



Original Research Article

Urinary incontinence among women attending a tertiary care center: Prevalence, associated factors, and quality of life

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Abstract

Background: Urinary incontinence (UI) is a major global health issue that primarily affects elderly women, resulting in social isolation and reduced quality of life (QOL). The objective of this study was to determine the prevalence of UI, identify associated factors, and analyze how it affects the overall well-being of women.

Methodology: A cross-sectional study was conducted at a hospital, involving 500 women aged 40 and above who visited the gynaecology outpatient department over a period of six months, starting from July 2022. The data were gathered by structured interviews and using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and analysed using SPSS 25 (Armonk, NY, USA).

Results: The study revealed an overall UI prevalence of 37% among participants. The prevalence of stress incontinence was 52.4%, making it the most common type. Urge incontinence accounted for 27.3% of cases, while mixed incontinence accounted for 20.3%. The UI displayed strong correlations with chronic cough ($p < 0.0001$), constipation ($p = 0.03$), previous vaginal birth ($p = 0.029$), and prolonged labour ($p = 0.007$). The majority of affected women (59.9%) experienced urinary incontinence (UI) once a week or less, whereas just 18% reported daily or more regular episodes. In addition, almost 77% of the participants experienced small amounts of leakage and majority had a negative impact on quality of life.

Conclusion: Urinary incontinence is a complex health problem that has significant effects on the quality of life for women. The study findings suggest that around 25% of older women experience urine incontinence (UI), with stress urinary incontinence being the most common subtype. Gaining insight into the frequency and related variables of UI would enable the adoption of efficient preventive measures, hence enhancing the overall welfare of affected individuals.

Keywords: Urinary incontinence, Associated factors, Quality of life, Women.

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1. Introduction

Urinary incontinence (UI) is a prevalent yet often unreported and underdiagnosed condition that has a substantial influence on an individual's quality of life. The World Health Organization has designated UI as a top health issue. The International Continence Society (ICS) has defined urinary incontinence (UI) as "the complaint of any involuntary leakage of urine and which is a social and hygienic problem."^{1,2} Urinary incontinence (UI) is prevalent in both males and females, although it is more prevalent in females. The occurrence of incontinence in women is caused by bladder dysfunction and the weakening of pelvic floor muscles.³ Stress urinary incontinence (SUI), urgency urinary

incontinence (UUI), and mixed urinary incontinence (MUI) are the three main types of urine incontinence.⁴ Stress Urinary incontinence refers to the condition where individuals have unintentional urinary leakage during activities such as exertion, sneezing, or coughing. Urgency urinary incontinence refers to the involuntary leakage of urine from the urethra, which occurs at the same time as a sudden and intense urge to urinate that is hard to control.⁵ Mixed urinary incontinence refers to the simultaneous presence of stress urinary incontinence (SUI) and urge urinary incontinence (UUI).

Studies conducted in various nations have found that the occurrence of urinary incontinence (UI) varies between 5%

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and 70%, with the majority having a prevalence rate between 25% and 45%.⁶ Prior studies indicate that the prevalence of urinary incontinence (UI) among women in Asia ranged from 8.7% to 69.8%.⁴ A study carried out in West Bengal found that 27.7% of the population had the condition,² whereas a study conducted at a tertiary centre in Kerala discovered a prevalence rate of 26.4%.⁷ The broad range of prevalence estimates can be explained by differences in research techniques,⁸ women not accurately reporting symptoms, or healthcare providers not correctly identifying the disorder.⁵

The research identifies various potential risk factors linked to UI, including non-modifiable factors such as advancing age, parity, mode of delivery, menopause, diabetes and prior gynaecological procedures.⁷ Additionally, the risk factors that can be altered include Body Mass Index (BMI), constipation, recurrent urinary tract infection, and persistent cough. Therefore, possessing a thorough understanding of the risk factors would enable individuals to implement efforts aimed at mitigating the impact of the illness by raising awareness and advocating for appropriate preventive measures.^{9,10} UI, an overlooked medical condition, disturbs the regularity of daily activities and affects mental and social well-being, resulting in a deterioration of overall life satisfaction.¹¹ Women often view it as an inherent part of the aging process and a consequence of giving birth, which can cause discomfort, reduced self-confidence, and a feeling of powerlessness. UI is widely regarded as an excessive burden on the society, particularly in nations where a substantial portion of women actively contribute to domestic and financial relevance.

The majority of research on this topic has been conducted among women belonging to affluent study populations within developed nations. Insufficient research has been carried out on the prevalence and factors that contribute to urinary incontinence (UI) in Kerala. This has resulted in a substantial lack of information in comprehending and effectively addressing this disease among the public. Urinary incontinence (UI) is often underreported in developing countries because of the embarrassing nature of the ailment. Many women hesitate to seek help or reveal their symptoms to healthcare providers. Therefore, the objective of this study is to examine the frequency of UI, determine related factors, and investigate its influence on quality of life (QOL), in order to facilitate the development of appropriate interventions.

2. Materials and Methods

The study was conducted at Pushpagiri Institute of Medical Sciences, a tertiary care centre in Thiruvalla, South Kerala. It was a cross-sectional study conducted in a hospital OPD setting. Following the acquisition of institutional ethical committee approval, we recruited women aged 40 years and older who were attending the gynaecology Out Patient Department. Prior to their participation, we obtained their informed consent. Individuals who were pregnant, gave birth

within the past three months, or had undergone gynaecological procedures within the past three months were not included.

Data was gathered utilizing a semi-structured questionnaire administered via in-person interviews. A total of 500 patients were questioned over a period of 6 months, starting from July 2022. An assessment was conducted on several socio-demographic characteristics, BMI, history of hypertension, diabetes, chronic cough, history of constipation lasting more than three months, recurrent UTI, and gynaecological and obstetric predisposing factors.

The second section of the questionnaire included the International Consultation Incontinence Questionnaire - Short Form (ICIQ-SF), which is a concise tool used to assess the frequency, severity, and impact of urinary incontinence on quality of life. The ICIQ-SF questionnaire requires participants to provide information on the frequency of urinary incontinence (UI), the amount of leakage, the overall impact of UI on quality of life (QOL), and the situation surrounding the leakage. The ICIQ-SF is a scale that ranges from 0 to 21, where higher values indicate greater severity. The poll had initial validation in the United Kingdom and was subsequently translated into 35 different languages.^{8,12,13} A score ranging from 1 to 10 indicated mild UI, while a score between 11 and 15 indicated moderate UI, and a score between 16 and 21 indicated severe UI respectively. Women are classified as having stress UI (SUI) if they answer 'yes' to either or both of the following statements: (1) urine leaks occur during coughing or sneezing and/or (2) urine leaks occur when physically active/exercising. A woman is diagnosed with urgency UI (UII) if urine leakage occurs before she can get to a toilet. Women are diagnosed with mixed UI (MUI) if they have features of both SUI and UII. A classification of other UI is used for those who answer 'yes' to the following statements: urine leaks occur (1) during sleep, (2) when finished urinating and dressed, (3) for no obvious reason or (4) all the time.

2.1. Statistical analysis

Frequencies and percentages were used to express the socio-demographic features and prevalence. The continuous data were summarized by calculating the mean and standard deviation (SD). The relationship between urinary incontinence and categorical factors were assessed using a chi-square test. A multivariate analysis was performed to discover the independent components that are linked with incontinence. The data were analyzed using SPSS 25, a statistical software package developed by IBM in Armonk, NY, USA. A significance level of 0.05 and a confidence interval (CI) of 95% were utilized.

Ethical approval was granted by the Institutional Ethical committee (IEC No.PIMSRC/E1/388A/05/2022). Written informed consent was obtained from each participant.

3. Results

The study encompassed a cohort of 500 women who sought medical care at the gynaecology outpatient department (OPD). The study found that 37% of the study population (187 women) had urinary incontinence (UI).

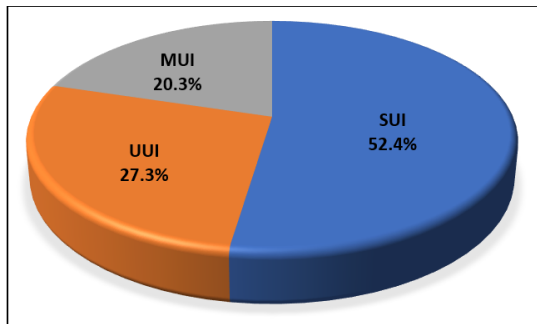


Figure 1: Percentage distribution of type of incontinence

Among those experiencing UI, 52.4% had stress urinary incontinence (98 women), 27.3% had urge urinary incontinence (51 women) and 20.3% had mixed urinary incontinence (38 women) as shown in **Figure 1**.

The majority of participants (52.8%) belonged to the age bracket of 40-50 years in terms of age distribution. The mean age of the study population was $46 \pm SD 4.69$ years. In terms of education, 64% of the participants had obtained a high school education, whereas the majority of them (77%) were engaged in homemaking. The incidence of hypertension was 39.6%, diabetes was 24.8%, and chronic cough was reported by 10.2% of subjects. Out of the individuals involved in the study, 71% had previously given birth vaginally, and 14.6% had prolonged labour lasting over 12 hours. **Table 1** contains further details on comorbidities, surgical history, and obstetric variables.

When socio-demographic parameters were considered, there was no significant correlation seen between UI and different characteristics, as shown in (**Table 2**).

When examining clinical and obstetric factors individually, individuals with diabetes ($p < 0.04$), chronic cough ($p < 0.001$), constipation ($p < 0.03$), recurrent UTI ($p = 0.14$), a history of vaginal delivery ($p < 0.007$), and prolonged labor ($p < 0.001$) demonstrated a significantly elevated risk of developing urinary incontinence (UI) compared to those without these characteristics, as indicated in **Table 3**.

A logistic regression analysis was conducted to determine the individual risk of each component in the presence of UI, while accounting for the impact of other factors. The study found that only four factors were significantly associated with UI: chronic cough (AOR=9.04; 95% CI: 4.22-19.37; $p = 0.09$), constipation (AOR=1.82; 95% CI: 1.08-3.04; $p = 0.023$), history of vaginal delivery (AOR=1.72; 95% CI: 1.06-2.80; $p = 0.029$), and prolonged labour (AOR=2.21; 95% CI: 1.24-3.92; $p = 0.007$).

Table 1: Distribution of study participants based on socio-demographic, clinical and obstetric factors

Factors	N (%)
Age	
≥40-50	264 (52.8)
51-60	121 (24.2)
61-70	82 (16.4)
71-80	28 (5.6)
≥81	5 (1.0)
Education	
Illiterate	45 (9.0)
High School	323 (64.6)
Graduate	120 (24.0)
Postgraduate	12 (2.4)
Occupation	
Not Working	385 (77.0)
Professional	115 (23.0)
BMI	
Underweight	12 (2.4)
Normal	280 (56.0)
Overweight	180 (36.0)
Obese	28 (5.6)
Hypertension	
Yes	198 (39.6)
No	302 (60.4)
Diabetics	
Yes	124 (24.8)
No	376 (75.2)
Chronic Cough	
Yes	51 (10.2)
No	449 (89.8)
Constipation	
Yes	98 (19.6)
No	402 (80.4)
Recurrent UTI	
Yes	69 (13.8)
No	431 (86.2)
Menopause	
Yes	227 (45.4)
No	273 (54.6)
Incont Surgery	
Yes	7 (1.4)
No	493 (98.6)
Prolapse Surgery	
Yes	16 (3.2)
No	484 (96.8)
Parity	
<4	479 (95.8)
≥4	21 (4.2)
H/o vaginal delivery	
Yes	355 (71.0)
No	145 (29.0)
Prolonged Labour	
Yes	73 (14.6)
No	427 (85.4)
Instrumental Delivery	
Yes	16 (3.2)
No	484 (96.8)

Table 4 presents the adjusted odds ratio, its 95% confidence interval, and the significance level of these components determined from the logistic regression study.

In **Table 5** the symptoms of urinary incontinence were assessed using the ICIQ-SF. The subjects were categorized into types of incontinence as follows: 52.4% of the participants experienced stress incontinence, 27.27% experienced urge incontinence, and 20.32% experienced mixed incontinence. Upon evaluating the frequency of leakage, it was discovered that 59.9% of individuals experienced leaking once a week or less, whilst only 18%

reported leakage occurring at least once a day or more. With respect to the amount of leakage, 77.5% of participants encountered a small quantity. Moreover, 81.8% of the participants indicated a modest impact on their quality of life, with a score ≤ 6 .

According to the overall score obtained from the ICIQ-SF (**Table 5**), 72.2% of participants had a total ICIQ score below 10, which indicates mild urinary incontinence, 21.4% exhibited a total ICIQ score between 11 and 15, suggesting a moderate urinary incontinence and 6.4% of participants had a total ICIQ score between 16 and 21, indicating a severe level of urinary incontinence.

Table 2: Prevalence of urinary incontinence according to according to socio-demographic factors

Risk Factors	Urinary Incontinence		Crude odds ratio	CI	p-value
	Yes (n=187) n(%)	No (n=313) n(%)			
Age					
<50	93 (35.2)	171 (64.8)	1.00	-	0.26
51-60	41 (33.9)	80 (66.1)	0.94	0.60-1.48	
61-70	37 (45.1)	45 (54.9)	1.51	0.91-2.50	
71-80	13 (46.4)	15 (53.6)	1.59	0.73-3.49	
>80	3 (60.0)	2 (40.0)	2.76	0.45-16.8	
Education					
Illiterate	12 (26.7)	33 (10.5)	1.00	-	0.07
High School	115 (35.6)	208 (66.5)	1.52	0.76-3.06	
Graduate	56 (46.7)	64 (53.3)	2.41	1.13-5.10	
Postgraduate	4 (33.3)	8(66.7)	1.38	0.35-5.41	
Occupation					
Not Working	138 (35.8)	247 (64.2)	1.33	-	0.19
Professional	49 (43.4)	66 (56.6)	0.753	0.87-2.03	
BMI					
Underweight	3 (25.0)	9 (75.0)	1.00	0.15-2.10	0.77
Normal	105 (37.5)	175 (62.5)	1.8	-	
Overweight	67 (37.2)	113 (62.8)	1.78	0.67-1.46	
Obese	12 (42.9)	16 (57.1)	2.25	0.57-2.74	

Table 3: Prevalence of urinary incontinence according to clinical and obstetric factors

Risk Factors	Urinary Incontinence		Crude odds ratio	CI	p-value
	Yes (n=187) n(%)	No (n=313) n(%)			
Hypertension					
No	106 (35.1)	196 (64.9)	-	-	0.19
Yes	81 (40.9)	117 (59.1)	1.28	0.89-1.85	
Diabetics					
No	131 (34.8)	245 (65.2)	-	-	0.04*
Yes	56 (45.2)	68 (54.8)	1.54	1.02-2.33	
Chronic Cough					
No	146 (32.5)	303 (67.5)	-	-	<0.001*
Yes	41 (80.4)	10 (19.6)	8.51	4.15-17.5	
Constipation					
No	141(35.1)	261(64.9)	-	-	0.03*
Yes	46(46.9)	52(53.1)	1.64	1.05-2.56	
Recurrent UTI					
No	152 (35.3)	279 (64.7)	-	-	

Yes	35 (50.7)	34 (49.3)	1.89	1.13-3.15	0.014*
Table 3 continued....					
Menopause					
No	98 (35.9)	175 (64.1)	-	-	0.45
Yes	89 (39.2)	138 (60.8)	1.15	0.80-1.66	
Hysterectomy					
No	160(37.4)	268(62.6)	-		0.99
Yes	27(37.5)	45(62.5)	1.01	0.6-1.68	
Incontinence Surgery					
No	184 (37.3)	309 (62.7)	-	-	0.76
Yes	3 (42.9)	4 (57.1)	1.26	0.28-5.69	
Prolapse Surgery					
No	183 (37.8)	301 (62.2)	-	-	0.29
Yes	4 (25.0)	12 (75.0)	0.55	0.17-1.73	
Parity					
<4	178 (37.2)	301 (62.8)	-	-	0.59
≥4	9 (42.9)	12 (57.1)	1.27	0.52-3.07	
H/o of Vaginal Delivery					
No	41 (28.3)	104 (71.7)	-	-	0.007*
Yes	146 (41.1)	209 (58.9)	1.77	1.17-2.69	
Prolonged Labour					
No	147 (34.4)	280 (65.6)	-	-	<0.001*
Yes	40 (54.8)	33 (45.2)	2.31	1.40-3.82	
Instrumental Delivery					
No	178 (36.8)	306 (63.2)	-	-	0.113
Yes	9 (56.3)	7 (43.8)	2.21	0.81-6.04	

*P value less than 0.05 is considered as significant.

Table 4: Association between urinary Incontinence and risk factors: results of logistic regression

Factors		Adjusted odds ratio	95% CI	P value
BMI	Over weight	1.78	0.47-6.8	0.645
	Obese	2.25	0.5-10.14	0.621
Hypertension		0.90	0.57-1.41	0.64
Diabetes Mellitus		1.32	0.80-2.18	0.27
Chronic Cough		9.04	4.22-19.37	<.001*
Constipation		1.82	1.08-3.04	0.023*
Recurrent UTI		1.69	0.95-3.02	0.08
H/o Incontinence surgery		1.46	0.25-8.51	0.672
H/o prolapse surgery		0.35	0.09-1.43	0.144
Parity more than 4		1.40	0.48-4.04	0.534
H/o vaginal delivery		1.72	1.06-2.80	0.029*
Prolonged labour		2.21	1.24-3.92	0.007*
Instrumental delivery		1.44	0.47-4.48	0.525

*P value less than 0.05 is considered as significant.

Table 5: International consultation on incontinence questionnaire-urinary incontinence short form (ICIQ-UI SF)

	Characteristics of UI (n=187)			n	%
1.	Frequency of leakage	0	Never	0	0
		1	Once a week or less	112	59.9
		2	Two or three times a week	41	21.9
		3	Once a day	18	9.6
		4	Several times in a day	16	8.6
		5	All the time	0	0

Table 5 Continued...					
2.	Amount of leakage	0	None	0	0
		2	Small	145	77.5
		4	Moderate	40	21.4
		6	Large	2	1.1
3.	Impact on QoL (0-10)		0-3	96	51.3
			4-6	57	30.5
			7-10	34	18.18
	ICIQ score-sum scores 1+2+3				
4.	Type of incontinence with ICIQ-SF		Stress	98	52.4
			Urge	51	27.27
			Mixed	38	20.32
			Other UI	0	0

ICIQ score: 1-10 mild -135(72.2%), 11-15 Moderate-40(21.4%), 16-21 severe 12(6.4%)

4. Discussion

Urinary incontinence is a prevalent condition in women that not only leads to medical issues but also results in psychological, social, and economic challenges, as well as a diminished quality of life. This study examined the prevalence of UI, along with the associated factors and their quality of life, in a tertiary care centre located in Kerala. Approximately 37% of the individuals in our study exhibited urinary incontinence (UI). Multiple studies have documented consistent findings, with prevalence rates ranging from 31.7% to 37.2%, as reported by Batmani et al.¹, Al Kiyumi et al.⁸ and Xie et al.¹⁴ Several research, such as Biswas et al.² and Ajith et al.⁷ found a lower prevalence of (27.7%, 26.5%), while studies by Almutairi (41.7%) and Daneshpajooh et al. (63%) indicated a greater prevalence.^{3,15} The significant disparity in prevalence could be attributed to variations in study techniques and populations. The most common form of urinary incontinence (UI) in the current investigation was SUI, which aligns with the findings of several studies.^{2,11,16-18} Nevertheless, in contrast to our findings, Pathiraja et al. and Ozdemir et al. documented UUI and MUI, respectively, as the most prevailing kinds of UI.^{18,19}

This study demonstrated a strong relationship between persistent cough, constipation, a history of vaginal delivery, prolonged labour and urinary incontinence (UI). Our study indicated a strong positive link between a history of chronic cough and UI, as regularly documented by various prior studies.^{2,3,7,8,14} Chronic cough induces abrupt and recurrent elevations in abdominal pressure, resulting in the fatigue of pelvic floor muscles, which leads to UI.⁷ Xie et al. proposed that persistent cough, in conjunction with advanced age, chronic sinusitis, and exercise-induced coughing, exacerbates the correlation with UI.¹⁴ Our research identified a significant association between constipation and UI, corroborating with findings from various previous

studies.^{2,11,16-18} Constipation can cause increased abdominal pressure and diminished pelvic floor muscular strength, leading to pelvic floor damage and ligament weakening from persistent straining. This then elevates the probability of experiencing UI. Faecal impaction can alter the positioning of the pelvic organs and exert pressure on the bladder, thus diminishing its capacity to retain urine, leading to UI.¹⁷

Consistent with other studies our research also identified that a history of vaginal delivery correlates with a heightened risk of UI.^{8,15,20,21} Urinary incontinence may be associated with the disruption of pelvic floor muscle innervation resulting after delivery. The delivery process, as well as pregnancy-related events, appears to be significantly linked to the prevalence of UI. Another characteristic we examined in our study was prolonged labour, defined as labour exceeding 12 hours. Prior research has demonstrated that prolonged labour can directly compromise the pelvic floor and urinary tract tissues, resulting in damage and perhaps facilitating UI. The concept regarding the correlation between prolonged labour and incontinence posits that the second stage of labour may result in irreversible nerve injury and deterioration of the pelvic floor muscles and fascial supports (endopelvic, urethro-pelvic, and vesico-pelvic) of the urethra. This may ultimately result in UI.²¹

Multiple studies have identified chronic conditions such as diabetes and hypertension as risk factors for urinary incontinence (UI).^{1,2,17,18,20} This could be linked to neurological disorders resulting from these chronic illnesses and the medications prescribed for them. Our study also found a substantial correlation between UI and diabetes, although no such correlation was observed with hypertension. This study found that individuals with a history of recurrent urinary tract infections (UTIs) were more likely to experience urinary incontinence (UI). This finding aligns with previous studies that has also identified recurrent UTIs

as a risk factor for UI, as UTIs can stimulate involuntary contractions of the detrusor muscle.^{1,3,7,16,18}

Previous studies have found various risk factors for UI in women, including menopause, obesity, multiple childbirths, and a history of gynaecological treatments. Nonetheless, our investigation found no association between these features and UI. Higher parity had no significant correlation with urinary incontinence in our investigation. Many believe that the strain on the pelvic floor during the initial delivery is the primary cause of harm to the pelvic floor muscles, rather than the frequency of deliveries. Furthermore, majority of our study population had low parity, which may account for the weak connection between urinary incontinence and high parity. The history of incontinence surgery or prolapse surgery did not significantly influence the development of urinary incontinence in our participants, as only few individuals with incontinence had such a history.

Our study utilized the ICIQ-SF questionnaire to evaluate the type and impact on quality of life (QOL) of women reported to have UI. The results indicated that the majority of participants experienced a negative impact on their quality of life though it was modest (81.8%). Out of the group, 27.8% experienced moderate to severe urinary incontinence which affected their quality of life. These findings were in line with studies undertaken in other regions of the globe.^{18,22,23} Nevertheless, the studies conducted in Middle Eastern countries revealed a notably greater influence on quality of life (QOL) due to the fact that being dry is regarded as a necessary condition for the daily routine of doing the five prayers.^{3,8,17} The adverse effects of urinary incontinence (UI) on quality of life (QOL) can have repercussions for social and emotional connections, physical activity, job, and travel.

Despite Kerala's high literacy rate and health indices, the under-reporting of this ailment is common due to women's reluctance to seek medical assistance. Many remain unaware of the available treatment options. This study underscores the significance of early identification of urinary incontinence to avert its adverse effects on quality of life. Very few studies have been carried out in South Kerala on the risk factors associated with UI, and its impact on quality of life. This study aims to provide knowledge about this topic within our population. This study is advantageous since it utilizes a validated incontinence questionnaire that demonstrates strong correlation with objective data in any group. Although this study utilized a pre-validated questionnaire and included a clinical examination to establish the diagnosis, it had certain limitations such as the absence of urodynamic investigations or a voiding diary. The cross-sectional design of the study merely allowed for the identification of associated risk factors, without being able to establish a causal association. The data mostly focused on verbal responses, which may have introduced recall bias for some factors.

Large scale community based studies are recommended in future to find out the prevalence and risk factors for UI

across the life course of women. Healthcare providers should be more vigilant and proactive in cases of UI. Physicians should screen female patients routinely for symptoms suggestive of UI, particularly targeting those at higher risk for this condition. Future studies utilizing the voiding diary and urodynamic studies can increase the reliability of information presented by the study population.

5. Conclusion

Urinary incontinence (UI) is a substantial health concern that specifically impacts women and can have a negative effect on their overall well-being. Roughly one in four women suffer from UI, with stress urine incontinence being the predominant kind. Chronic cough, constipation, previous vaginal birth and prolonged labour were identified as significant risk factors of UI. Healthcare providers should increase knowledge regarding this illness and encourage persons to seek appropriate healthcare, particularly focusing on those who are at a greater risk of developing UI.

6. Source of Funding

None.

7. Conflict of Interest Statement

The authors declare no conflict of interest

8. Author Contributions

RM, RR & JJ significantly contributed to the conception of the article, while RM and SSV were responsible for acquiring, analyzing, and interpreting the data for the paper. They also authored or critically revised the article to ensure it had key intellectual content. SM³ contributed to the design concept and composed the essay, providing significant intellectual material. The version to be published was approved by SM.

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