

# OUTCOME MEASURES FOR URINARY INCONTINENCE

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## ABSTRACT

**Objectives.** To discuss the rudiments of data that need to be collected in order to develop validated, reproducible, well-accepted efficacy instruments for assessing treatment outcomes in urinary incontinence (UI).

**Methods.** Information is presented from two reports issued by the Urodynamics Society: "Definition and Classification of Urinary Incontinence" and "Standards of Efficacy for Evaluation of Treatment Outcomes in Urinary Incontinence."

**Results.** Instruments to assess the efficacy of treatment should be reliable and valid. Such instruments include structured histories, questionnaires, structured physical examinations, urodynamics, voiding diaries, and pad tests. Recommended primary outcome variables include the number of incontinent episodes, volume of urinary loss, and type of incontinence. Secondary measures include patient satisfaction, quality of life, bladder symptoms, uroflow, postvoid residual urine, and other urodynamic variables. General considerations for the development of clinical trials include 1) using a standard lexicon, 2) consistent timing of follow-up, 3) proper outcome assessment at each follow-up, 4) proper data collection, 5) proper data analysis, and 6) formulating conclusions that are supported by the data.

**Conclusions.** At the present time, there are no validated, reproducible, well-accepted efficacy instruments for assessing treatment outcomes in UI. Further work directed toward the development of such instruments is warranted. *UROLOGY* 51 (Suppl 2A): 11-19, 1998. © 1998, Elsevier Science Inc. All rights reserved.

Urinary incontinence (UI) is the involuntary loss of urine. This term denotes a symptom, a sign, and a condition. The symptom is the patient's (or caregiver's) statement of involuntary urine loss; the sign is the objective demonstration of urine loss; and the condition is the pathophysiology underlying incontinence, as demonstrated by clinical or urodynamic techniques (Tables I and II).<sup>1-3</sup> In order to adequately assess the results of therapy for UI, outcomes should be measured and quantified in a consistent manner that permits rational conclusions to be formulated. This is the goal of outcomes research.

Outcome measures may be characterized by quantifiable areas or domains that include 1) symptoms, 2) amount of urinary loss, 3) associated anatomic abnormalities, 4) pathophysiology, and 5) quality of life. At the present time, there are no validated, widely accepted instruments to assess any of these domains. What follows are generic guidelines for the development of such instru-

ments and a rational plan for their implementation. The discussion is based on two reports from the Urodynamics Society entitled "Definition and Classification of Urinary Incontinence"<sup>2</sup> and "Standards of Efficacy for Evaluation of Treatment Outcomes in Urinary Incontinence."<sup>3</sup>

## OUTCOMES RESEARCH: GENERAL CONSIDERATIONS

Whereas the physician and surgeon are primarily concerned with the individual patient, outcomes research is concerned with populations of patients and the effect of treatment on those populations with respect to such concerns as safety, efficacy, and the economic impact on society, third-party payers, and the patient and his or her family. Physicians and surgeons generally formulate a non-quantifiable global assessment of UI by history taking, physical examination, laboratory tests, urodynamics, and cystoscopy. Outcomes research focuses on quantifiable measures using validated instruments, as described below.

Outcome instruments should be reliable, valid, and quantifiable. Reliability refers to how reproducible the instrument is over time (assuming that

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**TABLE I. Conditions causing urethral incontinence**

Bladder Abnormalities	Sphincter Abnormalities
Detrusor overactivity	Urethral hypermobility
Detrusor instability	Intrinsic sphincter deficiency
Detrusor hyperreflexia	
Low bladder compliance	
Urinary fistula	

the underlying condition that it measures has not changed over the time interval). There are 5 measures of reliability: 1) alternate form, 2) test-retest, 3) interobserver, 4) intraobserver, and 5) internal consistency.

Alternate form reliability refers to using 2 or more different wordings of items and stems to obtain the same information about a specific domain in an instrument. The degree of agreement between the items is a measure of alternate form reliability.

Test-retest reliability measures how reproducible a response is over time. The instrument is administered 2 or more times over a time interval during which the domains of interest are not expected to change. The correlation coefficient between the responses measures test-retest reliability.

Internal consistency measures the similarity of responses among items that are intended to assess

the same variable. The degree of agreement is measured by Cronbach's coefficient alpha.

Intraobserver and interobserver reliability measure the degree of agreement between 2 or more observations of the same variable by 1 or more observers, respectively.

Validity refers to how accurately an instrument measures what it intends to measure. There are 5 means of assessing validity: 1) content validity, 2) construct validity, 3) concurrent criterion validity, 4) predictive criterion validity, and 5) face validity. Content validity is a qualitative assessment of the scope and content of the instrument and is assessed by a formal review of the instrument by a panel of experts. Construct validity, also assessed by a panel of experts, is a theoretic measure of how meaningful a survey instrument is. Concurrent criterion validity measures how well an item actually correlates with a gold standard measure of the same variable. Predictive criterion validity is a measure of how well an item is ultimately shown to predict future observations.

For history taking, the basic element of outcomes research is the questionnaire. Questionnaires consist of a series of questions, called items. Each item consists of a stem and a response. A stem may be a question or a statement. There are 3 kinds of responses: 1) categorical response, 2) Likert response, and 3) visual analog response. A categorical response consists

**TABLE II. Symptoms, signs, and conditions causing urinary incontinence**

Symptom	Condition	Medical/Surgical Causes
Urge incontinence	-Detrusor overactivity	-Idiopathic -Neurogenic -Urinary tract infection -Bladder cancer -Outlet obstruction
Stress incontinence	-Sphincter hypermobility -Intrinsic sphincter deficiency	-Pelvic floor relaxation -Prior urethral, bladder, or pelvic surgery -Neurogenic
Unaware incontinence	-Detrusor overactivity -Sphincter abnormality -Extraurethral incompetence	-Idiopathic -Neurogenic -Prior urethral, bladder, or pelvic surgery -Vesico-, uretero- or urethrovaginal fistula -Ectopic ureter
Continuous leakage	-Sphincter abnormality -Impaired contractility -Extra urethral incontinence	-Neurogenic -Prior urethral, bladder, or pelvic surgery -Ectopic ureter -Urinary/vaginal fistula
Nocturnal enuresis	-Sphincter abnormality -Detrusor, overactivity	-Idiopathic -Neurogenic -Outlet obstruction
Postvoid dribble	-Postsphincteric collection of urine	-Idiopathic -Urethral diverticulum
Extra urethral incontinence	-Vesico- or urethrovaginal fistula -Ectopic ureter	-Trauma; surgical, obstetrical, other -Congenital

## Categorical Response

How much leakage of urine do you now have?

- A. none
- B. mild
- C. moderate
- D. severe

FIGURE 1. *Categorical response.*

of choices that are mutually exclusive and collectively exhaustive (Fig. 1). A Likert response is composed of several levels of agreement or disagreement with the stem. A visual analog response uses a visual scale, such as a straight line anchored on each end by a phrase characterizing the extreme range of variability (Fig. 2). The respondent makes a mark on the line to indicate where his or her response fits on the scale.

### OUTCOMES RESEARCH IN UI

Outcomes research in UI is in its infancy; there are no validated, reproducible, well-accepted instruments for assessing even the most basic elements of efficacy. What follows is a scheme for the development of such instruments using a standardized lexicon<sup>2</sup> (Appendix I) and a standardized list of particulars for pretreatment and posttreatment data collection<sup>3</sup> (Appendix II). Instruments should assess primary and secondary measures of outcome.

Ideally, for each of the primary and secondary outcome measures, data should be collected using quantifiable subjective and objective criteria. Dis-

crepancies between the data should be reconciled as best as possible. For example, a patient may state that she is incontinent 3 times per day, but on a questionnaire she marks that she is incontinent once per day and a voiding diary and pad test show that she has not been incontinent at all. There are several methods by which these data can be reconciled. First, the patient can be confronted with the differences and a new answer negotiated. Second, the data from each instrument can be analyzed as separate data points. Finally, a visual analog scale may be used to rate the validity of the information derived from the instrument (Fig. 3) and a mathematical adjustment of the response, based on the patient's own rating of validity, can be calculated.

Primary outcome measures refer to those variables that directly assess continence and include 1) the number of incontinent episodes per unit of time, 2) the volume of urinary loss per unit of time, 3) the ease with which the incontinence can be provoked, and 4) the type of incontinence (sphincteric or detrusor). All of the primary variables can be assessed by history taking, questionnaires, diaries, and pad tests. In addition, the ease with which incontinence can be provoked and the type of incontinence can be assessed through the physical examination and during urodynamic studies.

Secondary outcome measures include factors that deal with patient satisfaction and the effect of treatment on physiology and pathophysiology. Other outcomes include the side effects and complications of treatment. Specific secondary outcome measures include 1) global assessment of patient satisfaction, 2) quality-of-life assessment, 3) symptom assessment, 4) symptom "bothersomeness" assessment, and 5)

## Visual Analogue Scale

Overall, how satisfied are you with the results of your sling surgery?

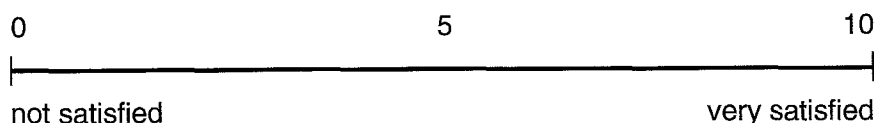


FIGURE 2. *Visual analog scale for history taking.*

## Visual Analogue Scale

On a scale of 0-10, rate this day in terms of your overall symptoms.

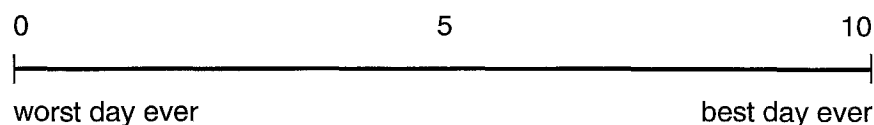


FIGURE 3. *Visual analog scale to rate validity of information.*

anatomic/functional assessment. Anatomic and functional measures include assessments of urethral hypermobility and pelvic organ prolapse as well as urodynamic variables including uroflow, postvoid residual urine, leak-point pressure, presence or absence of detrusor overactivity, detrusor pressure/uroflow, and vesical neck integrity. These can be assessed by examination, Q-tip test, urodynamic studies, and radiologic studies.

For a description of other instruments for outcome assessments in UI, the interested reader is referred to the original articles.<sup>2,3</sup>

## CONCLUSIONS

At the present time, there are no validated, reproducible, well-accepted efficacy instruments for assessing treatment outcomes in UI. Further work directed toward the development of such instruments is warranted.

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## APPENDIX I. DEFINITION AND CLASSIFICATION OF URINARY INCONTINENCE

(Modified from Blaivas et al.<sup>2</sup>)

### URINARY INCONTINENCE IS THE INVOLUNTARY LOSS OF URINE

It denotes a symptom, a sign, and a condition. The symptom is the patient's (or caregiver's) statement of involuntary urine loss. The sign is the objective demonstration of urine loss, and the condition is the pathophysiology underlying incontinence as demonstrated by clinical or urodynamic techniques.

### CONDITIONS CAUSING URINARY INCONTINENCE

Conditions may be presumed or definite. Definite conditions are documented by urodynamic techniques. Presumed conditions are documented clinically, by history or examination. When reporting results, it should be clearly stated whether the conditions causing urinary incontinence were definite or presumed. The technique by which the condition is documented should always be specified.

### BLADDER ABNORMALITIES CAUSING URINARY INCONTINENCE

*Detrusor Overactivity.* Detrusor overactivity is a generic term for involuntary detrusor contractions. This term should be used when the etiology of the involuntary detrusor contractions is unclear.

*Detrusor Instability.* This denotes involuntary detrusor contractions that are not due to neurologic disorders.

*Detrusor Hyperreflexia.* This denotes involuntary detrusor contractions that are due to neurologic conditions.

*Low Bladder Compliance.* Low bladder compliance denotes an abnormal (decreased) tonic volume/pressure relationship during bladder filling.

### SPHINCTER ABNORMALITIES CAUSING URINARY INCONTINENCE

There are 2 generic types of sphincter abnormalities—urethral hypermobility and intrinsic sphincter deficiency. The 2 conditions may coexist.

*Urethral Hypermobility.* In urethral hypermobility, the basic abnormality is a weakness of the pelvic floor. During increases in abdominal pressure there is a descent of the vesical neck and proximal urethra. If the urethra opens concomitantly, stress urinary incontinence ensues. Urethral hypermobility is often present in women who are not incontinent. Thus, the mere presence of urethral hypermobility is not sufficient to make a diagnosis of a sphincter abnormality unless incontinence is also demonstrated.

*Intrinsic Sphincteric Deficiency.* This denotes an intrinsic malfunction of the urethral sphincter itself.

### OVERFLOW INCONTINENCE

Overflow incontinence is leakage of urine associated with incomplete bladder emptying due to either impaired detrusor contractility or bladder outlet obstruction.

### EXTRAURETHRAL INCONTINENCE

This denotes leakage of urine from a source other than the urethra. It may be due to urinary fistula or ectopic ureter.

### SIGNS AND SYMPTOMS OF INCONTINENCE

*Urge Incontinence.* The symptom urge incontinence is the complaint of the involuntary loss of urine associated with a sudden, strong desire to void (urgency). The sign is the observation of involuntary urinary loss from the urethra synchronous with an uncontrollable urge to void. The condition urge incontinence is due to detrusor overactivity.

*Stress Incontinence.* The symptom stress incontinence is the complaint of involuntary loss of urine during coughing, sneezing, or physical exertion, such as sport activities, sudden changes of position, etc. The sign is the observation of loss of urine from the urethra synchronous with coughing, sneezing, or physical exertion. The condition is due to sphincter abnormalities.

*Unconscious (Unaware) Incontinence.* The symptom unconscious incontinence is the involuntary loss of urine that is unaccompanied by either urge or stress. The patient may be aware of the incontinent episode by feeling wetness. The sign is the observation of loss of urine without patient awareness of urge or stress. The condition may be caused by detrusor overactivity, sphincter abnormalities, overflow, or extraurethral incontinence.

*Continuous Leakage.* The symptom continuous leakage is the complaint of a continuous involuntary loss of urine. The sign is the observation of a continuous urinary loss. The condition may be caused by sphincter abnormalities or extraurethral incontinence.

*Nocturnal Enuresis.* The symptom nocturnal enuresis is the complaint of urinary loss that occurs only during sleep. The condition may be caused by a sphincter abnormality, detrusor overactivity, or extraurethral incontinence.

*Postvoid Dribble.* The symptom postvoid dribble is the complaint of a dribbling loss of urine that occurs after voiding. The sign postvoid dribble is the complaint of a dribbling loss of urine that occurs after voiding. The condition underlying postvoid dribble has not been adequately defined, but is thought to be due to retained urine in the urethra distal to the sphincter in men. In women it may be caused by retained urine in the vagina or in a urethral diverticula.

## APPENDIX II. STANDARDS OF EFFICACY FOR EVALUATION AND MANAGEMENT OF TREATMENT OUTCOMES IN URINARY INCONTINENCE

(Modified from Blaivas et al.<sup>3</sup>)

### GENERAL CONSIDERATIONS

At each posttreatment interval, the following data should be recorded:

- The total number of patients treated during that time interval,
- The total number of patients actually evaluated during that time interval,
- The total number of patients lost to follow-up during that time interval, and
- The reasons why patients were lost to follow-up.

### PRETREATMENT EVALUATION SHOULD CONSIST OF

1. Structured micturition history or questionnaire including at least:
  - Number of micturitions/day,
  - Number of micturitions/night,
  - Number of incontinent episodes/day,
  - Number of incontinent episodes/night,
  - Type of incontinence (stress, urge, unconscious, continuous leakage), and
  - Description of voiding (emptying) symptoms.
2. Structured physical examination with full bladder including at least:
  - a. Neurourologic exam:
    - Perianal sensation,
    - Anal sphincter tone and control,
    - Bulbocavernosus reflex, and
    - Brief screening neurologic exam to discriminate normal, paraplegic, quadriplegic, hemiplegic, dementia, etc.
  - b. (Women) vaginal exam:
    - 1) Demonstration of urinary leakage
      - Spontaneous/continuous
      - Synchronous with stress
      - After stress
    - 2) Presence and degree of:
      - Cystocele
      - Urethrocele

- Uterine prolapse
  - Enterocele
  - Rectocele
- c. (Men) prostate exam:
- Size and consistency of prostate
  - Demonstration of urinary leakage
    - Continuous
    - Synchronous with stress
    - After stress

3. Micturition diary—self-reported by patient
  - Time of micturition
  - Time and type of incontinence
  - Voided volume
4. Pad test—A quantitative or semiquantitative pad test should be done to estimate the amount of urinary loss.
5. Urodynamics—Videourodynamics is the most comprehensive method of evaluation. The minimum evaluation should consist of:
  - Cystometry (liquid) with simultaneous measurement of vesical and abdominal pressure for determination of detrusor pressure,
  - Synchronous detrusor pressure/uroflow study,
  - Simple uroflow,
  - Assessment of the relative contribution of urethral hypermobility and intrinsic sphincter deficiency, such as the Q-tip test and leak-point pressure, and
  - Estimation of postvoid residual urine, eg, by ultrasound or catheterization.

### POSTTREATMENT EVALUATION

1. Structured micturition history or questionnaire at each follow-up.
2. Structured physical examination with full bladder at least once during follow-up.
3. Micturition diary at each follow-up.
4. Pad test at each follow-up.
5. Uroflow at least once during follow-up.
6. Estimation of postvoid residual urine at least once during follow-up.
7. Other urodynamic techniques are optional.

## Appendix III

Patient's Name: \_\_\_\_\_ Date: \_\_\_\_\_

# Female Bladder Questionnaire

1) On average, how often do you urinate from the time you awake until the time you go to bed?

- more than once an hour
- every hour
- every 2 hours
- every 3 hours
- every 4 hours
- more than every 4 hours

2) On average, what is the longest time you go without urinating during the day?

- about 1 hour
- about 2 hours
- about 3 hours
- about 4 hours
- more than 4 hours

3) On a scale of 0-10 (0 is not at all, 10 is intolerable), how badly does the frequency of urination bother you?

0 1 2 3 4 5 6 7 8 9 10

4) What is the main reason you urinate as often as you do?

- normal feelings you have to urinate
- because it hurts too much
- because you are afraid you may lose control
- out of convenience

5) On average, how many times are you awakened from sleep because you have to urinate?

- never or rarely
- about every 1-2 hours
- about every 2-3 hours
- about every 3-4 hours
- about every 5 hours
- after 5 or more hours

5a) On average, how many hours do you sleep at night?

- less than 4 hours
- 4-6 hours
- 6-8 hours
- 8-10 hours
- greater than 10 hours

6) On a scale of 0-10 (0 is not at all, 10 is intolerable), how badly does waking up to urinate bother you?

0 1 2 3 4 5 6 7 8 9 10

7) How often do you have difficulty holding your urine and have to rush to the toilet because you are afraid you might wet yourself (urgency)?

- never or rarely
- sometimes but not every day
- most days
- 1-2 episodes daily
- 3-4 episodes daily
- 5-6 episodes daily
- more than 6 episodes daily

Continued on next page

8) On a scale of 0-10 (0 is not at all, 10 is intolerable), how badly does the urgency of urination bother you?

0 1 2 3 4 5 6 7 8 9 10

9) How often do you lose control of urination and wet yourself or your pads (incontinence)?

- never or rarely
- sometimes, but not every day
- most days
- 1-2 episodes daily
- 3-4 episodes daily
- 5-6 episodes daily
- more than 6 episodes daily

10) How often do you lose control of urination and wet yourself because you get a sudden urge to urinate (urge incontinence)?

- never or rarely
- sometimes, but not every day
- most days
- 1-2 episodes daily
- 3-4 episodes daily
- 5-6 episodes daily
- more than 6 episodes daily

11) On a scale of 0-10 (0 is not at all, 10 is intolerable), how badly does your urge incontinence bother you?

0 1 2 3 4 5 6 7 8 9 10

12) How often do you find yourself or your pads wet without any awareness of how it happened?

- never or rarely
- sometimes, but not every day
- most days
- 1-2 episodes daily
- 3-4 episodes daily
- 5-6 episodes daily
- more than 6 episodes daily

13) How often do you lose control and wet yourself when you cough, sneeze, laugh, strain, change position, or exercise (stress incontinence)?

- never or rarely
- sometimes, but not every day
- most days
- 1-2 episodes daily
- 3-4 episodes daily
- 5-6 episodes daily
- more than 6 episodes daily

14) On a scale of 0-10 (0 is not at all, 10 is intolerable), how badly does your stress incontinence bother you?

0 1 2 3 4 5 6 7 8 9 10

15) Does your urine loss occur only when you cough, laugh, strain, change position, or exercise?

- YES
- NO

16) How often do you wear pads or other form of protection (such as paper towels or tissue) because of the loss of urinary control?

- never or rarely
- sometimes but not every day
- most days
- daily
- only at night

17) How wet are your pads or other forms of protection when you change them?

- moist or damp
- clearly wet
- soaked through
- not applicable

Continued on next page



18) On average, how many pads do you use a day?

0 1 2 3 4 5 6 7 8 9 10

19) If you do not wear pads, how wet are you when you lose urine?

- few drops
- would have to change underwear
- not applicable
- would have to change outerwear

20) On a scale of 0-10 (0 is not at all, 10 is intolerable), how badly does the loss of urinary control bother you?

0 1 2 3 4 5 6 7 8 9 10

21) How often must you push or strain to start urination?

- never
- few times per year
- few times per month
- few times per week
- daily

22) How would you describe the force of the stream?

- strong
- not as strong as it used to be
- weak
- interrupted
- dribbling

23) How often do you feel that you have not emptied your bladder after urinating?

- never
- few times per year
- few times per month
- few times per week
- daily