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#### Review

## A generic health-related quality of life instrument, the Medical Outcomes Study Short Form-36, in women with urinary incontinence

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#### Abstract

The paper reviews the literature concerning health-related quality of life in women with urinary incontinence by using the Medical Outcomes Study Short Form (SF-36). The aim of this study was to determine the role of the SF-36 in the evaluation of urinary incontinence. Although some information regarding factors associated with health-related quality of life in women with urinary incontinence is currently available, this issue remains controversial since these factors had not been consistently found to have effects on quality of life. The scales of the SF-36 questionnaire have poor content validity for urinary incontinence, multidimensionality with difficulty of interpretation of any changes, and limited sensitivity to small changes in symptoms. The problem with using the SF-36 is that results are often insensitive to the specific condition measured and therefore fail to address many of the issues relevant to the disease. As a result, disease-specific instruments may be more beneficial in evaluating the impact of a specific urinary incontinence on quality of life and are more sensitive than their generic counterparts in detecting changes as a result of treatment. Since generic quality of life may be more susceptible to other factors such as comorbid diseases than disease severity and reflect a wider aspect of daily life, these factors should also be evaluated in future studies.

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Keywords: Urinary incontinence; Quality of life; Questionnaires; Women; SF-36

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#### 1. Introduction

Urinary incontinence, defined by the International Continence Society as 'a complaint of any involuntary leakage of urine' [1], is a common problem affecting around 20–30% of the adult population [2,3]. Although urinary incontinence is not life-threatening, loss of urinary control can affect the social, psychological, domestic, occupational, physical and sexual aspects of patients' lives [2]. Assessment of the severity of incontinence symptoms has been the main indicator used to understand the burden of the patient's condition, but it is now recognized that a patient's psychosocial adjustment to illness is as important as the status of the physical disease itself. However, it is difficult to appreciate the extent of disruption in the patient's daily lives that the troublesome symptoms of urinary incontinence can cause.

Several disease-specific quality of life instruments have been developed to provide detailed information on how urinary incontinence affects patients' lives. However, probably, the most important limitation is the lack of a generally accepted questionnaire for the assessment of urinary incontinence. The variety of instruments and their core content make results difficult to compare, evaluations unpredictable and conclusions sometimes contradictory.

The Medical Outcomes Study Short Form (SF-36), a generic health outcome-measuring instrument was developed to survey health status [4]. It consisted of 36 questions grouped into 8 dimensions:

(1) 'physical function' (PF; 10 items);

- (2) 'role limitations due to physical health problems' (RP; 4 items);
- (3) 'bodily pain' (BP; 2 items);
- (4) 'general health perception' (GH; 6 items);
- (5) 'energy and vitality' (VT; 4 items);
- (6) 'social function' (SF; 2 items);
- (7) 'role limitations due to emotional problems' (RE; 3 items);
- (8) 'mental health' (MH; 5 items).

The number of questions directed to each health concept ranged from 2 to 10, and the number of response options per question ranged from 2 (no or yes) to 6 (none, very mild, mild, moderate, severe, or very severe). Each of the dimension scores was expressed as a value between 0 and 100, with higher scores representing better health. The eight domains are collapsed to create two global components, a physical component score (PCS) and a mental component score (MCS). Scores on the PCS are associated with high scores on the PF, RP, BP and GH scales and low scores on the RE and MH scales. Conversely, for the MCS, positive weights are placed on the MH, RE, SF and VT scales, whereas substantial negative ones are placed on the PF and RP scales. Experience to date suggests that the SF-36 can be adapted for use in other countries with relatively minor changes to the content of the form, providing support for the use of these translations in multinational clinical trials and other studies [5]. We assessed the literature concerning health-related quality of life in women with urinary incontinence by using the SF-36 (Table 1) [6-21].

Table 1 Studies using the short form-36

First author/reference	Study design	Number of patients (n)	Age of patients in years
Sand [6]	Randomized, double-blinded,	Pelvic floor electrical stimulation	Pelvic floor electrical stimulation
	placebo-controlled, longitudinal	35, sham 17	$50.9 \pm 9.8$ , sham $57.7 \pm 13.3$
Johannesson [7]	Cross-sectional	461 <sup>b</sup>	$61.1 \pm 14$
Schlenk [8]	Cross-sectional	30	$76.9 \pm 8.1$
Sand [9]	Longitudinal	63	55 (35–75)
Jeyaseelan [10]	Randomized, double-blinded,	Pelvic floor electrical stimulation	Not available
	placebo-controlled, longitudinal	12, sham 12	
Hagglund [11]	Cross-sectional, population-based	Stress incontinence 440, urge	18–72
		incontinence 71	
Ward [12]	Randomized, longitudinal	Colposuspension 169, TVT 175	Colposuspension 50 (45–59) <sup>a</sup> ,
			TVT 50 (42–56) <sup>a</sup>
Hagen [13]	Cross-sectional (validation study)	Community 79, clinic 75, surgery 83	Community $76 \pm 12$ , clinic $50 \pm 14$ , surgery $50 \pm 12$
Stewart [14]	Cross-sectional, nation-wide	2735	≥18
Ho-Yin [15]	Cross-sectional	Stress incontinence 94, urge	Stress incontinence 47 (42–55) <sup>a</sup> ,
		incontinence 76	urge incontinence 84 (42-67) <sup>a</sup>
Margalith [16]	Cross-sectional	131	$49 \pm 8.8 \ (22-65)$
Hagglund [17]	Longitudinal, population-based	118	22–50
Corcos [18]	Randomized, longitudinal	Surgery 54, collagen injection 64	Surgery 58.2, collagen injection 57.6
Clyne [19]	Longitudinal	72	46.1 (17–63)
Bjelic-Radisic [20]	Longitudinal (validation study)	Physiotherapy 37, TVT 108	$58.1 \pm 12.2$
Araki [21]	Cross-sectional, nation-wide	3734	$35.2 \pm 10.8 \; (20-64)$

TVT: tension-free vaginal tape.

<sup>&</sup>lt;sup>a</sup> Data presented are median (interquartile ranges).

b Proportion of women: 95%.

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