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Patient Characteristics Impacting Health State Index Scores, Measured by the EQ-5D of Females with Stress Urinary Incontinence Symptoms

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ABSTRACT _

Objective: To describe the characteristics of women seeking treatment for symptoms of stress urinary incontinence (SUI) and to investigate the association of SUI symptoms with generic health-related quality of life (HRQoL) as measured by the EuroQol (EQ-5D) instrument.

Methods: The Stress Urinary Incontinence Treatment (SUIT) study was a 12-month observational study in four European countries that evaluated the cost-effectiveness of duloxetine compared with other forms of nonsurgical intervention in the treatment of the symptoms of SUI. Four hundred thirty-one physicians observed women seeking treatment for their SUI, and recorded the care provided and the outcomes of that care at enrollment and at 3, 6 and 12 months afterward The impact of SUI on baseline HRQoL as expressed by the EQ-5D index score was assessed by linear and logistic regression.

Results: Three thousand seven hundred sixty-two women were enrolled into SUIT, with the largest patient group from Germany. Overall, the

majority of women were postmenopausal, had a mean age of 58.0 years, were not current smokers, and tended to be overweight (mean body mass index [BMI] = 27.7 kg/m²), with at least one comorbidity. The health state index scores were significantly and independently influenced by the presence of comorbidity(ies) affecting quality of life, total number of stress and urge incontinence episodes, urinary incontinence subtype, comorbidity(ies) affecting incontinence, BMI, socioeconomic status, educational status, age, and country.

Conclusion: This article describes the characteristics of patients at the SUIT enrollment visit, and demonstrates that the number of incontinence episodes has a significant impact on the EQ-5D index score.

Keywords: EQ-5D, outcomes research, patient-reported outcomes, women's health.

Introduction

Urinary incontinence (UI), or the "involuntary leakage of urine" [1], affects between 10% and 60% of women worldwide [2–6] and can be categorized as either stress UI (SUI), which is the involuntary leakage of urine upon exertion, sneezing or coughing; or urge UI (UUI), which is the involuntary leakage of urine accompanied by, or immediately preceded by, urgency. Both symptoms are present in women with mixed UI (MUI) [1]. Pure SUI accounts for approximately half of all UI in adult women [2,3,5].

Initial management of SUI is recommended in general practice using conservative treatments, including lifestyle interventions and pelvic floor muscle training [7]. The prospective urinary incontinence research (PURE) study [8] was the first European study to investigate the economic and self-assessed impact of UI. The PURE baseline data showed that many women with symptoms of SUI were receiving off-label medications, including anticholinergics, tricyclic antidepressants, and estrogens, or no pharmaceutical treatment at all [9]. These drugs show limited evidence of efficacy in SUI, and some have significant side effects [10]. Duloxetine is the first drug approved in Europe to

treat women with moderate to severe SUI. The safety and efficacy of duloxetine were globally assessed in large randomized clinical trials [11–15].

Economic considerations are increasingly important in health-care decision-making [16]. The Stress Urinary Incontinence Treatment (SUIT) study, a 12-month observational study undertaken in four European countries, was designed with the primary objective of evaluating the "real-life" cost-effectiveness of duloxetine compared with other forms of nonsurgical intervention.

The primary effectiveness measure to be used in this costeffectiveness evaluation is the quality adjusted life year (QALY). A QALY can be calculated from a health-related quality of life (HRQoL) index score ("utilities") derived from patients' responses to the EuroQol (EQ-5D) instrument [17].

This article presents baseline data describing the characteristics of the patients enrolled in the SUIT study, as well as an analysis undertaken to investigate the association between baseline patient characteristics and EQ-5D index scores. In particular, the association between the severity of UI symptoms and the EQ-5D index score is of interest to establish that this HRQoL measure is sensitive to changes in the severity of incontinence symptoms.

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Methods

Study Design

SUIT was a longitudinal, observational, multicenter, 12-month study conducted in Germany, the UK, Sweden, and Ireland to

evaluate the cost-effectiveness of duloxetine compared with other forms of nonsurgical intervention in the outpatient treatment of the symptoms of SUI in females. The outcomes and direct costs associated with any medical treatment of SUI were secondary objectives.

Women aged 18 years or over were eligible if they: 1) were suffering from SUI symptoms (with or without urge symptoms) according to the clinical opinion of the investigator; 2) presented during the normal course of care; 3) had been under treatment or were seeking treatment for SUI, and 4) initiated or changed (i.e., switched or added on) SUI treatment at the time of the enrollment visit.

The questionnaires were in local languages, in which participants had to be competent. Participants were excluded if they were pregnant or had been in the preceding 6 months, were concurrently participating in another study that included an investigational drug or procedure, or were awaiting surgery for SUI. To ensure a representative sample of treatment-seeking women was enrolled, the participants were identified during the course of a routinely occurring visit. The initiation or change of SUI treatment was at the investigator's discretion during the normal course of care, and enrollment only took place after the decision to initiate or change treatment had been made.

The study was approved by the local ethics committees and/or review boards of each participating center. A written informed consent was obtained from each patient and from each investigator.

Data Collection

The care provided and outcomes of that care were recorded at enrollment, and 3, 6 and 12 months afterward. The data recorded at the first observation included demographic characteristics, medical and UI history, and 12 months of retrospective data on health-care resource utilization for SUI treatment.

The impact of SUI on HRQoL was assessed using the EQ-5D instrument [17], which is composed of five domains of health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), each rated by the patient on a three-point scale: "no problems," "some/moderate problems," and "extreme problems." Complete sets of five responses generated up to 243 possible sequences, each mapped to a health state index ("utility") to provide a summary value across all domains where the scale runs from 0 (equivalent to death) to 1 (equivalent to full health). Negative values were possible [17]. EQ-5D has been validated in 36 official languages. For the purposes of this study, an EQ-5D index based on an algorithm derived using time trade-off values from a sample of the UK public was employed [17,18] and compared with UK population norms [19].

Incontinence episode frequencies were captured using the two-item stress and urge incontinence questionnaire (S/UIQ) [20], which relies on a recall of the number of UI episodes experienced during the preceding week. Women were classified into relevant UI subtype groups according to the S/UIQ answers: "stress episodes and no urge episodes" was classified as pure SUI, "urge episodes and no stress episodes" as pure UUI, and "1 or more stress episodes and 1 or more urge episodes" as MUI. Patients with two zeroes (indicating no stress or urge episodes) or missing data for either question (133 patients, or 3.6% of the total) were excluded from the analyses.

All study documents were prepared in English and translated into the local country languages, with back translation to ensure homogeneity, and validation by native-speaking local clinical experts. Patient questionnaires were provided in each relevant, officially available language version from the EQ-5D group [21]

and the Medical Outcomes Trust [22]. Key data fields in the data collection forms (DCFs) were checked for completeness, and data were then forwarded for entry into the electronic study database.

Analysis

A statistical analysis plan and rules for handling incomplete and implausible data were finalized before database lock. All analyses were conducted in SAS® 8.2 (SAS Institute Inc, Cary, NC). An "enrolled" patient was one who was entered into the study and provided DCFs for entry into the database, and patients were "eligible for analysis" if their DCF showed that they fulfilled the inclusion criteria.

Categorical data were summarized by counts and percentages, and continuous variables by means, standard deviations, medians, minima and maxima, lower and upper quartiles, and 95% confidence limits as appropriate.

The baseline characteristics and EQ-5D index scores of enrolled patients are presented by country in Tables 1 to 4 and compared using analysis of variance for continuous variables and Fisher's exact tests for binary variables. Because of the observational nature of this study, it is probable that there were many confounding factors leading to the differences observed between the countries so the results of the statistical tests should be interpreted with caution.

The EQ-5D index scores showed a non-normal distribution, with 35% of the patients having a perfect score of 1. Although the mean and median scores were similar, the distribution had a long tail toward the lower values, although at the upper end of the distribution, a large percentage of perfect scores was observed. Hence, a multivariate logistic regression was performed, with a binary dependent variable of whether an EQ-5D index score of 1 or less than 1 was recorded, and all demographic characteristics, disease severity, and medical history variables collected at the baseline observation as the independent variables in the full model. The effect of removing variables was investigated using backward elimination methods until a reduced model containing only statistically significantly ($P \le 0.05$) independent variables was obtained. Correlations between pairs of independent variables were calculated to test for collinearity.

To test the sensitivity of the results to the choice of analysis method and to the statistical distribution of the EQ-5D index scores, a multivariate linear regression was also performed using the actual EQ-5D health state index scores (rather than the binary dependent variable) and the same set of independent variables as for the logistic regression.

Results

Demographic and Clinical Characteristics

A total of 3762 women were enrolled in the study between April 7, 2005 and February 28, 2006 in Germany, Ireland, Sweden, and the UK. Four hundred thirty-one investigating physicians participated, including primary care physicians (PCPs), gynecologists, urologists, and geriatricians/others. Eighty-two percent of the investigators in Germany and 69% in Sweden were gynecologists, whereas all of the investigators in Ireland and 98% in the UK were PCPs. Germany was the only country where urologists participated, accounting for 15% of the German investigators.

A total of 3739 women were eligible for analysis (over 99% of the enrolled number). The patients' baseline characteristics are presented in Table 1. Two-thirds of the women were postmenopausal. The differences in the level of education between the countries are evident: most participating women from Germany, Ireland, and the UK were not educated above the local

Table I Baseline demographics and medical history of participating women by country

	All	Germany	Ireland	Sweden	UK	P-value*
Number of patients entered	3762	2605	601	480	568	
Number of patients available for analysis	3739	2597	801	471	563	
	58.0/58.0 (20.0-99.0)	58.5/59.0 (20.0-99.0)	55.4/54.0 (27.0-87.0)	57.6/58.0 (25.0-85.0)	56.6/57.0 (22.0-89.0)	P = 0.002
↓(%) t	55.3	55.3	78.7	32.9	0.89	P < 0.0001
Postmenopausal (%)	69.5	71.5	1.19	64.3	1.99	P = 0.001
Patients participating in workforce (%)‡	39.3	36.9	33.3	51.9	41.1	P < 0.0001
Mean BMI (SD) (in kg/m²)	27.7 (5.2)	27.5 (4.8)	28.4 (6.6)	26.7 (4.7)	29.7 (6.5)	P < 0.0001
Current smoker (%)	15.2	13.5	23.1	17.0	20.2	P < 0.0001
Smoked in the past (%)	38.5	32.6	38.0	56.5	51.8	P < 0.0001
Mean number of children given birth to (SD)	2.2 (1.2)	2.1 (1.2)	2.8 (2.1)	2.3 (1.1)	2.4 (1.3)	P < 0.0001
Mean number of children given vaginal birth to for those with one or more children (SD)	2.2 (1.2)	2.1 (1.1)	3.2 (1.8)	2.3 (1.0)	2.4 (1.3)	P < 0.0001
Patients with any concurrent medical conditions (%)§	72.8	75.3	62.0	60.3	74.1	P < 0.0001
Patients diagnosed with urinary tract infection twice or more in the last year (%)	19.5	22.8	21.3	8.9	13.0	P < 0.0001
Patients who had a hysterectomy (%)	29.2	32.4	16.7	13.6	29.5	P < 0.0001
Patients with constipation (%)	13.0	13.3	16.7	8.6	13.5	P = 0.094
Patients with pelvic organ prolapse (%)	6.11	13.9	2.8	5.1	0.01	P < 0.0001
Patients with obstructive lung disease or persistent cough (%)	8.2	6.2	10.2	13.0	13.0	P < 0.0001
Patients with diabetes (%)	0.01	9.11	6.5	7.4	5.9	P < 0.0001
Patients with depression (%)	4.	8.6	12.0	9.3	20.7	P < 0.0001
Patients with hypertension (%)	32.6	35.1	21.3	24.2	30.4	P < 0.0001
Patients with the baseline visit being their first consultation for SUI symptoms (%)	42.2	42.5	32.4	42.0	42.3	P = 0.221

*Analysis of variance for continuous variables (e.g., age, BMI), Fisher's exact tests for binary variables (e.g., level of education, smoking) removing "unknown" responses.

†As opposed to further education and university education.

†Part- or full-time employed as opposed to student, housewife, retired, and unemployed.

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Parties are not the note ocnocomination medical condition from the following list urinary tract infection, constipation, pelvic organ prolapse, obstructive lung disease or persistent cough, hysterectomy, neurological disorder that affects the lower urinary tract.

BMI, body mass index, SUI, stress urinary incontinence.

Table 2 Proportions of urinary incontinence (UI) symptoms and ongoing treatment by country

	All	Germany	Ireland	Sweden	UK	P-value*
Type of UI by symptoms (%) [†]						
SUI	37.2	35.7	31.4	51.7	33.3	
MUI	61.5	63.I	68.6	47.0	64.4	P < 0.0001
Patients with any ongoing medication for SUI symptoms (%)	18.0	18.2	25.9	21.2	13.0	P < 0.001
Patients with any ongoing conservative treatment for SUI symptoms (%) [‡]	36.I	31.6	35.5	54.8	41.2	P < 0.000 I

^{*}Fisher's exact tests removing UUI responses for type of UI

Table 3 Leakage episodes by country and UI type by S/UIQ

	Distribution of leakage episode frequency					
	S/UIQ stress	S/UIQ urge				
Country	Mean (SD) IEF/week	Mean (SD) IEF/weel				
Germany						
SUI	12.8 (13.9)	_				
MUI	16.8 (14.1)	8.0 (9.3)				
All*	15.0 (14.2)	5.1 (8.5)				
UK	• •	, ,				
SUI	10.2 (12.8)	_				
MUI	15.4 (16.1)	7.8 (9.4)				
All	13.1 (15.2)	5.0 (8.4)				
Ireland	` ,	` '				
SUI	7.3 (13.5)	_				
MUI	9.7 (10.0)	6.7 (8.8)				
All	8.8 (11.2)	4.5 (7.9)				
Sweden	, ,	, ,				
SUI	11.4 (14.3)	_				
MUI	14.5 (16.1)	6.8 (8.2)				
All	12.3 (15.1)	3.2 (6.6)				
P-value [†]	P < 0.000 Í	P < 0.0001				

^{*&}quot;All" includes patients classified as UUI.

mandatory level, although in Sweden, two-thirds of the participants had a further or university education. A few of the women were current smokers, although more than half of the patients in Sweden and the UK had smoked in the past. The SUIT participants tended to be overweight, with a mean body mass index of 27.7 kg/m². Most of the patients had at least one concurrent medical condition, most commonly hypertension. For most of the women, the first observation in SUIT was not their first consultation for UI. MUI was more common than SUI (Table 2) in all countries except Sweden where SUI was more common. Most women were not receiving ongoing drug therapy for SUI symptoms at baseline; conservative treatment for SUI symptoms was more common in all countries, particularly in Sweden.

Differences in the frequency of the stress leakage episodes were noted between SUI and MUI in all four countries (Table 3) with women with SUI having fewer episodes per week than women with MUI. The women in Ireland typically experienced fewer stress leakage episodes per week for both SUI and MUI than women in the other three countries.

EQ-5D

Of the five domains of the EQ-5D health state profile, the patients' pain/discomfort was most affected, although their self-care was least affected (Fig. 1). The patients' EQ-5D index scores are shown in Table 4.

The final logistic regression model for the health score index included 3346 (89%) patients with complete data and had a

Hosmer and Lemeshow goodness of fit chi-square statistic of 5.443 (8 df, P = 0.709), suggesting an adequate fit of the model to the data. The single variable with the most missing data was the UI subtype, with data missing for 3.6% of patients. Age and socioeconomic status were the most strongly correlated pair of independent variables (r = 0.54), with older patients less likely to be participating in the workforce and also more likely to have comorbidities (r = 0.24 for comorbidities affecting incontinence and r = 0.31 for those affecting QOL). Previous surgery for UI was also correlated with having comorbidities affecting incontinence (r = 0.24), as were being in the workforce and having a further/university education (r = 0.27). All of these variables were still included in the full model.

The variables statistically significantly associated with the EQ-5D index score included in the final model are shown in Table 5. Each additional stress and urge episode per week was associated with a decrease in the odds of having an EQ-5D index score of 1 of 0.986, although each comorbidity affecting HRQoL was associated with a reduction in the odds of having a perfect EQ-5D index score by a factor of 0.524. Each comorbidity affecting incontinence was associated with a reduction in the odds of having a perfect EQ-5D index score by a factor of 0.726. There appeared to be a relationship between better health state and socioeconomic status, and a higher health status among women with SUI only. The effect of country is also significant. The estimates reflect the observed differences between the countries in the raw data for EQ-5D health state score.

Among the independent variables included in the linear regression model with 3381 patients (90%), their relative importance and the direction of the effect estimates were very similar to those found in the logistic regression, indicating that the models

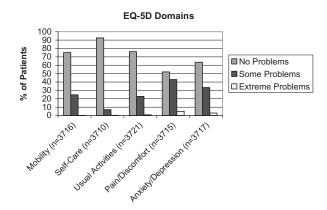


Figure I EQ-5D five domain descriptions for all countries (pooled).

[†]Type by S/UIQ.

[‡]Includes lifestyle interventions, bladder diary, all forms of pelvic floor exercises.

MUI, mixed urinary incontinence; S/UIQ, stress and urge incontinence questionnaire; SUI, stress urinary incontinence; UUI, urge urinary incontinence.

[†]Analysis of variance between countries, all UI types.

IEF, incontinence episode frequencies; MUI, mixed urinary incontinence; S/UIQ, stress and urge incontinence questionnaire; SUI, stress urinary incontinence; UI, urinary incontinence.

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Table 4 EQ-5D index

	Mean (SD) HSI	Median HSI	N	P-value*
Country				P < 0.000 I
Germany	0.80 (0.22)	0.80	2557	
Ireland	0.89 (0.15)	1.00	107	
Sweden	0.80 (0.23)	0.80	466	
UK	0.73 (0.29)	0.80	553	
Total IEF	` ,			P < 0.000 I
7 per week or less	0.86 (0.18)	0.85	996	
7 to 13 per week	0.81 (0.21)	0.80	760	
14 per week or more	0.74 (0.26)	0.80	1856	
Socioeconomic status	` ,			P < 0.000 I
In workforce	0.85 (0.19)	0.85	1449	
Other	0.75 (0.25)	0.80	2230	
Comorbidity affecting HRQoL	` ,			P < 0.000 I
No	0.86 (0.19)	0.85	1510	
Yes	0.74 (0.25)	0.80	2104	
Comorbidity affecting UI	` '			P < 0.0001
No	0.82 (0.22)	0.85	1984	
Yes	0.75 (0.25)	0.80	1651	
Previous surgery	,			P = 0.012
No	0.79 (0.24)	0.80	3287	
Yes	0.76 (0.24)	0.80	380	
UI subtype	` '			P < 0.000 I
Mixed SUI/UUI	0.75 (0.25)	0.80	2181	
Pure SUI	0.85 (0.20)	0.85	1325	
Pure UUI	0.81 (0.18)	0.80	49	

^{*}Analysis of variance.

HRQoL, health-related quality of life; HSI, Health State Index; IEF, incontinence episode frequencies; SUI, stress urinary incontinence; UI, urinary incontinence; UI, urinary incontinence; UII, urinary incontinence urinary incontinence.

are fairly robust to the deviation of the health state index score from the normal distribution.

Discussion

The aim of this article is to present the baseline characteristics of patients enrolled in the SUIT study and to describe the association of these characteristics with EQ-5D index scores. In particular, it was important to understand the association of the severity of incontinence symptoms with EQ-5D index score before performing the planned economic evaluation using the longitudinal study data.

The logistic regression analysis of the association between the patients' baseline characteristics and the patients' EQ-5D index scores showed that the scores declined with increased frequency of incontinence episodes. With each additional weekly stress or urge episode, there was a decrease in the odds of having an index

score of 1 of 0.986. Thus, an increase of one incontinence episode per day would decrease the odds of a perfect health state score by 0.908 times. This is consistent with other studies that have shown increasing severity of incontinence to be negatively correlated with quality of life [23,24]. The analysis also showed that the subtype of UI was important, with MUI impacting more greatly on the EQ-5D index score than SUI. This is also consistent with the results from other studies [23,24].

The EQ-5D index scores declined with the presence of comorbidities that affect HRQoL and UI. Each comorbidity affecting HRQoL was associated with a reduction in the odds of having a score of 1 of 0.524, although each comorbidity directly affecting incontinence was associated with a smaller reduction by a factor of 0.726.

The relationship between incontinence and significant comorbidity, and their adverse effect upon HRQoL, is likely to be complex. Some of the conditions we defined as having an effect

Table 5 Adjusted odds ratios for EQ-5D index (in order of strength of association of variables—multivariate logistic regression)

	Adjusted [†] odds ratios with 95% CI			Wald chi-square	
Variable*	Estimate	95%	6 CI	value	P-value
Comorbidity(ies) affecting HRQoL (reference: none)	0.524	0.446	0.614	62.9	P < 0.000
Total number of stress & urge episodes	0.986	0.981	0.991	30.3	P < 0.000
Pure SUI (reference mixed SUI/UUI)	1.563	1.326	1.841	29.7	P < 0.000
Comorbidity(ies) affecting incontinence (reference: none)	0.726	0.620	0.851	15.6	P < 0.000
BMI (kg/m²)	0.972	0.957	0.988	12.1	P < 0.001
Participating in the workforce (reference: Socioeconomic status other)	1.341	1.115	1.614	9.7	P = 0.002
Further/university education (reference: no/mandatory education)	0.830	0.705	0.977	5.0	P = 0.025
Age (years)	0.992	0.985	1.000	4.4	P = 0.036
Country (reference UK)				18.1	P < 0.001
Sweden	1.183	0.874	1.602		
Ireland	2.489	1.557	3.981		
Germany	1.392	1.113	1.741		

^{*}Estimated intercept value is 0.8647 with a standard error of 0.3460, a Wald chi-square value of 6.2448, and a P-value of 0.0125.

[†]Factor by which the odds of having a score of 1 on the EQ-5D index changes with each increase of 1 unit for continuous variables (e.g., number of episodes) or between the specified levels of categorical variables.

BMI, body mass index; CI, confidence interval; HRQoL, health-related quality of life; SUI, stress urinary incontinence; UUI, urge urinary incontinence

on HRQoL rather than incontinence may, in actual fact, have an influence upon both. Nevertheless, these figures help to compare the magnitude of the impact of incontinence episodes and different comorbidities on HRQoL, and to demonstrate that incontinence is a significant disturber of well-being.

This observational study included a heterogeneous sample of investigators and patients in the different countries. The first step in analyzing the data was therefore to summarize the patient and investigator characteristics. The investigators with different specialities were represented in differing proportions in the participating countries. Our data could not confirm whether the types of investigators in SUIT are representative of the delivery of UI treatment in the respective countries. In many European countries, both PCPs and gynecologists provide initial UI care; in Germany, urologists also have a role [25]. In the UK, however, most women will be initially treated by PCPs [26].

Despite the heterogeneous patient and investigator sample, there was a striking concordance of patient characteristics across the recruiting countries. The mean age of the women was 58.0 years, two-thirds were postmenopausal, and two-thirds were not participating in the workforce. The majority of the women tended to be overweight, and most had at least one comorbidity. In accordance with the general population data [27], most of the women in SUIT were not current smokers. The women in Sweden appeared different from those of the other countries, with a higher proportion of participants who were employed, were ex-smokers, and had received further education, although only a lower proportion with current comorbidities.

Symptoms varied between countries; SUI and MUI were roughly equally prevalent in Sweden unlike the other countries. The women in Ireland typically experienced fewer leakage episodes per week for both SUI and MUI than women in the other three countries. They also had higher median EQ-5D index scores, indicating a higher HRQoL. The relative prevalence of MUI compared with pure SUI is comparable with that from other large-scale community-based studies [5].

The women enrolled in the study reported lower EQ-5D health state index scores than the general female population in Germany, Sweden, and the UK [19]. There is no population norm data available for Ireland.

In the logistic regression analysis, the impact of country on the EQ-5D index score reflects the observed differences between the countries in the raw data. Country, however, should be regarded more as a known source of variation than as a predictor. The rate of self-reported problems with EQ-5D is known to be highly variable between countries as the EQ-5D data from 15 different countries demonstrate [19]. Cross-country differences exist in EQ-5D results even after population data are standardized for demographic differences.

This study and the data it generated have certain limitations. Although the observational nature of the study intentionally allowed the enrollment of a heterogeneous sample of any female patient seeking treatment for SUI rather than a highly selected patient population as enrolled in clinical trials, this presents challenges with regard to the analysis and interpretation of the study data. The observed differences may be due to unobserved confounding factors and can therefore only be described rather than explained. The goodness-of-fit of the model may also be affected by unobserved factors that influenced the EQ-5D index scores. The UK EQ-5D utility weights were used for all patients, although most of the study population came from other countries.

In summary, this article describes the characteristics of women seeking treatment for SUI symptoms and provides a unique snapshot of incontinent women in different European countries. This analysis of the baseline data demonstrates that the number of incontinence episodes has a significant impact on the EQ-5D index score, which gives us confidence in using it as the effectiveness measure for the cost-effectiveness analysis that will be performed on the 12-month longitudinal study data from SUIT.

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The publication of study results is not contingent on the approval of the sponsors. The data, models, and methodology used in the article are nonproprietary.

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