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Comparison of two methods for evaluating lower urinary tract symptoms in cervical cancer patients following radical hysterectomy

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ABSTRACT

Objective: To compare the degree of agreement and consistency of urodynamic studies (UDS) with low urinary tract symptoms (LUTS) questionnaires for evaluating LUTS in cervical cancer patients following radical hysterectomy (RH) and pelvic lymphadenectomy.

Methods: From January 2012 to March 2015, 204 cervical cancer patients who underwent RH in 13 hospitals were evaluated using the Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and the Overactive Bladder Symptom Score (OABSS). Urodynamic tests were also performed on these patients during the same period.

Results: Study participants' age ranged from 23 to 75 years, with a mean (standard deviation) of 48.0 ± 9.3 years. Using questionnaires, the prevalence of patients with LUTS symptoms, including storage symptoms, voiding symptoms, stress urinary incontinence (SUI) and overactive bladder (OAB) was 86.3%, 77.0%, 62.7%, 52.9% and 14.7%, respectively. For UDS, the corresponding prevalence was 89.7%, 70.1%, 66.7%, 46.6% and 13.2%, respectively. The diagnostic concordance of questionnaires and UDS for storage symptoms, voiding symptoms, SUI and OAB was 79.9%, 66.7%, 66.7%, 57.4% and 79.9%, respectively. For voiding symptoms, the correlation coefficient was 0.272, which was higher than that of storage symptoms, SUI and OAB.

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Conclusions: In cervical cancer patients who have undergone RH, there was a moderate degree of agreement between UDS and symptom questionnaires in evaluating LUTS, but the consistency was poor. Medical personnel should be adequately trained in UDS to ensure LUTS are adequately diagnosed in patients.

1. Background

Cervical cancer is one of the most common gynecological tumors; it is the second most common cancer in women in developing countries.[1] There are approximately 471,000 new cervical cancer cases every year globally[2] and approximately 130,000 new cases in China each year, which represents approximately 28% of new global cases.[3] Radical hysterectomy (RH) plus pelvic lymphadenectomy is the treatment of choice for patients with early-stage cervical cancer. During surgical resection of cardinal ligaments, uterosacral ligaments and vaginal cuff, pelvic vessels, autonomic nerve fibers and ligaments may be affected. The unintended iatrogenic damage may result in pelvic floor dysfunction, including a wide range of lower urinary tract symptoms (LUTS) and other complications.[4]

Two approaches widely used in evaluating and diagnosing LUTS include questionnaires on LUTS and urodynamic studies (UDS). Several studies have reported wide variations in the prevalence of LUTS based on any of these approaches.[5–8] Furthermore, most of these studies employed small sample sizes, usually less than 50 cases.[6–8] In this study, we sought to compare the degree of agreement and consistency of UDS with LUTS questionnaires for assessing postoperative LUTS in cervical cancer patients following RH and pelvic lymphadenectomy.

2. Materials and methods

This was a cross-sectional study of pelvic floor dysfunction after radical hysterectomy in CC patients. It utilized secondary data analysis based on a project funded by the Major Scientific and Technological Project of the Beijing Science and Technology Committee (D151100001915003). The Institutional Review Board (IRB: 2015PHB021-04) approved the study and all patients involved in the study provided informed consent. We recruited 690 patients who underwent type Querleu–Morrow C (QM-C) RH plus pelvic lymphadenectomy from January 2012 to March 2015 in 13 hospitals in China. Patients were evaluated in the outpatient department by questionnaires that employed the International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and the Overactive Bladder Symptom Score (OABSS).[9] Of the 690 patients, 204 voluntarily agreed to undergo concurrent UDS. We compared the consistency of the two assessment methods in the diagnosis of LUTS in these patients.

Inclusion criteria: Participants satisfying the following inclusion criteria were enrolled: (1) aged 18–80 years; (2) diagnosed with early-stage cervical squamous carcinoma (FIGO stage Ia2∼ IIB1); (3) having undergone RH; and (4) willing to participate in the study and sign an informed consent form.

Exclusion criteria： Patients with any of the following criteria were excluded from the study: (1) history of nerve-sparing surgery; (2) severe urinary system injury during a gynecologic operation; (3) preoperative moderate-to-severe stress urinary incontinence (SUI) and urinary retention; (4) participant's inability to fully comply with the study procedures due to uncontrolled epilepsy, central nervous system diseases or psychosis.

A total of 204 patients were included in the final analysis. Their ages ranged from 23 to 75 years, with a mean (standard deviation, SD) of 48.0 ± 9.3 years. The body mass index (BMI) ranged from 17.5 to 36.0 kg/m^2, with a mean (SD) of 24.2 ± 3.1 kg/m^2. The demographic and clinical characteristics of study participants are shown in Table 1.

2.1. The questionnaire survey

LUTS as defined by the International Continence Society (ICS) in 2002, refers to changes in the function and structure of the lower urinary tract, resulting in clinical symptoms and performance abnormalities in the entire cycle of urination. Storage symptoms mainly include urgency, increased daytime frequency, urinary incontinence and nocturia. Voiding symptoms include flow stream, splitting or spraying of the urine stream, intermittent urine stream, straining to void, hesitancy and dribble. Postmicturition symptoms include postmicturition dribble and incomplete micturition.[10]

Stress urinary incontinence refers to the patient's or caregiver's statement of involuntary loss of urine during physical exertion.[11]

OAB was defined as a syndrome characterized by urgency, with or without UI, usually with frequency and nocturia in the absence of a confirmed infection or other obvious pathology in patients with a history longer than 3 months inclusively. Using the OABSS questionnaire, urgency, nocturia, frequency and urge incontinence were scored. Patients with a score of 2 points or more for the symptom of urgency and with a total score of 3 points or more were diagnosed with OAB.[12]

2.2. Urodynamic study

Detrusor overactivity (DO): DO during bladder perfusion was observed during urodynamic investigation.[13]

SUI: leakage of urine during valsalva exercise or cough after the initial sensation of bladder perfusion.[14]

Storage stage symptoms: including bladder compliance, bladder sensation, the first sensation of bladder filling, a first desire to void, a strong desire to void, maximal urethral closure pressure, urethral pressure, functional urethral length, detrusor overactivity and urine

Table 1
Baseline patient demographic and clinical characteristics.

Variate	N (%)
Age	
≤50	124 (60.8)
> 50	80 (39.2)
BMI	
<18.5	4 (2.0)
18.5–23.9	99 (48.5)
24.0–27.9	79 (38.7)
≥28.0	22 (10.8)
FIGO stage	
IA_2	13 (6.4)
IB_1+IIA_1	144 (70.6)
IB_2+IIA_2	36 (17.6)
IIB_1	11 (5.4)
Chemotherapy	50 (24.5)
Radiation therapy	8 (3.9)
Pathological type	
Squamous cell carcinoma	165 (80.9)
Adenocarcinoma	33 (16.2)
Adenosquamous carcinoma	2 (1.0)
Others	4 (2.0)
Follow-up time	
3–6 months	37(18.1)
6–12 months	61 (29.9)
12–24 months	106 (52.0)

The definitions of LUTS, SUI and overactive bladder (OAB) based on questionnaires and UDS.

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incontinence. Abnormalities in the above indicators were diagnosed as storage stage symptoms.

Voiding stage symptoms: including maximum urine flow rate, average urine flow rate, flow time, uroflowmetric curve, voiding time when the maximum flow rate is achieved and post-voided residual urine volume. Abnormalities in the above indicators were evaluated as voiding stage symptoms.

LUTS: having at least one of the storage stage symptoms or voiding stage symptoms.

Table 2
Prevalence of lower urinary tract symptoms in patients using LUTS questionnaires and UDS.

Symptoms	Questionnaires		Urodynamics	
	n	%	n	%
LUTS	176	86.3	183	89.7
Storage	157	77.0	143	70.1
Voiding	128	62.7	136	66.7
SUI	108	52.9	95	46.6
OAB/DO	30	14.7	27	13.2

LUTS, low urinary tract symptoms; SUI, stress urinary incontinence; OAB, overactive bladder, DO, detrusor overactivity; UDS, urodynamic studies.

Table 3
The prevalence of LUTS as assessed by questionnaires.

	LUTS	n	%
Storage	Nocturia	68	33.3
	Urgency	72	35.3
	Frequency	53	26.0
	UI	124	60.8
	SUI	108	52.9
	UUI	64	31.4
	OAB	30	14.7
Voiding	Pain	19	9.3
	Hesitancy	87	42.6
	Straining	100	49.0
	Intermittency	101	49.5

UI, urinary incontinence; SUI, stress urinary incontinence; UUI, urge urinary incontinence; OAB, overactive bladder.

Table 4
The prevalence of LUTS as assessed by urodynamics.

Anomaly indicators of urodynamics		n	%
Storage	Compliance	47	23.0
	Sensation	90	44.1
	First sensation of bladder filling	35	17.2
	First desire to void	106	52.0
	Strong desire to void	62	30.4
	Maximal urethral closure pressure	106	52.0
	Urethral pressure	105	51.5
	Functional urethral length	15	7.4
	DO	27	13.2
	SUI	95	46.6
Voiding	Maximum flow rate	127	62.3
	Average flow rate	127	62.3
	Uroflowmetric curve	114	55.9
	Flow time	122	59.8
	Voiding time when the maximum flow rate is achieved	125	61.3
	PVR	26	12.7

DO, detrusor overactivity; SUI, stress urinary incontinence; PVR, postvoid residual urine volume.

2.3. Statistical analysis

Descriptive statistics were used to summarize the demographic characteristics, the prevalence of LUTS and coincidence rate in diagnosing LUTS. Kappa test was used to evaluate the consistency of the two assessment methods. All analyses were performed using SPSS 22.0.

3. Results

3.1. Prevalence of LUTS using the two assessment methods

The prevalence estimates of LUTS, storage stage symptoms, voiding stage symptoms, SUI and OAB using LUTS questionnaires and UDS are presented in Table 2. The prevalence of LUTS was high irrespective of the assessment method; the prevalence of storage stage symptoms was higher than voiding stage symptoms.

ICIQ-FLUTS and OABSS questionnaires were used to evaluate various LUTS and their prevalence estimates are shown in Table 3. Among measures of storage, UI had the highest prevalence, followed by SUI and urgency. Straining and intermittency were more frequent among the measures of voiding stage symptoms.

Urodynamic studies were used to assess abnormalities in various urine storage indicators and the voiding phase; prevalence estimates of these measures are shown in Table 4. Maximum flow rate and average flow rate were the most frequent, followed by voiding time when the maximum flow rate is achieved. All three urodynamic indices were indicators of the voiding stage and their prevalence estimates were all above 60%.

3.2. Consistency of the questionnaires and urodynamics in the diagnosis of LUTS

There was a moderate degree of agreement between urodynamics and symptom questionnaires in the evaluation of LUTS, but the consistency was poor. Details are shown in Table 5.

4. Discussion

The current and main assessment methods for evaluating female LUTS include questionnaires such as ICIQ-FLUTS and OABSS and urodynamic studies. Cystoscopy, ultrasound and magnetic resonance imaging are also used but less frequently.[15] However, there are no generally accepted guidelines or recommendations regarding when any of the above should be used.[16]

Questionnaires are more widely used in clinical practice and clinical research studies.[17] Questionnaire surveys have the advantage of being used to ascertain patients' discomfort in a comprehensive and detailed way; but due to different levels of education, ways of expression and tolerance, the same disease in different patients is often expressed in different ways.[18]

Table 5
Agreement and consistency of the two assessment methods in the diagnosis of LUTS.

Symptoms	Coincidence rate		Consistency	
	n	%	Kappa	*P*-value
LUTS	163	79.9	0.052	0.457
Storage	136	66.7	0.151	0.031
Voiding	136	66.7	0.272	< .001
SUI	117	57.4	0.152	0.030
OAB/DO	163	79.9	0.165	0.019

LUTS, low urinary tract symptoms; SUI, stress urinary incontinence; OAB, overactive bladder; DO, detrusor overactivity.

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The process of urine storage and voiding can be simulated through urodynamics to detect the key indicators associated with the lower urinary tract symptoms.[19] Urodynamics is a more objective method without the need for self-evaluation, and it plays an essential role in the diagnosis of female LUTS and the formulation of optimal treatment plans. We have previously used UDS to clarify the etiology of LUTS.[20] However, the clinical utility and effectiveness of UDS for diagnosing LUTS remain poorly defined due to the lack of high-quality evidence. Clinical decisions based on urodynamics are not based on a solid evidence base and may be affected by a subjective interpretation by the healthcare professional.[21] Furthermore, UDS do not apply to all patients because it is an invasive test that requires specialized sites and equipment, skills and patient acceptance. Due to the invasive nature of UDS and the specialized setting in which it is conducted, patients usually experience tension and discomfort, which affect the results of the evaluation. There is also a possibility of false-positive and false-negative results after UDS with failure to diagnose the true extent of the LUTS.

In our study, 204 patients were assessed concurrently using symptom questionnaires and UDS. We observed that the consistency of the two assessment methods was poor. For the diagnosis of LUTS, urine storage symptoms, voiding stage symptoms, SUI and OAB, the correlation coefficients were all less than 0.4, indicating poor consistency.

In our study, 30 patients were diagnosed with OAB using OABSS, while only 8 cases were diagnosed with DO using UDS. In the study by Jiménez-Cidre MA, a total of 247 women with OAB were evaluated, of which 103 had DO.[22] Mancini V et al. also showed that symptoms of OAB are common syndromes, which urodynamic tests may show to be caused by detrusor overactivity (DO) and detrusor underactivity (DU), but can also be associated with other urethro-vesical dysfunction.[23] Therefore, for patients diagnosed with OAB by questionnaire survey, UDS should also be performed to ascertain the underlying etiology.

The role of UDS in SUI has been a topic of intense debate. The findings of the VaLUE and VUSIS-II randomised clinical trials (RCTs) published in 2012 appeared to suggest that UDS is not valuable for women with uncomplicated SUI.[24] In our study, only 117 cases (57.4%) had a consistent diagnosis of SUI using the two assessment methods. 95 cases were diagnosed with SUI using UDS, with 11cases being severe SUI. As mentioned previously, a variety of factors interfere with UDS, which may be inconsistent with the symptoms experienced by the patients, especially when the degree of urinary incontinence is mild, and urine leakage cannot be induced in UDS by increasing abdominal pressure. The quality of UDS affects the accuracy of the results, hence, the need for skilled personnel to do this procedure.

Questionnaires and urodynamics had a moderate coincidence rate for the diagnosis of LUTS and hence, both could be used to evaluate LUTS.[25] Symptom questionnaires should first be administered to patients at the initial visit. A urodynamic investigation may not be necessary if the diagnosis is reliable and the administered treatment is effective.[26] For patients with complex LUTS, questionnaire administration may yield wrong diagnoses and treatments may be ineffective. In such situations, a urodynamic examination may be necessary. In our study, LUTS in cervical cancer patients following RH were complex, and the consistency between questionnaires and UDS was poor. The concurrency of the two assessments for LUTS in such patients would approximate real-life situations.

Limitations of our study: Our study participants comprised of patients with cervical cancer following RH, which may not be representative of populations commonly used in urodynamics scenarios; pelvic floor disorders such as pelvic organ prolapse and urinary incontinence are the conditions most often used in UDS. Comparing the consistency of the two assessment methods in patients with pelvic floor disorders has more clinical significance, and the results may be different. Further studies are needed in these target populations.

This study compared the consistency of two assessment methods. Therefore, given the poor consistency and the absence of a gold standard for comparison, it is impossible to determine which assessment method is more effective in a given scenario.

5. Conclusions

In cervical cancer patients who have undergone RH, LUTS prevalence using UDS and symptom questionnaires is high. There was a moderate degree of agreement between the two assessment methods in evaluating LUTS, but the consistency was poor. Medical personnel should be adequately trained in UDS to ensure correct diagnoses of LUTS in patients.

Foundations

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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