

# Impact of Female Stress Urinary Incontinence on Quality of Life, Mental Health, Work Limitation, and Healthcare Seeking in China, Taiwan, and South Korea (LUTS Asia): Results from a Cross-Sectional, Population-Based Study

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**Background:** Stress urinary incontinence (SUI) is common among adult women with negative effects on psychosocial well-being, mental health, and health-related quality of life. The purpose of the research is to determine if SUI in women is a factor implicated in changes in health-related quality of life (HRQoL) in both physical and mental health domains and in work difficulties.

**Methods:** Data of women 40 years or older from a cross-sectional, population-based, internet survey were examined post-hoc. The effect of SUI frequency on HRQoL (SF12 score), in physical and mental health domains, was assessed. In addition, multivariate and univariate analyses were used to show the influence of SUI on HADS (Hospital Anxiety and Depression Scale) depression score and HADS anxiety score. The effects of demographic factors and physical ailments and SUI on work difficulties were similarly analyzed using multivariate logistic regression.

**Results:** A total of 4208 women with mean age of 60 were included in the analysis. The more frequent SUI episodes were associated with a greater reduction of HRQoL in both physical and mental health domains. In addition, both multivariate and univariate analyses showed that SUI could be correlated with a negative effect on HADS anxiety score (OR 1.617, CI 1.335–1.958,  $p=0.000$ ) and HADS depression score (OR 1.263, CI 1.044–1.527,  $p=0.016$ ). Univariate analyses suggested that work difficulties were correlated with SUI. Available data revealed that many sufferers, including up to 40% of individuals with SUI frequency rating 1 (less than once a month) to 3 (a few times a week), failed to seek treatment.

**Conclusion:** SUI, common in women  $\geq 40$  years of age, impairs quality of life in both physical and mental health domains. SUI is an independent risk factor for anxiety and depression and has been linked to significant work dysfunctions.

**Trial Registration:** This study is registered at ClinicalTrials.gov: NCT02618421 (Date of registration: December 1, 2015).

**Keywords:** stress urinary incontinence, quality of life, China, South Korea, Taiwan

## Plain Language Summary

This is a summary of a secondary analysis of an internet-based survey called LUTS Asia. In total, 8284 adults aged at least 40 years from China, Taiwan and South Korea took part in the one-time survey. The purpose of the survey was to determine how commonly adults experience bother originating in the lower urinary system. A key type of lower urinary bother is called stress urinary incontinence, and it is common in women. The current research aimed to aid the understanding about how stress urinary incontinence affects quality of life and mental health and diminishes work productivity among the female respondents included in the LUTS Asia survey.

Research results showed that stress urinary incontinence was the reason the affected women experienced anxiety and depression. In addition, the more severe the symptoms of stress urinary incontinence were, the more negative impact to both physical and mental aspects of health-related quality of life was seen. Analyses also showed that stress urinary incontinence tended to negatively affect work productivity. Despite these unfavorable effects, many women with stress urinary incontinence still do not seek behavioral counselling or medical treatments that may improve their condition.

## Introduction

Stress urinary incontinence (SUI) is the complaint of involuntary leakage of urine on exertion, sneezing or coughing<sup>1</sup> and is linked to major negative economic, emotional and health-related quality of life issues.<sup>2,3</sup> The condition occurs when the pelvic floor muscles that support the urethra weaken or the urinary sphincter muscles that control the release of urine lose strength. Vaginal delivery is one factor predisposing to SUI; additional risk factors include age, body weight, and hysterectomy. Most women with incontinence, including SUI, have been shown to improve with either pharmacologic or nonpharmacologic treatments.<sup>4,5</sup>

Large cohort studies for female SUI, however, are scarce. An earlier EpiLUTS study,<sup>3</sup> published in 2009, from the US, UK, and Sweden, was a large cohort study that provided comprehensive data correlating lower urinary tract symptoms (LUTS) to various aspects of quality of life, but it did not offer a correlation of the physical aspects of health-related quality of life with SUI. Other large studies of patients with LUTS likewise have not provided a separate analysis of SUI; these include the EPIC study, released in 2006;<sup>6</sup> a 2006 UK study of women visiting primary care providers;<sup>7</sup> and a more recent research based on the Brazil LUTS database.<sup>8</sup>

The current database (LUTS Asia) provides data on LUTS in males and females and can be analyzed to provide information highlighting the impact of female SUI on quality of life, mental health, work limitation, and healthcare seeking behaviors. Leveraging the LUTS Asia database, this study attempted to elaborate on the impact of female SUI on the psychosocial wellbeing of those affected. A significant advantage of LUTS Asia is that confounding factors such as age, diabetes, hypertension, and hyperlipidemia (see [Tables 1 and 2](#) and [Supplementary Table 1](#)) can be controlled.

This analysis took the women cohort (51% of 8284 male and female participants) included in the cross-sectional, population-based study of LUTS in China, South Korea, and Taiwan. The study aimed to evaluate prevalence of female SUI, to determine whether SUI in women is an effector of changes in health-related quality of life (HRQoL) in both the physical and mental domains and in work difficulties, and to analyze healthcare seeking behaviors.

## Methods

### Study Design

An internet-based survey was conducted in 2015 in a cross-sectional, population-based study group comprising individuals at least 40 years.<sup>9</sup> Exclusion criteria included pregnancy at the time of the survey and/or a urinary tract infection within the preceding month. Information about confidentiality and the voluntary nature of participation was included in the introduction to the survey, and informed consent was obtained from all patients being included in the study. The conduct of survey adhered to the principles of the Declaration of Helsinki.<sup>10</sup> Quality checks and survey management were previously described by Chapple et al.<sup>9</sup>

### Data Collection

Part of the general demographic information constituting the analysis included age and marital status. The following key general health and medical comorbidity data were collected: BMI, diabetes mellitus, hypertension, cardiac disease, hyperlipidemia, neurological disorder, smoking and alcohol consumption. Topics relating to LUTS were probed using established survey instruments, including the International Prostate Symptoms Score (IPSS), other International Continence Society (ICS) symptom questions (related to splitting/spraying, hesitancy, terminal dribble, urgency), the Overactive Bladder Symptom Score (OABSS), and a single-item global measure called the Patient Perception of Bladder Condition (PPBC). SUI, whose severity was scored from 1 to 5, was derived from Q31 in the questionnaire (see [Supplementary Tables 2–4](#)). Altogether, parameters derived from these survey tools included IPSS voiding subscore

**Table 1** Univariate and Multivariate Logistic Regression Analysis of Factors Determining HADS Score  $\geq 8$ 

Base: Woman												
Logistic Regression for HADS Score $\geq 8$	HADS Anxiety			HADS Anxiety			HADS Depression			HADS Depression		
	Univariate Analysis			Multivariate			Univariate Analysis			Multivariate		
	Coefficient <sup>a</sup>	95% CI	p-value <sup>b</sup>	Coefficient <sup>a</sup>	95% CI	p-value <sup>b</sup>	Coefficient <sup>a</sup>	95% CI	p-value <sup>b</sup>	Coefficient <sup>a</sup>	95% CI	p-value <sup>b</sup>
Age (numerical)	1.025	(1.017–1.032)	0.000				1.035	(1.027–1.042)	0.000			
Age (>60)	1.481	(1.287–1.703)	0.000	1.152	(0.978–1.356)	0.090	1.717	(1.498–1.969)	0.000	1.359	(1.165–1.584)	0.000
Married (Yes/No)	1.437	(1.112–1.856)	0.006				1.232	(0.969–1.567)	0.088			
DM (Yes/No)	2.818	(2.352–3.378)	0.000	1.287	(1.029–1.61)	0.027	2.774	(2.315–3.324)	0.000	1.290	(1.041–1.599)	0.020
HTN (Yes/No)	1.753	(1.516–2.027)	0.000	0.919	(0.763–1.107)	0.374	1.927	(1.672–2.222)	0.000	1.093	(0.918–1.302)	0.319
Cardiac disease (Yes/No)	2.155	(1.742–2.666)	0.000	1.047	(0.801–1.368)	0.738	1.797	(1.453–2.221)	0.000	0.832	(0.642–1.078)	0.165
Hyperlipidemia (Yes/No)	1.555	(1.343–1.8)	0.000	0.815	(0.868–1.237)	0.693	1.633	(1.415–1.885)	0.000	1.126	(0.952–1.331)	0.165
Neurological disorder (Yes/No)	3.192	(2.308–4.415)	0.000	0.685	(0.8–1.83)	0.365	3.551	(2.548–4.949)	0.000	1.712	(1.152–2.544)	0.008
Height (numerical)	1.010	(0.999–1.021)	0.087	0.282			0.995	(0.984–1.005)	0.335			
Weight (numerical)	1.007	(1–1.013)	0.040				1.006	(0.999–1.012)	0.077			
BMI (numerical)	1.011	(0.994–1.029)	0.213	0.988	(0.968–1.008)	0.241	1.021	(1.004–1.039)	0.014	0.998	(0.979–1.017)	
Smoking (Yes/No)	2.093	(1.645–2.662)	0.000	1.242	(0.916–1.684)	0.163	1.581	(1.242–2.013)	0.000	0.940	(0.698–1.267)	
Alcohol (Yes/No)	1.596	(1.3–1.961)	0.000	0.944	(0.728–1.226)	0.667	1.348	(1.098–1.654)	0.004	0.871	(0.678–1.12)	
PPBC	2.099	(1.966–2.241)	0.000	1.422	(1.303–1.553)	0.000	1.901	(1.786–2.024)	0.000	1.392	(1.279–1.517)	0.000
IPSS_V score	1.322	(1.291–1.354)	0.000	1.160	(1.124–1.198)	0.000	1.269	(1.24–1.298)	0.000	1.138	(1.103–1.174)	0.000
OABSS (numerical)	1.423	(1.382–1.466)	0.000				1.320	(1.285–1.356)	0.000			
OAB (Yes/No)	5.026	(4.306–5.865)	0.000				3.832	(3.293–4.459)	0.000			
Wet OAB (Yes/No)	5.505	(4.55–6.662)	0.000	1.138	(0.884–1.464)	0.316	4.140	(3.432–4.994)	0.000	1.007	(0.785–1.292)	0.956
SUI frequency (numerical)	1.917	(1.798–2.045)	0.000				1.694	(1.593–1.802)	0.000			
SUI (Yes/No)	4.383	(3.77–5.097)	0.000	1.617	(1.335–1.958)	0.000	3.215	(2.773–3.726)	0.000	1.263	(1.044–1.527)	0.016
Daily SUI (Yes/No)	8.634	(5.465–13.639)	0.000				10.604	(6.374–17.642)	0.000			

**Notes:** <sup>a</sup>Coefficient >1 indicates positive effect on the dependent variable (ie, presence of anxiety or depression) and coefficient <1 indicates negative effect on the dependent variable. <sup>b</sup>p-value<0.05 indicates significant influence of relevant variable.

**Table 2** Impact on Work Limitations

Multivariate Analysis for Different Aspects of Work Limitations											
	Start Working		Continue Working		Concentrate on Working		Interact with People		Complete the Work		Significant
	OR <sup>b</sup>	p-value <sup>a</sup>	OR <sup>b</sup>	p-value <sup>a</sup>	OR <sup>b</sup>	p-value <sup>a</sup>	OR <sup>b</sup>	p-value <sup>a</sup>	OR <sup>b</sup>	p-value <sup>a</sup>	
Age > 60	0.8300	0.1280	0.6190	0.0000	0.8030	0.0540	0.8140	0.1020	0.8770	0.2810	1
DM	2.3360	0.0000	1.1880	0.1030	2.2500	0.0000	2.3330	0.0000	1.6760	0.0000	4
HTN	0.9810	0.8830	0.9790	0.8020	1.1160	0.3700	0.9680	0.8140	1.0280	0.8390	0
Cardiac disease	1.2840	0.1580	1.2590	0.0620	1.3760	0.0510	1.5520	0.0130	1.2940	0.1380	1
Hyperlipidemia	0.7590	0.0390	1.0540	0.5160	0.7730	0.0360	0.6690	0.0040	0.6150	0.0000	4
Neurological disorder	2.7740	0.0000	0.9800	0.9170	2.8070	0.0000	3.5890	0.0000	3.7230	0.0000	4
BMI	0.9870	0.3840	0.9890	0.2410	0.9700	0.0350	0.9760	0.1290	0.9780	0.1500	1
Smoking	1.5560	0.0300	1.3050	0.0590	1.0920	0.6570	1.0270	0.9010	1.4140	0.0860	1
Alcohol	0.7830	0.2040	1.0480	0.6900	0.8080	0.2360	0.7550	0.1630	0.7810	0.1940	0
PPBC	1.1690	0.0080	1.1190	0.0070	1.2090	0.0010	1.1660	0.0100	1.1230	0.0470	5
IPSS_V score	1.2610	0.0000	1.0650	0.0000	1.2080	0.0000	1.2770	0.0000	1.2430	0.0000	5
Wet OAB	2.0450	0.0000	0.9300	0.5530	1.8810	0.0000	1.9450	0.0000	1.9620	0.0000	4
SUI	2.4580	0.0000	1.4120	0.0000	2.0650	0.0000	1.8640	0.0000	1.8270	0.0000	5

Notes: <sup>a</sup>p-value<0.05 indicates significant influence of relevant variable. <sup>b</sup>Odds ratio.

(IPSS\_V), presence of wet OAB, PPBC and SUI score, all of which were considered pertinent risk factors for diminished quality of life, mental stress and impaired work productivity.

Other standard survey instruments used included the WLQ (Work Limitation Questionnaire – 8 items); generic HRQoL\_SF12v2 (with the 12-item short form Health Survey version 2)<sup>11</sup> and HADS (Hospital Anxiety and Depression Scale – 14 items).<sup>12</sup> Further description of these survey instruments is provided in [Appendix 1](#).

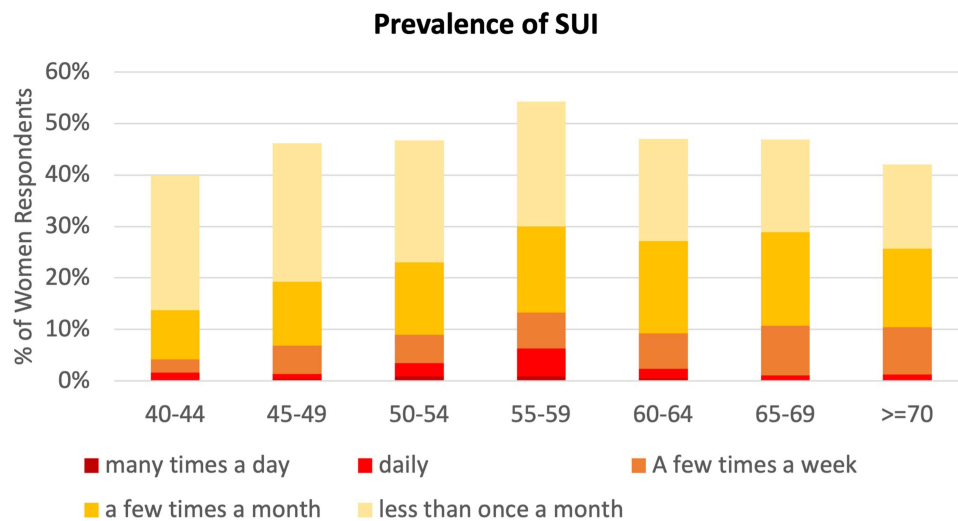
## Primary and Secondary Outcomes

The primary outcome of the female SUI arm of LUTS Asia was the effect of SUI frequency on HRQoL, mental and emotional factors, and work difficulty. The specific dependent variables were three-fold: (1) HRQoL for the physical domain and HRQoL for the mental health domain; (2) HADS anxiety score (numerical) greater than or equal to 8 (categorical) and HADS depression score (numerical) greater than or equal to 8 (categorical); and (3) difficulty in working greater than or equal to 50% of the time as defined by Q46 in the questionnaire (see [Supplementary Table 5](#)).

The secondary outcomes were as follows: (1) to determine the effect of SUI on the adoption of various treatment options; (2) to reveal the effect of SUI on healthcare seeking behaviors; and (3) to delineate how often female SUI occurs by leakage-inducing movement.

## Statistical Analysis

In the female SUI arm of this study, descriptive statistical analysis and multivariate and univariate logistic regression models were used to demonstrate how various risk factors deemed clinically relevant by the urologist investigators from the questionnaire, including SUI, PPBC, IPSS\_V score and presence of wet OAB, influenced quality of life, work productivity, and mental health. The influence of important patient factors and SUI on the HADS anxiety and depression scores was correlated using logistic regression models. The confounders were controlled by multivariate analysis.



**Figure 1** SUI prevalence by age group - highest frequency of any of the SUI.  
**Abbreviation:** SUI, stress urinary incontinence.

Treatment seeking behaviors, both pharmacologic and nonpharmacologic, were delineated with logistic regression models. An analysis of how often SUI occurred in relation to leakage-inducing movements was also provided.

## Results

### Survey Sample

In the original LUTS Asia study, 7.0% of e-mail survey invitation recipients responded, 5.4% provided informed consent and 1.7%, which amounted to 8284 participants, ultimately completed the survey and constituted the final valid sample.<sup>9</sup>

### Age

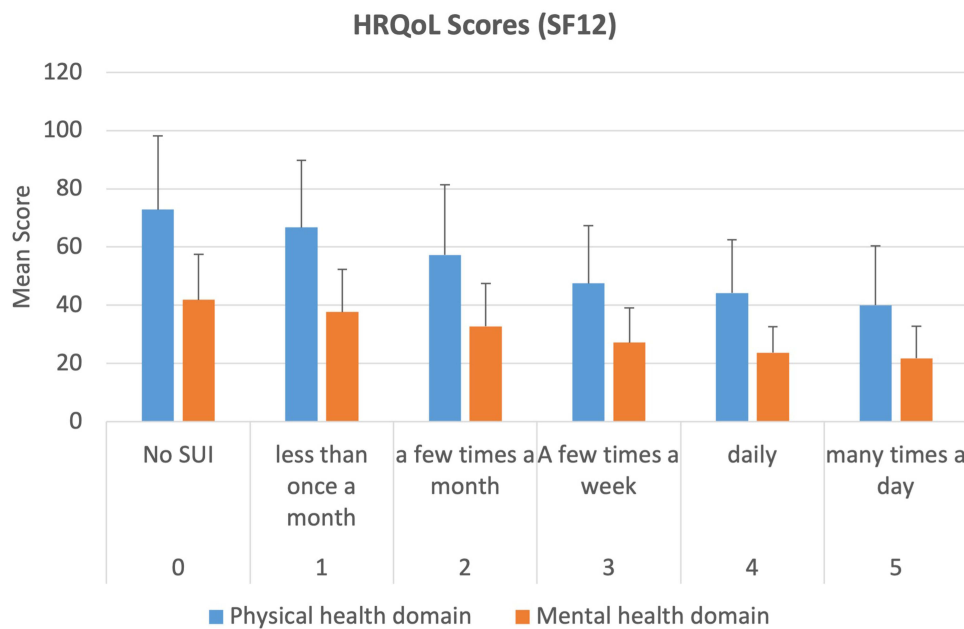
A total of 4208 women with mean age of 60 were included in the analysis. The overall prevalence of SUI in women greater than or equal to 40 years old was 23% (979/4208). The age distribution favors older women, and 42.3% of women with SUI in this study were greater than or equal to 60 years of age. The percentage of married women was higher in the SUI group, possibly related to childbirth, which is a major cause of SUI (see [Supplementary Table 1](#)). There was a clear increase in SUI prevalence and overall frequency with increasing age. Prevalence of SUI “a few times a month” or greater increased from 14% in women aged 40–44 years to 30% in women aged 50–59 years ([Figure 1](#)).

### Quality of Life

Study results showed that the quality of life, in both the physical and mental domains, was significantly affected by SUI. The average transformed SF12 score for the physical health domain decreased from 73 for women without SUI to 40 in women reporting SUI frequency of “many times a day”. Average transformed SF12 score for mental health domain decreased from 42 for women without SUI to 22 in women reporting SUI frequency of “many times a day” ([Figure 2](#)). The results of multivariate analyses indicated fewer factors with significant influence on HADS anxiety and depression scores, ie, SUI, PPBC score, IPSS-V score, and presence of diabetes. Age and presence of neurological disorder were significant factors with respect to depression, but not anxiety ([Table 1](#)).

### Work Limitation

SUI significantly impacted work limitation across WLQ measures. SUI, wet OAB, and neurological disorders showed the highest impact on work limitation in terms of starting working, continuing working, staying focused at work, interacting with people and completing work ([Table 2](#)).



**Figure 2** Avg. transformed SF12 scores by highest frequency of any of the SUI. The SF-12 is a general HRQoL survey in the 12-item short form from Health Survey version 2, and it measures general health status in 8 domains (physical functioning, role limitations due to physical problems, bodily pain, general health, vitality, social functioning, role limitations due to emotional problems, and mental health).<sup>10</sup>

**Abbreviation:** SUI, stress urinary incontinence.

## Management Approaches

Utilization of prescription medications increased with the increase in frequency of SUI. Among participants showing 1–3 frequency rating of SUI, use of prescription medications was 27%; use of prescription medicines increased to 34% among participants reporting an SUI frequency rating of  $\geq 4$ . Up to 40% of participants who reported SUI frequency rating of 1–3 did not follow any treatment/management approach (Figure 3).

## Leakage-Inducing Movements

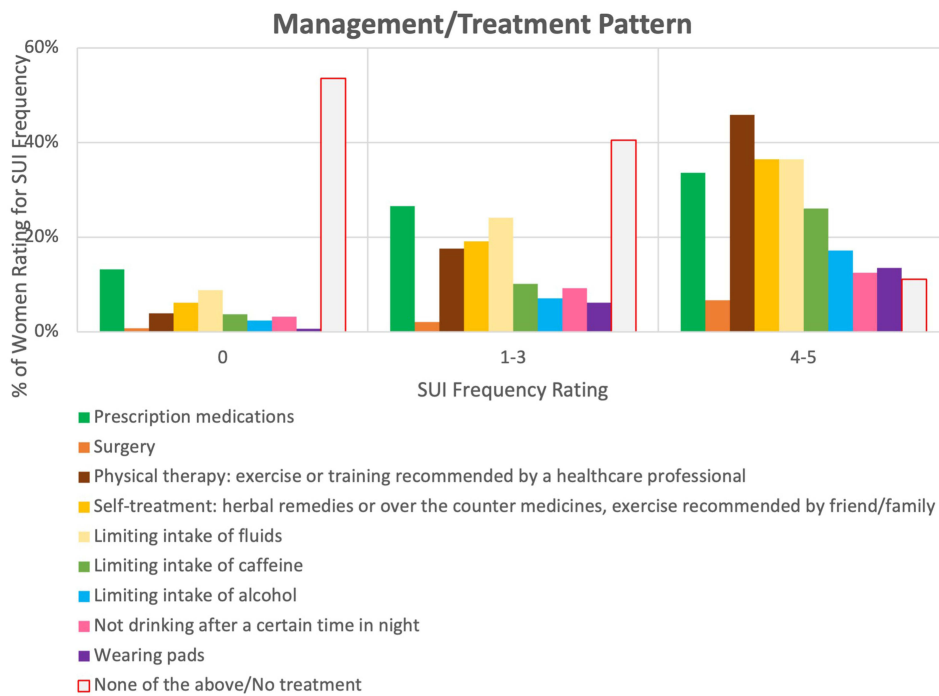
The role of various leakage-inducing movements in SUI is illustrated in Figure 4. The percentage of patients experiencing SUI symptoms many times a day, daily, a few times a week, or a few times a month was shown for each of the five leakage-inducing movements: sneezing, coughing, exercise, laughing, and lifting heavy objects. Sneezing and coughing are the more prominent triggers of incontinence, with a prevalence of 14% and 12%, respectively. Exercise, laughing, and lifting heavy objects, with prevalence of 7%, 5%, and 5%, respectively, played minor roles.

## Discussion

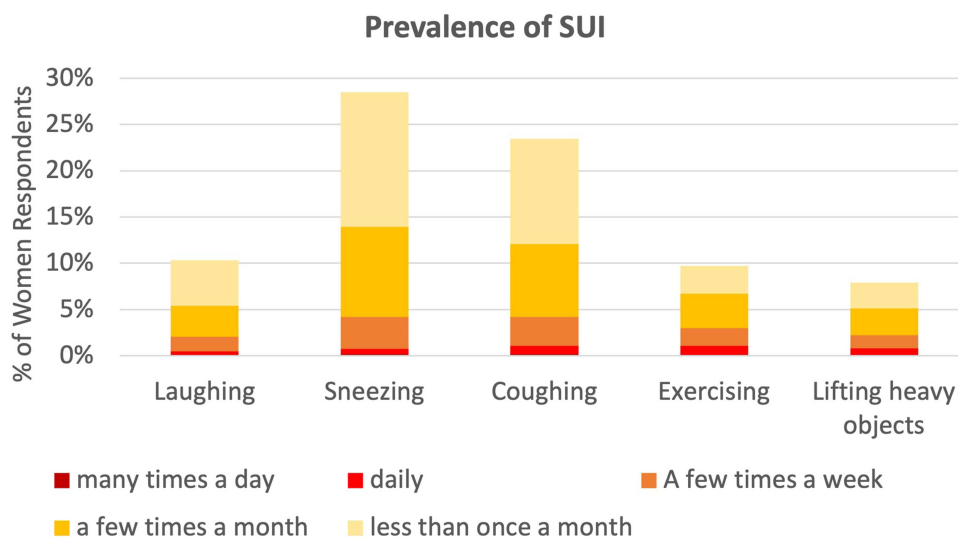
The results of this post hoc analysis of 4208 women with LUTS in China, South Korea, and Taiwan showed that SUI reduced quality of life in both the physical and mental health domains and that the condition was an independent risk factor for anxiety and depression and could negatively impact work function.

## Prevalence

SUI is a common condition in women  $\geq 40$  years of age, and in this analysis set of 4208 women, the overall prevalence was 23.3%. A similar overall prevalence of SUI of 25% was observed in a small study of women studying nursing.<sup>13</sup> In women aged 50–59 years of age in the current analysis, the prevalence was highest at 30%, and SUI remained at high prevalence at 26–27% in women over 60 years old. In another large study from the USA, UK and Sweden, SUI occurred at high percentages in more than 4000 female patients; SUI from laughing, sneezing and coughing occurred in 55.9% of female patients and SUI from physical activities occurred in 28.3% of patients.<sup>14</sup>



**Figure 3** Frequency of SUI and management approaches. The definition of SUI frequency rating is as follow: 0 = “no SUI”, 1 = “less than once a month”, 2 = “a few times a month”, 3 = “A few times a week”, 4 = “daily”, 5 = “many times a day”.  
**Abbreviation:** SUI, stress urinary incontinence.



**Figure 4** Frequency of SUI by leakage-inducing movement.  
**Abbreviation:** SUI, stress urinary incontinence.

### Quality of Life

This study uniquely examined the impact of SUI on QoL issues from two-pronged vantage points of both physical and mental domains. A small-scale study involving 120 Malaysian women with SUI similarly showed that females suffering from the condition have significantly poorer quality of life compared with continent women when measured using both condition-specific and generic quality of life measures.<sup>15</sup>

## Mental and Emotional Health: Anxiety and Depression

Comparable studies, not necessarily using the HADS, likewise showed the impact of SUI on emotional state. A recent controlled study of 177 women (80 patients with SUI and 97 control individuals) showed that women with SUI had a higher level of depression (50% vs 11%) and anxiety (29% vs 3.1%).<sup>16</sup> In the large EpiLUTS study out of the US, UK, and Sweden, SUI was among the urinary tract conditions associated with increased anxiety and depression.<sup>17</sup> In a third study of 275 women with SUI, nearly every third woman (28.7%) felt great mental discomfort related to the disease symptoms, 31.7% a considerable discomfort and 33.1% a moderate discomfort.<sup>18</sup>

## Work Function

This study expectedly demonstrated that SUI has a significant impact on work function. In another study involving more than 2000 working women, 88% of those with more severe incontinence symptoms, including but not limited to SUI, reported at least some negative impact on concentration, performance of physical activities, self-confidence or the ability to complete tasks without interruption.<sup>19</sup>

## Healthcare Seeking

Although SUI has major effects on quality of life, physical and mental health, and work functioning, in this analysis, up to 40% of female patients with a 1–3 SUI frequency rating did not seek treatment of any type. In the EpiLUTS study, patients with LUTS symptoms of any type sought treatment in fewer than one-third of instances.<sup>17</sup> In both large studies of patients with LUTS, and specifically with SUI, many sufferers did not seek intervention that would have been likely to alleviate their symptoms.<sup>5</sup> In addition, lack of apparent correlation between objective diagnostic findings of urodynamic voiding phase dysfunction, a common manifestation among female patients with SUI, and subjective complaints of LUTS<sup>20</sup> would mean that chance of incidental diagnosis of SUI is low unless female patients bothered by the condition proactively seek medical intervention.

## Strengths and Limitations

Strengths of the study included the large sample size and the use of well-validated instruments. Online surveys are suitable for extracting information on private, sensitive personal issues but also tend to favor individuals of higher socioeconomic status. An additional drawback was that information on prior medications was not collected as part of the LUTS Asia database. In addition to the general study design limitations described in the Chow et al paper,<sup>21</sup> for this analysis of SUI in females, the exclusion of pregnant women meant that the time of vaginal delivery, often a particularly important determinant of female SUI, was not captured in the analysis. Since this study was a post-hoc secondary analysis, research was constrained by parameter availability and data quality of the original LUTS Asia database not purposely created for the current research question of interest. A critical facet of such constraint was the lack of comprehensive medical history from survey respondents, including surgical history, which hampered the attempt of risk factor analysis for SUI as it is well recognized that prior pelvic surgery is strongly linked to the development of SUI.

The lack of confirmed SUI diagnosis among survey respondents could cloud the interpretation of SUI as a culprit in reduction in QoL, decline in work productivity and relative passivity in seeking treatment. Our study indicates that QoL was clearly reduced with an increase in SUI frequency, and that the impact of SUI on work productivity is as significant as other factors, such as wet OAB and neurological disorders, in multivariate analysis. Probing of healthcare seeking behavior involved all aspects of urinary symptoms, which were confounders that could not be adjusted by statistical methods. Regardless if these patients might seek treatment for LUTS of other nature, we can still conclude that a large portion of women with SUI (with or without other LUTS) did not receive any management.

## Conclusion

SUI is common in women over 40 years old. SUI has a negative impact on quality of life in both the physical and mental health domains. Along with some other urinary dysfunctions, it is an independent risk factor for anxiety and depression



and may cause significant work limitations. Despite these negative effects, many women still do not seek pharmacologic or nonpharmacologic treatments for SUI and other LUTS that might improve their condition.

## Abbreviations

BMI, body mass index; DM, diabetes mellitus; HADS, Hospital Anxiety and Depression Scale; HRQoL, health-related quality of life; HTN, hypertension; ICS, International Continence Society; IPSS\_V score, International Prostate Symptom Score – voiding; IRB, Institutional Review Board; LUTS, lower urinary tract symptoms; PPBC, Patient Perception of Bladder Condition; OABSS, Overactive Bladder Symptoms Score; OAB, overactive bladder; SF12, a measure of HRQoL (with the 12-item short form Health Survey version 2); SUI, stress urinary incontinence; WLQ, Work Limitations Questionnaire.

## Data Sharing Statement

All data generated or analyzed during this study are included in this published article as [Supplementary Information](#) files.

## Ethics Approval and Informed Consent

The National Taiwan University Hospital Research Ethics Committee waived the oversight of retrospective analyses using de-identified secondary database. The original survey was performed in compliance with Good Clinical Practice and the World Association for Social, Opinion and Market Research (ESOMAR) guidelines that enshrine legal and ethical considerations of consumer panel research. All procedures followed were in accordance with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients being included in the study.

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## Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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## Disclosure

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