven by results from a number of randomized controlled trials of new drug therapies, most of which have been developed for the assessment of treatment for overactive bladder. The studies have consistently shown that urge incontinence is more bothersome to patients compared with stress incontinence. However, these findings do not denigrate the impact of stress incontinence—urologists and other physicians see many patients who desire treatment for SUI, which clearly can be bothersome and adversely affect QOL.

The impact of SUI on QOL depends on several factors: frequency and severity of incontinence episodes; extent of the patient's desired physical function; effects on sexual activity; and influence on social functioning. In particular, women's interest in physical activity increased dramatically in the 1980s and 1990s, leading to a greater demand on physicians for treatment to minimize the impact of SUI on physical activity.

To some extent, women can minimize the impact of SUI on QOL by adherence to some simple management techniques, such as weight loss, bladder emptying before physical or sexual activity, and pelvic floor exercises. Many women, however, are not satisfied with the results of self-management and seek help from primary care physicians, urologists, gynecologists, and other clinicians. These patients may already have an idea of the type of treatment they want or will accept, based perhaps on the extent to which their QOL is being affected by SUI. One of the challenges faced by the clinician is to give patients an objective view of the different treatment options, which now include behavioral therapies, surgery, and possibly drug therapy.

**SUI TREATMENT OPTIONS AND QOL**

Although medical therapy has been used for decades in the management of SUI, many of the therapies are not approved for the condition, and some, such as the alpha-adrenergic agonist phenylpropanolamine, have proved to be risky. The newest drug to be evaluated in stress incontinence is duloxetine, a dual reuptake inhibitor of serotonin and norepinephrine. A recent phase III randomized, placebo-controlled trial of duloxetine incorporated QOL assessment by the 22-item IQOL questionnaire, which is a validated, incontinence-specific instrument.

The trial involved 683 women with diagnosed SUI. They were randomized to duloxetine 40 mg twice daily or to placebo for 12 weeks. As stipulated in the protocol, all patients completed the IQOL and the Patient Global Impression of Improvement (PGI-I) instruments.

The IQOL comprises 3 domains: avoidance, social embarrassment, and psychosocial. A comparison of baseline and 12-week data showed significant improvement in all 3 domains among duloxetine patients who completed the protocol. Additionally, patients who completed 12 weeks of duloxetine treatment exhibited significant improvement in the PGI-I. Results of a similar European trial involving 500 SUI patients have corroborated the findings of the first trial.

A favorable QOL impact of surgical therapy for SUI was demonstrated in a recent randomized comparison of colposuspension and tension-free transvaginal tape (TVT). The trial involved 344 patients with SUI who were randomized to 1 of the 2 procedures and followed up for 6 months. The Bristol Lower Urinary Tract Symptoms Questionnaire was administered before treatment and at 6 months. Data derived from the questionnaire was particularly revealing with respect to the degree to which SUI affected patients' lives prior to surgery. For example, in the patients treated with colposuspension, 93% of patients said SUI interfered with physical activity prior to surgery, reduced to 17% at 6 months after surgery; 63% said urinary symptoms negatively affected sexual activity, reduced to 27% after surgery; 63% had incontinence with sexual intercourse, reduced to 11% after surgery; and 77% said SUI interfered with social relationships, reduced to 13% after surgery. Overall, 94% of the patients said SUI interfered with their lives before surgery.
surgery, compared with 22% at 6 months after surgery. Results were similar for patients treated with T V T.

As part of the Q O L assessment, women in the surgical trial were asked to rate their feelings “if you had to spend the rest of your life with symptoms as they are now.” Before surgery, more than 70% described their situation as “very unhappy” or “desperate.” At 6 months, 80% of the patients were mostly satisfied, pleased, or perfectly happy.

Results of the duloxetine and surgery trials confirm that S U I has a substantial adverse effect on Q O L. The trials also demonstrate that Q O L improves with effective therapy.

**Summary**

Q O L is a multidimensional phenomenon that comprises physical, emotional, and social well-being. The patient’s perspective of Q O L is paramount and should be considered thoroughly before initiating treatment. Assessment of Q O L should be routinely incorporated into the initial evaluation of patients with incontinence. Numerous validated Q O L questionnaires are available, but no widely accepted instrument exists for evaluation of patients with urinary incontinence. The second I C I has begun work to develop a modular system of Q O L assessment, which could provide the standard for physicians who evaluate and treat patients with incontinence.

Until recently, Q O L research has concentrated on urge incontinence. Recent investigations have demonstrated that S U I also adversely affects patient Q O L. Recently published studies have further demonstrated that drug therapy, as well as surgery, can improve Q O L in patients affected by stress incontinence.

**REFERENCES**