



Burden of Lower Urinary Tract Symptoms among Nepalese Adults with Type 2 Diabetes Mellitus

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Received: 30 April 2026; Revised: 2 June 2026; Accepted: 5 June 2026

Abstract

Background: Lower urinary tract symptoms (LUTS) represents a significant burden in patients with Type 2 Diabetes Mellitus (T2DM). With a wide range of LUTS prevalence, a cross-sectional study aimed to assess the prevalence and burden of LUTS among Nepalese patients with Type 2 Diabetes. **Methods:** The burden was assessed in terms of quality adjusted life years (QALYs) and QALYs lost. Data were collected from patients with DM who lived in nine districts in Nepal during 2022-2023. **Results:** Among 480 respondents, more than a half of them were male with mean age of 59.90 ± 12.13 years. The LUTS was more present in Nepalese female (79.9%) than males (75.2%), with no statistical difference between sex ($p = 0.27$). There was statistically significant difference of Euro Quality of life (EQ-5D) between people who had only DM compared to people with DM and LUTS ($p < .001$). Using bivariate analysis, there was an association between LUTS and QALYs ($p < .001$). The QALYs lost was significantly higher in people who had both LUTS and DM. People with DM alone were three times more likely to have perfect health than those with DM and LUTS. Significant positive correlation between age, blood sugar levels, duration of diabetes and LUTS were found; whereas significant negative correlations between health behavior, social support, access to health and LUTS were reported. **Conclusion:** These findings suggest that diabetic patients should be screened for LUTS. Further, social perceptions and access to care should be managed to reduce the burden of LUTS among older DM patients.

Keywords: Diabetes, Lower urinary Tract symptoms, Burden of disease, Nepal

What was Known

- DM was confirmed to be strongly associated with patient-reported LUTS.
- LUTS are known to cause physical and psychological distress, particularly in women.

What's New and Next

- People with diabetes have increased risk of having LUTS, leading to overall worsening of quality of life, leading to increased burden of disease.
- People with diabetes should be screened for LUTS, so as to give appropriate counseling or treatment to prevent them from having a worsening quality of life.

Introduction

Diabetes has reached epidemic proportions around the world, with nearly half a billion people (463 million) in the age group 20 to 79 years living with diabetes, which represents 9.3% of the world population⁽¹⁾. It was estimated that 79.4% of those affected with diabetes lived in low- and middle-income countries. The number of deaths resulting as a direct consequence of diabetes and its complications was estimated as being 4.2 million in 2019^(2,3). From the 2017 Burden of disease study, diabetes mellitus type 2 was contributing to disease burden (1.85% of total DALYs) and disability (3.10% of YLDs). High blood glucose levels alone contributed to 2% of disease burden from cardiovascular diseases.

A link between LUTS and diabetes has long been suspected but is now confirmed⁽⁴⁾. Diabetes is associated with an earlier onset and increased severity of urologic diseases, resulting in costly and debilitating urologic complications that have a profound effect on the quality of life of men and women with diabetes⁽⁵⁾. LUTS, are a group of symptoms that can be caused by overactive bladder (OAB), urinary incontinence (UI) and bladder outlet obstruction (BOO) and many individuals can experience bothersome symptoms that may impair their health-related quality of life (HRQoL)^(6,7,8,9,10). These conditions are highly stigmatized and are associated with a substantial economic and human burden^(11,12,13,14).

The burden of LUTS is characterized by a high prevalence of infections (UTIs) and symptoms, which are driven by autonomic neuropathy, hyperglycemic-induced diuresis, and chronic complications. Little is known about the burden of disease in diabetic individuals with or without

LUTS in Nepal^(15,16,17,18). Within the context of Nepal, where physical and social environment, such as geography, culture, and believe play an important role influencing how people grow up and live. These conditions are known as the social determinants of health, which may drive the inequities in power, resources leading to inequities in health. Although predominantly non-fatal outcomes are the norm for LUTS, when present with diabetes the picture changes and may even usher caution for healthcare professionals. The aim of this study was to assess the prevalence and burden of LUTS among Nepalese patients with Type 2 Diabetes.

Materials and Methods

Research design

The research design was a cross-sectional study. Data were collected from those patients with type 2 diabetes mellitus diagnosis, who received the service from the three selected hospitals and six selected primary health centers, located across seven provinces from the western, eastern, and central part of Nepal.

Population and sample

For this study, multi-stage sampling was done to recruit the subjects. First, three geographical regions, including the central, eastern and western regions of Nepal, were randomly selected from a total of five regions. Next, one hospital representing each region from an urban area was randomly selected after identifying all the potential hospitals. Then, two primary health centres (PHC) each affiliated to the selected hospitals were randomly selected from the hills and the Terai belt of Nepal. Purposive sampling was used to recruit diabetic patients from these hospitals and primary health centres.

The study population for this study were adults aged 30 years and older, who had been diagnosed with type 2 diabetes mellitus and received the services at the selected hospitals and public health centers. The number of participants was estimated using G*Power program with effect size from the previous studies, where the proportion of LUTS among DM was about 40%^(19,20). The required sample size was estimated to be 369 adults with type 2 diabetes mellitus with an additional 20% dropout rate.

For each region, a convenience 160 subjects, who met inclusion criteria were recruited from a hospital (n=80) and 2 public health centers (n=80). The inclusion criteria were adult patients

diagnosed with type 2 diabetes mellitus for more than one year and able to provide informed consent to participate in the study. Exclusion criteria included pregnant women and patients with known urological conditions unrelated to diabetes. Data from a total of 480 subjects were available for data analysis.

Instruments

Data was collected by the researcher using a self-administered questionnaire that included demographic information, diabetic status, LUTS, and health related quality of life. LUTS was identified using the Bristol Male Urinary Tract Symptoms (BMLUTS) and the Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire developed by the Bristol Urological Institute for males and female, respectively.

The Bristol Male Urinary Tract Symptoms (BMLUTS) was a concise and psychometrically sound questionnaire completed by patients to assess male lower urinary tract symptoms and their effect on quality of life in research and therapeutic settings globally. It consisted of 13 items and was rated on a scale ranging from 0 to 20 for voiding symptoms and 0 to 24 for incontinence symptoms. Higher scores indicated more severe urine symptoms. The Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire was used to evaluate the effect of urine symptoms on female's quality of life. The assessment consisted of 12 items and was rated on a scale ranging from 0 to 16 for filling symptoms, greater scores indicated more severe symptoms. The instrument showed acceptable reliability with a Cronbach's alpha of 0.78, indicating high internal consistency for the symptom questions.

In order to measure burden of disease, the health related quality of life (HRQoL) was used in this current study⁽²¹⁾. Burden of disease was assessed in terms of summary measurements of population health (SMPH), which combined mortality and non-fatal health outcomes to represent the health of a population as a single number. For this study quality adjusted life years (QALYs) was used as a health state for the respondents. The overall QALYs for each respondent was calculated by combining the number of years a person lived in perfect health with the number of years lived in less than perfect health. The value for years lived in less than perfect health was derived by multiplying the number of years lived in less than perfect health by the EQ index for that person. Combining this with the years lived in perfect health gave the overall QALYs for the person.

In this study, the generic Euro Quality of Life with five-dimensional questionnaire (EQ-5D) was used to measure health-related quality of life. The generic EQ-5D is a standard measure of health status developed by the EuroQol group to provide a simple, generic measure of health for clinical and economic appraisal ⁽²²⁾. A modified version that included various subdivisions of the EQ-5D-5L questionnaire to include a 5-point-Likert scale was used to get the sum score of symptoms. The higher the sum score the more the disability and worse the quality of life. However, the score for each dimension from a scale 1 to 5 was used to calculate the EQ index.

For this study we used the Indian value set to calculate the EQ index score. The EQ VAS recorded the respondent's overall current health on a vertical visual analogue scale, where the endpoints were labelled 'The best health you can imagine being 100' and 'The worst health you can imagine being 0'. The EQ VAS provided a quantitative measure of the patient's perception of their overall health. The VAS represented the health state of the patient on the day of answering the questionnaire and ranged from 1 to 100, with 100 denoting perfect health perceived by the patient. These values were collected on a hard copy for each individual respondent and tabulated into a computer. Each state was referred to by a 5-digit code. For example, working clockwise with the five dimensions (mobility, self-care, usual activities, pain / discomfort and anxiety / depression), state 12,345 indicated no problems with mobility, slight problems with washing or dressing, moderate problems with doing usual activities, severe pain or discomfort and extreme anxiety or depression, while state 11,111 indicated no problems on any of the five dimensions. The value sets obtained were referenced in the EuroQol EQ 5D website and were used in the SPSS syntax to derive the respective EQ indices of the patients.

The questionnaire was translated into Nepali and then back translated into English. Content validity was examined by 5 experts, with an acceptable CVI of 0.8. The questionnaire was tried out in those who had similar characteristics as the participants. Cronbach's alpha of .915 for MLUTS, .896 for FLUTS and .970 for the EuroQol EQ-5D questionnaire were reported.

Data collection

After IRB approval, data collection was done using an approved validated questionnaire. Data were collected from a total of 480 participants from the selected three hospitals and six public health centers across the eastern, central and western regions of Nepal during December 2023 to February 2024. The research objectives were explained, along with questionnaire details, and data

confidentiality was ensured. Informed consent forms were provided to the participants and they were required to sign them. Participants were also given the opportunity to ask questions regarding the study. Additionally, if any participants felt uncomfortable, they had the right to withdraw from completing the questionnaire at any time. It took about 45 minutes for each participant to complete the questionnaire.

Data analysis

Data obtained was entered into statistical package for social sciences (SPSS) version 30, where the difference in means of EuroQol between respondents with DM and those with DM and LUTS was calculated using the T-test. The Chi squared test was used to demonstrate the difference between the health status of the patients who had DM and DM with LUTS. The EQ index for each individual was also calculated using the highest score for each dimension ranging from a scale 1 to 5. For this study we used the Indian value set to calculate the EQ index score⁽²³⁾. Following the calculation of the EQ index, the QALYs were calculated by the multiplicative method, by which the number of years of perfect health was multiplied by 1 (signifying perfect health) and the number of years of disability multiplied by the EQ index derived for each individual. This gave the quality-adjusted life years for that particular individual. The perceived health status of the participants was documented in the VAS of the EuroQol and a Spearman's correlation was done between this and QALYs, along with looking at correlation between the LUTS score and VAS, QALYs and QALYs lost.

Results

General characteristics and LUTS

Among the 480 participants who were known cases of diabetes mellitus, the mean age was 59.90 ± 12.13 years, with a male predominance (54.5%). More than a half of participants were aged 45 to 64 years (54.1%) followed by those were aged 65 to 75 years (21.8%). About 38% were from the Brahmin/Chettri ethnic group, followed by Janajatis (18.9%). The majority of the participants was married (85%); while 28.5% and 26.8% completed secondary school and primary school, respectively. More than a half of participants were living in the hills area (58.2%) and the rural area (54.5%). About 47.4% worked in agriculture/farming and 31.2% were self-employed. More than a half (54.1%) reported adequate household income. Out of pocket (OOP) payment for healthcare accounted for 54.9%, followed by the government insurance scheme (35.3%). About 56.1% had never smoked and 23.7% were current smokers. Similarly, 53% had never drink alcohol but 27.4%

were current drinkers. The mean body mass index (BMI) was 25.162 (SD=3.95). About 44.5% were overweight, followed by normal weight 26.4% and obese 26.2%.

Prevalence and burden of LUTS among adults with Type 2 diabetes mellitus

According to the MLUTS questionnaire, the overall prevalence of LUTS in this current study was 77.3%, with a higher prevalence in women (79.9%) compared to men (75.2%). There was no statistical difference in LUTS between the two genders ($p = 0.27$). The health index of the EuroQol 5D showed that 16.0% were in perfect health (health index 11111 in all 5 dimensions). The mean quality adjusted life years (QALYs) of the studied sample population was 56.42779 (SD= 10.858289). The overall EQ index showed a mean of 0.70313 (SD= 0.355518).

Comparison of the 5 dimensions of EQ-5D between the groups

The study compared the response between the two groups, i.e. diabetics with no LUTS and diabetics with LUTS using cross tabulations (Chi-square test). The analysis was done with all five dimensions. When comparing mobility scores between the two groups 75.2% of diabetics with no LUTS had no problem compared to 44.9% with LUTS. However, the group having LUTS had higher percentage of people having mobility issues as compared to the group with no LUTS as indicated in the table. This difference was statistically significant ($p < .001$) (Table 1).

Comparison between the groups as a health profile with the EQ-5D

The study also looked at the EQ-5D-5L descriptive system as a health profile, where a score of 11,111 in all 5 dimensions represented perfect health compared to less than perfect health. The difference between the groups who had diabetes alone against people who had both diabetes and LUTS was analyzed by the Chi-squared test. This showed a significant difference between the two groups, $\chi^2 (1, 481) = 33.723$, $p < .001$. People with DM alone were in more perfect health as compared to people with DM with LUTS. (Table 2)

Comparison between groups using the mean EQ index

The result of the EQ index calculation suggests that the mean EQ index score of respondents with DM and LUTS was significantly lower than that for people affected by DM alone (Table 3).

Table 1 Difference in percentage in the five dimensions scores between DM with no LUTS and DM with LUTS

Scores	1	2	3	4	5	p-value
Mobility						
No LUTS	75.2	15.6	7.3	1.8	0.0	<.001
LUTS	44.9	29.0	15.6	8.3	2.2	
Selfcare						
No LUTS	77.1	14.7	6.4	1.8	0.0	<.001
LUTS	49.2	26.9	10.5	10.2	3.2	
Usual activities						
No LUTS	74.3	13.8	5.5	6.4	0.0	<.001
LUTS	37.6	29.6	12.1	15.9	4.8	
Pain						
No LUTS	66.1	26.6	5.5	1.8	0.0	<.001
LUTS	29.0	37.6	20.7	11.3	1.3	
Anxiety/Depression						
No LUTS	44.0	41.3	7.3	7.3	0.0	<.001
LUTS	23.1	42.2	21.0	12.1	1.6	

Note 1: indicating no problem; 2: indicating slight problems; 3: indicating moderate problems; 4: indicating severe problems and 5: indicating unable to/extreme problems

Table 2 Difference in the proportion of people having perfect health and less than perfect health between DM and DM with LUTS

Health Status of respondent	DM (%)	DM with LUTS (%)	Total
Perfect health	37 (33.9)	40 (10.8)	77
Less than perfect health	72 (66.1)	332 (89.2)	404
Total	109 (100.0)	372 (100.0)	481

Table 3 Difference in the EQ index between people with DM alone and with DM and LUTS

	Mean	SD	t-test	p-value
DM (n=109)	.88	.18	8.806	<.001
DM with LUTS (n=372)	.65	.38		

Comparison between the groups using the visual analogue score of the EQ-5D

Similarly, we looked at the difference between the two groups using the VAS. The visual analogue scale was also based on a score from 0 to 100 describing a person's perceived health on that day. We compared the means of the two groups i.e. DM with LUTS and DM alone, which also suggested the mean of people with both the conditions had significantly lower perceived health state on the VAS (Table 4).

Table 4 Difference in VAS mean between DM with LUTS and DM alone

	Mean	SD	t-test	p-value
DM (n=109)	81.53	11.51	6.00	<.001
DM with LUTS (n=372)	72.95	13.55		

Discussion

Nepal diabetes is high in prevalence and data from the World Health Organization (WHO) STEPS survey put the prevalence of type 2 diabetes at 11.7%^(24,25). There was increasing evidence to suggest association between DM and LUTS, which was caused by various mechanisms owing to the effect of DM on the autonomic nervous system, peripheral neuropathy and directly on the bladder musculature leading to bladder overactivity or decreased contractility of the bladder^(5,22,26,27).

In this study the percentage of people with DM having LUTS was 77.3% when both genders were considered, although females were affected more by LUTS compared to males although not statistically significant. The number of individuals with DM affected by LUTS was similar to a study done in Indonesia which showed 75.57% affected. Other studies have shown various ranges with people affecting by overactive bladder alone ranging from 39 to 61%⁽²²⁾.

As suggested people living with DM and its complications complained of a reduced quality of life. It is similar with people who have LUTS, and studies have shown the overall health-related quality of life is lower than the general population^(28,29,30). In fact, studies have suggested that the impact of LUTS alone on their quality of life was similar to people suffering from various chronic illnesses^(31,32,33). So, it can be speculated that people who have the double burden of DM and LUTS will have a decreased health-related quality of life. As can be seen by the findings in this study the people who had LUTS associated with DM had higher scores in all five dimensions of the EQ-5D. This suggested worse quality of life indices in the dimensions of mobility, selfcare, usual activities, pain/discomfort and anxiety/depression.

However, studies have shown that DM alone can have significant impact on the health-related quality of life of patients when compared to the general population as suggested by a study done in India. The study also suggested the dimensions were also affected by the age of the patients and people with uncontrolled DM had a worse health-related quality of life⁽³⁴⁾. In this study people were affected most by anxiety/depression (56% in DM alone, 76.9% in the DM and LUTS group), followed by pain/discomfort (33.9% in DM alone, 71% in DM and LUTS) in both groups, with people with DM and LUTS affected statistically more significantly when compared between the groups. The study done in India suggested people complained more of pain/discomfort (53%) as compared to anxiety/depression (35%)⁽³⁴⁾. Most other studies have also suggested people with DM are mostly affected by pain/discomfort and anxiety/depression when compared to the other dimensions⁽³⁵⁾,

however, the majority of participants in these studies have complained of pain being a more prominent feature^(36,37). The findings in our study suggest that anxiety/depression is common among patients with DM which can be substantiated by a study done in Nepal where depression was observed in 57.8% of patients and 49.7% of patients had anxiety⁽³⁸⁾. Likewise, a systematic review and metaanalysis suggests there is a bidirectional relationship between DM and anxiety with people with DM having a 41% higher risk of having anxiety⁽³⁹⁾. Similarly, people with LUTS are also prone to develop anxiety and depression which was suggested by a systematic review of literature that found significant association between LUTS and anxiety in both genders⁽⁴⁰⁾.

The study also looked at the EQ index value between the two groups that reflects the overall health-related quality of life. There was a significant difference between the two groups with people with DM and LUTS having a worse EQ index value when compared to the group with DM alone, 0.65 compared to 0.88. The findings of the patients who had DM alone suggested a relatively high EQ index value which is similar to other studies. In the UK the prospective diabetes study group suggested diabetics without definite complications had an EQ index value of 0.83⁽⁴¹⁾, when compared to a value of 0.85 in a study in Norway and another study in India (0.80)^(34,42). A similar study done in Iran showed a relatively lower EQ index value of 0.70⁽⁴³⁾. Nevertheless, as could be expected, the added burden of LUTS on DM produced a lower average EQ index value of 0.65, as LUTS produces factors that negatively affect a person's health-related quality of life as suggested earlier. This is also reflected in the VAS scores between the two groups where the VAS mean was statistically significant when people with only DM (81.53) was compared to people who had both DM and LUTS (72.95). This is similar to the study done in India where the VAS of people affected with DM was 78.83, while it was low in a study done in Iran (56.8), which is even lower than people suffering from both DM and LUTS in our study⁽⁴³⁾.

Furthermore, the difference in the health-related quality of life between the groups is highlighted in the health profile of the individuals in the two groups. Our findings suggested there were more people in perfect health (33.9%) in the DM group as compared to only 10.8% in the DM with LUTS group. The difference was also statistically significant. This further proves that LUTS adds an added burden on people with DM, further worsening their health-related quality of life.

This study has several strengths, including multi-regional sampling, use of validated tools (EQ-5D, LUTS instruments), and relatively large sample size. However, its design could lead to potential selection bias (purposive sampling), and self-reported data (recall or reporting bias).

Conclusion

This study highlights the complications of diabetes can further affect the health-related quality of life of these individuals. As can be seen by this study people who have both DM and LUTS have a worse quality of life indicating a higher burden of disease when compared to patients with DM alone as evaluated using a generic quality of life questionnaire. Moreover, as can be seen by this study the proportion of people having both DM and LUTS is significantly high which can be seen to indicate increased burden of disease. It is imperative to address this at the primary health level so as make health workers aware of this and to implement counselling and simple measures to tackle this issue so as to prevent it from being a significant public health problem.

Ethical Approval Statement

This study was approved by the Ethical Committee for Human Research, Faculty of Public Health, Mahidol University, Thailand (project number 8/2023, February 27, 2023). The participants took part in the research voluntarily and Informed consent forms were signed by them, after receiving a clear explanation of the research objectives. The participants were informed of their right to withdraw from the study at any time without any negative consequences. The results were presented in an aggregated form to ensure confidentiality.

Author Contributions

AR was responsible for the initiation and conceptualization of the hypothesis for the research project, along with formulation of the research instruments, data collection and data analysis, the results of which are presented in the manuscript. KA was a correspondence, who provided guidance on research design and appropriate changes that were made following the Institutional Review Board recommendations, questionnaire development, data analysis and article drafting. All authors were dissertation committee who provided advices, read and reviewed the article before submission for publication.

Acknowledgements

The researcher would like to express sincere gratitude to all the hospital and primary health center health workers along with the administrative staff for helping with this research project. Similarly, the researcher would like to thank the research assistants without whom this research project would not be possible.

Source of Funding

The authors did not receive any funding to carry out the work presented in this article.

Conflicts of Interest

The authors declare no conflict of interests.

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