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## URINARY SYMPTOMS AND QUALITY OF LIFE IN WOMEN LIVING WITH HIV: A CROSS-SECTIONAL STUDY

Maryse Larouche MD MPH<sup>1,2</sup>, Arianne YK Albert PhD<sup>3</sup>, Nancy Lipsky BA<sup>3</sup>, Sharon Walmsley MD MSc<sup>4</sup>, Mona Loutfy MD MPH<sup>5</sup>, Fiona Smaill MBChB<sup>6</sup>, Sylvie Trottier MD MSc<sup>7</sup>, Ari Bitnun MD MSc<sup>8</sup>, Mark H Yudin MD MSc<sup>9</sup>, Geoffrey W Cundiff MD<sup>10</sup>, Deborah M Money MD<sup>3,10</sup>

1. Department of Obstetrics and Gynecology, McGill University, Montreal, QC, CAN
2. St. Mary's Research Centre, Montreal, QC, CAN
3. Women's Health Research Institute, Vancouver, BC, CAN
4. Department of Infectious Diseases, Toronto General Hospital, Toronto, ON, CAN
5. Department of Infectious Diseases, Women's College Hospital, Toronto, ON, CAN
6. Department of Pathology and Molecular Medicine, McMaster University, Hamilton, ON, CAN
7. Department of Microbiology, Infectious Diseases and Immunology, CHUQ/CHUL, Quebec, QC, CAN
8. Department of Infectious Diseases, SickKids, Toronto, ON, CAN

9. Department of Obstetrics and Gynecology & Reproductive Infectious Diseases, St. Michael's Hospital, Toronto, ON, CAN

10. Department of Obstetrics and Gynecology, University of British Columbia, Vancouver, BC, CAN

Institution where work was performed: Multicenter Canadian Study with the principal investigator (Dr Deborah Money) based in Vancouver (BC). Other study sites included Toronto (ON), Hamilton (ON), Kingston (ON), Ottawa (ON), Windsor (ON), Montreal (QC), and Quebec (QC)

Corresponding author: Maryse Larouche  
St. Mary's Hospital, Hayes Pavilion, room 4729  
3830 Lacombe  
Montreal, Quebec, Canada, H3T 1M5  
Phone: 1 (514) 934-1934 ext. 32931  
Fax: 1 (514) 373-6071  
ml.larouche@mcgill.ca

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Authors Contributions:

1. Larouche M: Original idea, design of study methods, manuscript writing
2. Albert AYK: Data analysis, manuscript editing
3. Lipsky N: Coordination between authors, contribution to study design, data analysis and manuscript editing
4. Walmsley S: Parent study design and management, patient recruitment, manuscript editing
5. Loutfy M: Parent study design and management, patient recruitment, manuscript editing
6. Smaill F: Parent study design and management, patient recruitment, manuscript editing
7. Trottier S: Parent study design and management, patient recruitment, manuscript editing
8. Bitnun A: Parent study design and management, patient recruitment, manuscript editing
9. Yudin MH: Parent study design and management, patient recruitment, manuscript editing
10. Cundiff GW: Contribution to study design, manuscript editing

11. Money DM: Study design, parent study design and management, patient recruitment,  
manuscript editing

## **Abstract**

**Introduction and Hypothesis:** To determine prevalence and quality of life impact of lower urinary tract symptoms (LUTS) in women living with HIV (WLWH).

**Methods:** Cross-sectional urinary questionnaires were included in a multicenter national prospective study of the HPV vaccine in WLWH. Demographic and clinical information were abstracted from the parent study. Urinary Distress Inventory (UDI-6) and Urinary Impact Questionnaire (UIQ-7) were administered. Wilcoxon rank-sum, two sample chi-square or Fisher's exact tests were used as appropriate to compare women with UDI-6 score  $\geq 25$  to those with lower UDI-6 scores, on demographic and HIV-related factors. Significant categorical variables were followed-up with logistic regression to estimate odds ratios (OR).

**Results:** 177 women completed urinary questionnaires (85.5% of cohort). Median age was 44.1 (37.2 - 50.6). Mean CD4 count was 621 (410-785), and 132 women (74.6%) were virologically suppressed. Median UDI-6 score was 4.2 (0-25). Fifty-one women (28.8%) had UIQ-7 score greater than zero. Among those with UDI-6 score of at least 25, median UIQ-7 was 9.5 (0-47.6). UDI-6  $\geq 25$  was significantly associated with increasing age, higher BMI, Canada as country of origin, peri/post-menopausal status (OR 3.37, 95%CI = 1.71, to 6.75), and being parous (OR 2.92, 95%CI = 1.27, to 7.59) (all  $p < 0.05$ ). HIV-related factors were not associated with UDI-6  $\geq 25$ .

**Conclusions:**

LUTS were common, but we did not demonstrate a negative impact on quality of life in this sample of WLWH. Large comparative studies are needed to determine whether HIV is a risk factor for bothersome LUTS in women.

**Abstract word count:** 250

**Keywords:** HIV, urinary incontinence, lower urinary tract symptoms (LUTS), women living with HIV

**Brief Summary:** In a multicenter urban sample of clinically well-managed women living with HIV, urinary symptoms were associated with general demographic factors and not with HIV severity.

**Abbreviations:**

- AIDS: Acquired immunodeficiency syndrome
- HIV: Human Immunodeficiency Syndrome
- HPV: Human papillomavirus
- IQR: Interquartile range
- LUTS: Lower urinary tract symptoms
- OR: Odds Ratio
- UDI-6: Urinary Distress Inventory

- UIQ-7: Urinary Impact Questionnaire
- WLWH: Women living with HIV

## **Introduction**

Lower urinary tract symptoms (LUTS) are common, being present in approximately 20-50% of women, and can have a profound negative impact on women's quality of life.[1-3] LUTS have been associated with significant mental and physical distress, with studies showing associations between LUTS and relationship and workplace concerns, health-related quality of life, and anxiety and depression.[4] Multiple factors are implicated in the incidence of these symptoms, such as aging, number of vaginal deliveries, obesity, smoking, and menopausal status.[5,6] It is not known whether Human Immunodeficiency Virus (HIV) status can contribute independently to the incidence or severity of LUTS in women. As HIV treatments have drastically improved life expectancy and quality of life of WLWH, there is a growing interest in studying the ageing population living with HIV.

Studies done before the implementation of combination antiretroviral therapy (cART) showed urodynamic evidence of overactive bladder in people with HIV, mainly as a consequence of cerebral pathology, such as toxoplasmosis or HIV encephalitis.[7,8] More recent data about urinary symptoms in women living with HIV (WLWH) is lacking. Another proposed link between urinary symptoms and HIV is related to anti-retroviral therapy affecting renal and/or hepatic function. Specifically, indinavir is known to be associated with formation of crystals in the urine leading to symptoms of dysuria and urinary frequency in 8%.[9] In addition, immune system deficiency can lead to a propensity for urinary tract infections,[10] and neuropathy can impair proper bladder function. With the newer anti-retroviral therapies, these problems are less of a concern.



Sexual risk factors and other associated sexually transmitted infections may contribute, especially in the era of HIV Undetectable = Untransmissible.

LUTS are common in women, and prevalence increases with age, but data specific to aging WLWH is needed. Our objectives were to determine prevalence and quality of life impact of LUTS in WLWH, as well as to identify demographic characteristics associated with urinary symptoms in this population.

### **Materials and Methods**

A cross-sectional urinary questionnaire was included in the observational follow-up study after a multicenter Canadian prospective interventional study of human papillomavirus (HPV) vaccination in WLWH.[11,12] Ethics approval was obtained by the study coordinating centre (H14-02364) and local ethics review board of each participating institution. Although the primary objective of the study was to assess the long-term safety and efficacy of the HPV vaccine in WLWH, additional ethics approval was obtained to add the urinary questionnaire to this study protocol. Hence, adult women (18 years and older) followed at 12 different HIV clinics across the country were invited to participate in this sub-study between April 2016 and November 2018. If they agreed, a urinary questionnaire was added at one of their visits. The questionnaire included the Urinary Distress Inventory (UDI-6) and Urinary Impact Questionnaire (UIQ-7).[13] The UDI-6 questionnaire addresses urinary symptoms burden, whereas the UIQ-7 addresses quality of life impact of urinary symptoms. Both have been validated, are responsive to change,

and are extensively used in lower urinary tract symptoms research.[13] Demographic information was collected, including age, country of origin, parity, body mass index (BMI), habits, previous genitourinary infections, and hepatitis status. We also recorded current CD4 count, viral load, and antiretroviral regimen. Acquired immunodeficiency syndrome (AIDS)-defining illnesses were in accordance with the Center for Disease Control and Prevention 2008 report.[14] HIV-related conditions included a list of conditions commonly used in the field of HIV research and agreed upon by a group of experts involved in the multicenter trial (Appendix I).

Descriptive statistics are presented as N (%), or median and interquartile range (IQR). Wilcoxon rank-sum, two sample chi-square or Fisher's exact tests were used as appropriate to compare women with UDI-6 score of at least 25 to their counterparts on multiple demographic factors (Table 1), as well as on a history of HIV-related factors (Table 2). The UDI-6 cut-off of 25 (maximum score of 100) was chosen as it was previously found to correlate with care seeking.[15] In one study, this cut-off was found to have 83.3% sensitivity and 83.6% specificity to discriminate care seekers due to urinary incontinence from non-care seekers.[15] Significant categorical variables were followed up with logistic regression to estimate odds ratios (OR).

Sample size estimation was based on the precision of our estimate of the prevalence of women with UDI-6 scores > 25. A previous study found this prevalence to be approximately 25% [15]. A sample size of 115 would allow us to estimate this prevalence using 95%CI with  $\pm 6.5\%$  precision.

## **Results**

A total of 177 women completed the urinary questionnaire out of 207 adult women enrolled in the HPV follow-up study (85.5%). Median (IQR) UDI-6 score was 4.2 (0.0-25.0). Eighty-six women (48.6%) had a UDI-6 score above zero, and 52 (29.4%) had a UDI-6 score of 25 or more. Median UIQ-7 score was 0 (0.0-4.8). In the UDI-6  $\geq 25$  group, 30 women (57.7%) had a UIQ-7 score  $> 0$ , compared to only 21 (16.8%) in the group with less urinary symptoms.

Demographic characteristics associated with UDI-6  $\geq 25$  were older age, higher BMI, Canadian country of origin, and peri or postmenopausal status (OR 3.37, 95% CI 1.71-6.75 compared to premenopausal women). (Table 1) Parity was not associated with UDI-6  $\geq 25$ , but being parous was (OR 2.92, 95% CI 1.27-7.59 for parous compared to nulliparous women). Sixty-five women (36.7%) reported not drinking alcohol, 89 (50.3%) drank occasionally, and 23 (13.0%) drank more than one alcoholic beverage per week. Twenty-three women (13.0%) reported current use of opioids, 16 (9.0%) used crystal meth, 25 (14.1%) used cocaine, and 8 (4.5%) used benzodiazepine. Smoking status, alcohol consumption and drug use were not associated with urinary symptoms ( $p=0.24$ ,  $0.24$  and  $0.70$  respectively). Previous history of sexually transmitted infections (including chlamydia, gonorrhea, trichomonas, and syphilis) or vaginitis (bacterial vaginosis or candidiasis) was not associated with LUTS. Twenty-seven women (15%) reported ever having genital or perianal herpes infection (13% in the UDI-6  $<25$  group

and 21% in the UDI-6  $\geq 25$ ,  $p = 0.18$ ). Twenty-eight (15.8%) women reported a urinary tract infection within the last year. None of the HIV-related factors were found to be associated with LUTS (Table 2). Given that only 2 women reported peripheral neuropathy, this variable could not be included in the analysis. No indinavir use was reported.

Sixty-five women (36.7%) reported stress urinary incontinence, and 25 (14.1%) women reported moderate or quite a bit of bother from that symptom. Fifty-two women (29.4%) reported urge urinary incontinence, with 20 (11.3%) reporting moderate or quite a bit of bother. Thirty-three women (18.6%) reported mixed urinary incontinence (Table 3).

## **Discussion**

Although many of the WLWH in our cohort had LUTS, domain-specific quality of life, as determined by the UIQ-7, was not significantly affected in most cases. Stress urinary incontinence was the most commonly reported urinary symptom. Contrary to results of one study in HIV-infected men, where those with AIDS-defining illnesses were more likely to report bothersome lower urinary tract symptoms,[16] none of the severity factors of HIV (including CD4 count, unsuppressed viral load, HIV-related conditions, and AIDS defining illnesses) were associated with LUTS in our sample. However, this was a cohort of women who were generally well treated with good CD4 counts. The studied cohort of medically well-managed WLWH is a great representation of the contemporary

population of women transitioning through various stages of life and encountering issues frequently associated with ageing, while living with HIV.

Urinary symptoms tend to increase in prevalence with advancing age in the general population. Unfortunately, women are often reluctant to discuss issues of urinary symptoms and incontinence with their health care providers unless asked directly, due to fear of embarrassment. Data specific to WLWH was lacking. A study of 155 individuals over the age of 50 years old living with HIV reported a prevalence of urinary incontinence of 25%.[17] However, results are not necessarily generalizable to WLWH since 94% of the study population was male. Another survey in HIV-infected men revealed that HIV was an independent predictor of LUTS, and that those symptoms had a negative effect on quality of life.[16] A recent study designed to study dyspareunia rates in HIV positive vs. HIV negative women found a prevalence of urinary incontinence of 32% among middle-aged WLWH, and an association between urinary incontinence and dyspareunia in that group.[18] However, they did not use validated urinary questionnaires to determine the rates. Another study showed an increased prevalence of urinary tract infections in both HIV positive men and women, but did not address urinary symptoms outside of infections.[19] Our study adds to the literature, by using validated questionnaires to determine the rate of LUTS and urinary incontinence, as well as their associated factors, in a clinically well-managed population of WLWH.

Clinicians require information about LUTS in WLWH in order to inform their patients and to identify those at greatest risk. Although our population was relatively young

(median age 44 years old), 48.6% reported LUTS, and peri or post-menopausal women were more commonly affected. Active case finding might be required in a population of WLWH, as most women in our sample did not attribute much importance to their LUTS symptoms, and may not have self-reported urinary symptoms unless asked directly. The prevalence of urinary incontinence using a similar validated condition specific questionnaire in a sample of US non-institutionalized women (National Health and Nutrition Examination Survey) was 16%,<sup>[20]</sup> which is similar to the prevalence we noted in WLWH. Moreover, risk factors of older age, higher BMI, and parity were also significant predictors of urinary incontinence in that general population sample of women.<sup>[20]</sup> This suggests that in a population of WLWH, standard demographic parameters impact the prevalence of LUTS and urinary incontinence, rather than health status or medications for HIV. Further, we did not identify factors such as being sexually active, the number of recent sexual partners or condom use to be associated with LUTS in our sample. Comparative studies should be performed in the future to further assess the impact of LUTS in the aging population of women living with and without HIV.

Strengths of our study include a large sample of WLWH with detailed information about the status of their HIV, with participants of diverse background from multiple centres across the country. Our sample could thus be easily generalizable to urban populations of women living with HIV in high-income countries. Limitations of our study include its non-comparative design, due to difficulty in finding an appropriate control group for this multicenter sample. Future comparative studies are needed in women. In addition, this

was a group of generally well-treated women living with HIV, which may not allow us to see the full effect of HIV severity on LUTS.

## **Conclusions**

In this large sample of women living with HIV, LUTS were common, but self-reported quality of life, assessed by the UIQ-7, was not significantly affected in most cases. This is reassuring for women living with HIV, but large comparative studies are needed to further assess whether HIV is a risk factor for bothersome urinary symptoms in women, especially in the aging population.

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### Legend of Tables:

Table 1: Demographic Characteristics and Urinary Symptoms Burden

<b>Table 1: Demographic Characteristics and Urinary Symptoms Burden*</b>					
<b>Characteristics</b>		<b>All N= 177</b>	<b>UDI-6 &lt; 25 N = 125</b>	<b>UDI-6 ≥ 25 N = 52</b>	<b>P-value</b>
Age		44.1 (37.2-50.6)	43.4 (35.2-49.5)	48.3 (39.7-52.6)	<b>0.04</b>
Body Mass Index (32 missing values)		28.2 (23.0-33.2)	27.3 (22.2-31.7)	31.3 (24.7-34.2)	0.05
Ethnicity	- White	59 (33.3)	38 (30.4)	21 (40.4)	0.23
	- Black	75 (42.4)	55 (44.0)	20 (38.5)	
	- Aboriginal	26 (14.7)	17 (13.6)	9 (17.3)	
	- Other	17 (9.6)	15 (12.0)	2 (3.8)	
Country of Origin	- Canada	94 (53.1)	62 (49.6)	32 (61.5)	<b>0.03</b>
	- HIV endemic country	71 (40.1)	51 (40.8)	20 (38.5)	
	- Other	12 (6.8)	12 (9.6)	0 (0.0)	
Parity		2 (0-3)	2 (0-3)	2 (1-3)	0.07
Menopausal status (2 missing values)	- Pre-menopausal	117 (66.1)	93 (74.4)	24 (46.2)	<b>0.001</b>
	- Peri-menopausal	14 (7.9)	6 (4.8)	8 (15.4)	
	- Post-menopausal	44 (24.9)	25 (20.0)	19 (36.5)	
Smoking status	- Current smoker	56 (31.6)	35 (28.0)	21 (40.4)	0.24
	- Past smoker	31 (17.5)	22 (17.6)	9 (17.3)	
	- Never smoker	90 (50.8)	68 (54.4)	22 (42.3)	
Sexually active (8 missing values)	- Yes	106 (59.9)	79 (63.2)	27 (51.9)	0.48
	- No	63 (35.6)	43 (34.4)	20 (38.5)	
Number of sexual partners since last visit** (if sexually active) (8 missing values)	- 1	92 (86.8)	71 (89.9)	21 (77.8)	0.20
	- 2+	14 (13.2)	8 (10.1)	6 (22.2)	
Condom use (if sexually active) (8 missing values)	- Every time	45 (39.5)	32 (39.0)	13 (40.6)	0.20
	- Most of the time	11 (9.6)	8 (9.8)	3 (9.4)	
	- Sometimes	20 (17.5)	17 (20.7)	3 (9.4)	
	- Never	30 (26.3)	22 (26.8)	8 (25.0)	
UIQ-7 Score		0.0 (0.0-4.8)	0.0 (0.0-0.0)	9.5 (0.0-47.6)	<b>&lt; 0.001</b>

\* Data presented as N (%) or median (IQR)

\*\* Last visit: mean 2.2 ±1.5 years ago

Table 2: HIV-Related Factors and Urinary Symptoms

<b>Table 2: HIV-Related Factors and Urinary Symptoms*</b>					
<b>Characteristics</b>		<b>All N= 177</b>	<b>UDI-6 ≥ 25 N = 23</b>	<b>UDI-6 &lt; 25 N = 59</b>	<b>P-value</b>
Time since HIV diagnosis (years)		15.8 (11.4-19.6)	15.1 (11.0-19.6)	16.9 (13.5-19.6)	0.15
CD4 count (cells/mm <sup>3</sup> ) (7 missing values)		621 (410-785)	596 (410-779)	660 (413-794)	0.45
CD4 category (7 missing values)	- ≤ 200	15 (8.5)	11 (8.8)	4 (7.7)	0.64
	- 201-350	15 (8.5)	9 (7.2)	6 (11.5)	
	- > 350	140 (79.1)	100 (80.0)	40 (76.9)	
Suppressed HIV viral load (8 missing values)		132 (74.6)	92 (73.6)	40 (76.9)	0.54
Any AIDS-defining illness diagnosis (28 missing values)		26 (14.7)	17 (13.6)	9 (17.3)	0.48
Any HIV-related conditions (28 missing values)		41 (23.2)	28 (22.4)	13 (25.0)	0.69
Hepatitis C (HCV) status (15 missing values)	- HCV active	14 (7.9)	7 (5.6)	7 (13.5)	0.076
	- HCV cleared	17 (9.6)	9 (7.2)	8 (15.4)	
	- Never infected	131 (74.0)	95 (76.0)	36 (69.2)	
Hepatitis B (HBV) status (14 missing values)	- HBV ever	10 (5.6)	7 (5.6)	3 (5.8)	1.0
	- Never infected	153 (86.4)	106 (84.8)	47 (90.4)	
Current antiretroviral regimen † (1 missing value)	- INSTI-based	84 (47.5)	63 (50.4)	21 (40.4)	0.40
	- NNRTI	36 (20.3)	24 (19.2)	12 (23.1)	
	- NRTI	4 (2.3)	4 (3.2)	0 (0.0)	
	- PI	49 (27.7)	31 (24.8)	18 (34.6)	
	- None	3 (1.7)	2 (1.6)	1 (1.9)	

\* Data presented as N (%) or median (IQR)

† INSTI (integrase strand transfer inhibitor), NNRTI (non-nucleoside reverse transcriptase inhibitor), NRTI (nucleoside/nucleotide reverse transcriptase inhibitor), PI (protease inhibitor)

Table 3: Answers to UDI-6 Questionnaire

<b>Table 3: Answers to UDI-6 Questionnaire*</b>					
<b>Question</b>	<b>No</b>	<b>Yes, but not bothered</b>	<b>Somewhat bothered</b>	<b>Moderately bothered</b>	<b>Bothered quite a bit</b>
1. Frequent urination	113 (63.8)	16 (9.0)	22 (12.4)	9 (5.1)	17 (9.6)
2. Urge urinary incontinence (1 missing value)	125 (71.0)	11 (6.3)	20 (11.4)	5 (2.8)	15 (8.5)
3. Stress urinary incontinence	111 (62.7)	23 (13.0)	18 (10.2)	10 (5.6)	15 (8.5)
4. Drops of urinary incontinence	132 (74.6)	9 (5.1)	16 (9.0)	6 (3.4)	14 (7.9)
5. Difficulty emptying bladder	151 (85.3)	5 (2.8)	11 (6.2)	4 (2.3)	6 (3.4)
6. Pain or discomfort in lower abdominal or genital area	145 (81.9)	1 (0.6)	18 (10.2)	7 (4.0)	6 (3.4)

\* Data presented as N (%)

## **Appendix:**

### Appendix I: HIV-Related Conditions

1. Seborrheic dermatitis
2. Persistent generalized lymphadenopathy >1 month
3. Fever higher than 38.5C or 101.3 F, otherwise undiagnosed
4. Idiopathic thrombocytopenic purpura (ITP)
5. Oral thrush (candida infection)<sup>[SEP]</sup>
6. Oral hairy leukoplakia<sup>[SEP]</sup>
7. Microsporidiosis<sup>[SEP]</sup>
8. Shingles (herpes zoster)
9. Diarrhea (otherwise undiagnosed) >1 month
10. Cryptosporidiosis (with diarrhea)
11. Peripheral neuropathy (not drug-related)
12. Peripheral neuropathy (unknown)
13. Cervical dysplasia or cervical intraepithelial neoplasia<sup>[SEP]</sup>
14. Candida (yeast) vaginitis - persistent
15. Pelvic inflammatory disease (PID)
16. Lymphocytic interstitial pneumonitis (LIP)