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Urology

Characteristics of Lower Urinary Tract Symptoms in Female Bladder Outlet Obstruction

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Abstract

Original Research Article

Objective: To investigate the characteristics of lower urinary tract symptoms (LUTS) in female patients with bladder outlet obstruction (BOO), and provide basis for the diagnosis of female patients with BOO. Method: Based on the fact that BOO can be diagnosed when the maximum flow rate (Qmax) is < 12ml/s and the detrusor pressure at maximum flow rate (Pdet.Qmax) is > 20cmH₂O. The differences in the incidence of LUTS between female patients with BOO and the control group (female patients without BOO) and the characteristics of LUTS in female patients with BOO of two different groups (one is < 50 years old while the other is ≥ 50 years old) was compared. Results: The main symptoms of LUTS were urine storage period (72.1%), and the urination frequency was the most common. The incidence of urinary retention in women over 50 years of age had increased (P<0.05), as well as urinary incontinence (P=0.087) and nocturia (P=0.091). The incidence of frequent urination, urgent urination, increased nocturia, insufficient urination and dysuria in female patients with BOO was higher than those female patients without BOO (P<0.05). The incidence of symptoms in the urine storage phase in BOO female patients were higher than that in urination phase (P<0.05), The second age group (patients ≥ 50 years of age) tends to have similar manifestation (P<0.05), but different in the first age group (patients < 50 years of age) (P>0.05). Conclusions: LUTS of female patients with BOO were mainly characterized by symptoms in the urine storage phase. Compared with female patients with LUTS without BOO, the incidence of frequent urination, urgent urination, nocturia, insufficient urination, and dysuria were higher.

Keywords: Bladder outlet obstruction; Female; Lower urinary tract symptoms.

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Introduction

With the acceleration of population aging, the number of female patients seeking medical treatment for lower urinary tract symptoms (LUTS) is increasing year by year. A study found that 56% of adult women in China have experienced LUTS, and the incidence increased with age, which not only seriously endangers the physical and mental health of patients, but also brings a heavy burden to society [1]. LUTS has various clinical manifestations and complex pathogenic mechanisms, bringing significant challenges for its diagnosis and treatment. LUTS mainly include symptoms in urine storage period and symptoms in urination period. The former includes frequent urination, urgent urination, increased nocturia and urinary incontinence, while the insufficient includes dysuria, intermittent urination and urinary retention. A part of patients of LUTS can be identified its causes through

urodynamic studies (UDS) examination, which mainly include bladder outlet obstruction (BOO), detrusor unactive (DU), detrusor overactivity (DO), and stress urinary incontinence (SUI) [2]. The female urethra is short and straight, and the incidence of BOO in females is lower than that in males. Their symptoms are easily ignored, leading to poor effect of diagnosis and treatment.

The International Continence Society (ICS) and the International Urogynecological Association (IUGA) defined BOO as "the urine flow rate is decreased and the detrusor pressure is increased during urination, or the post-voiding residual urine is increased" [3]. In recent years, with the application of UDS examination in the diagnosis of LUTS, it is found that the incidence of BOO in female patients with LUTS is different (2.7% \sim 29%), which deserves clinical attention [4]. At present, there is an international unified standard for the diagnosis of

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pressure-flow rate in male patients with BOO. Due to the differences in the structural and physiological characteristics of the pelvic floor in females, the diagnostic criteria for males are not applicable to females [5].

With the development of UDS, some scholars had proposed their own diagnostic criteria for female patients with BOO. In 1988, Massey and Abrams [6] proposed the urodynamic diagnostic criteria for BOO in a literature review of the clinical characteristics, causes, and treatment of 163 female patients with BOO (two or more criteria were met): the maximum flow rate (Qmax) is <12ml/s, the detrusor pressure at maximum flow rate (Pdet.Qmax) is >50cmH2O, the urethral resistance is >0.2 or increased post-voiding residual urine (PVR). In 2000, Blaivas and Groutz [7] established the nomogram for female BOO for the first time by using Qmax is <12ml/s and Pdet.Qmax is >20cmH2O as diagnostic criteria for BOO. In 2014, Orasanu et al., [8]. proposed that female patients with BOO was diagnosed based on the maximum flow rate (Qmax) is <12ml/s and the detrusor pressure at maximum flow rate (Pdet.Qmax) is >20cmH2O. Although urodynamic studies examination can qualitatively diagnose female BOO, it is difficult to identify the sites and causes of obstruction, which affects the effect of diagnosis and treatment. Therefore, on the basis of confirming the lower urinary tract function through urodynamic studies examination, if the changes in the urethra and surrounding pelvic floor structures in female patients with BOO can be clearly identified, it will help to make treatment plans and improve the effect of treatment.

The Urology Laboratory of Shaoyang Hospital Affiliated to University of South China combines urodynamic studies examination with ultrasound through software to perform Sonography video urodynamic studies (SVUDS). This allows for simultaneous display of urodynamic results and pelvic floor ultrasound images on the same screen, and enables dynamic analysis not only through single images but also through video recordings. it is helpful for the accurate diagnosis of BOO. This study will retrospectively analyze the female patients undergoing SVUDS for LUTS, to analyze the characteristics of LUTS in this group of patients, and collect clinical data from female patients with BOO. The aim is to analyze the characteristics of LUTS in female patients with BOO, improve the understanding of the clinical symptoms of female BOO, and provide bases for the diagnosis of female BOO.

MATERIALS AND METHODS

From January 2020 to September 2023, 271 female patients who had undergone Sonography video urodynamic studies (SVUDS) in Shaoyang Hospital Affiliated to University of South China for LUTS were enrolled and their clinical data were collected.

There were inclusion criteria: ① Female patients with LUTS, both the test subjects and their families are aware of and agree with the research project, and have signed informed consent. ② All patients undergo SVUDS examination by the same senior chief physician, and the SVUDS parameters such as PVR, BWT, Qmax, Pdet.Qmax, Pdet.max are recorded. ③ Their examination data are recorded and preserved well.

There were exclusion criteria: ① Individuals with a clear history of neurological disorders or mental disorders; ② Have a long history of diabetes; ③ Diagnosed as a patient with neurogenic bladder; ④ Patients with spinal injury, pelvic nerve injury, history of pelvic surgery, and other neurological disorders.

The Sonography video urodynamic studies examination was performed by the Canadian Laborie urodynamic analyzer (imaging version) and the Shenzhen Mindray DC-65 color Doppler ultrasound. The urodynamic examination and ultrasound were combined using software to perform an SVUDS examination, and the urodynamic examination steps were completed in strict accordance with the International Continence Society (ICS) operation guidelines.

According to the diagnostic criteria for female patients with BOO proposed by Blaivas and Groutz: the maximum flow rate (Qmax) is less than 12ml/s and the detrusor pressure at the maximum flow rate (Pdet.Qmax) is greater than 20cmH₂O.

Analysis of the characteristics of LUTS: the 271 patients for LUTS underwent examinations during the same period, the 50 years old was used as the cutoff (female patients aged ≥50 years are generally in menopause and their estrogen levels have significantly decreased). Compared the distribution characteristics and differences of female patients with LUTS of two different groups (one is < 50 years old while the other is \geq 50 years old). There are 41 cases was diagnosed with BOO, so the control group (female patients without BOO) has 230 cases, and compared the differences in the incidence of LUTS between female patients with BOO and the control group (female patients without BOO), and compared the characteristics of LUTS in female patients with BOO of two different groups (one is < 50 years old while the other is ≥ 50 years old).

The data were statistically analyzed using SPSS 26.0 software. The normal distribution of quantitative data was represented by mean \pm standard deviation xs, and was compared using t-tests. The non-normal distribution data was represented by median and interquartile range [Md(P25-P75)], and was compared using the Mann-Whiteny U test method. The enumeration data was represented by rate or constituent ratio, and was compared using chi-square test or continuity correction chi-square test or Fisher's test. The

test standard α was taken as 0.05, and P<0.05 was considered statistically significant.

RESULTS

The 271 female patients for LUTS underwent SVUDS examinations. The age distribution was 16 to 85 years old, with an average age of (55.27 \pm 13.97) years

old, of which 89 (32.8%) were < 50 years old, 182 (67.2%) were ≥50 years old. The highest incidence of LUTS was frequent urination (42.4%), followed by urinary incontinence (39.9%), increased nocturia (29.2%), urgent urination (28.8%), dysuria (19.2%), insufficient urination (16.2%), urinary retention (12.9%), and intermittent urination (6.3%) (Figure 3.1).

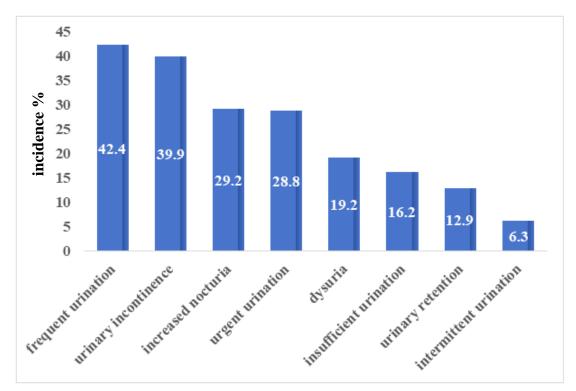


Figure 3.1: Distribution of the incidence of LUTS in 271 women

In all patients, comparing the incidence of LUTS in two age groups (one is <50 years old while the other is ≥ 50 years old), it was found that the incidence of urinary retention in women over 50 years of age had increased(P<0.05), as well as the urinary incontinence

(P=0.087) and increased nocturia (P=0.091). but the incidence of frequent urination, urgent urination, dysuria, insufficient urination and intermittent urination in the two groups were similar. (P>0.05) (Table 3.1).

Table 3.1: Comparison of the incidence of LUTS in different age groups of women

LUTS	<50 (n, %)	≥50 (n, %)	χ^2	p
frequent urination	34 (38.2)	81 (44.5)	0.972	0.324
urinary incontinence	29 (32.6)	79 (43.4)	2.921	0.087
increased nocturia	20 (22.5)	59 (32.4)	2.863	0.091
urgent urination	23 (25.8)	55 (30.2)	0.342	0.559
insufficient urination	12 (13.5)	32 (17.6)	0.739	0.390
dysuria,	16 (18.0)	36 (19.8)	0.125	0.723
urinary retention	4 (4.5)	31 (17.0)	8.355	0.004
intermittent urination	4 (4.5)	13 (7.1)	0.713	0.398

There are 41 female patients with LUTS were diagnosed with BOO, with the highest incidence of frequent urination (28/41, 68.3%). The incidence of frequent urination, urgent urination, increased nocturia, insufficient urination and dysuria in female patients with BOO was higher than those female patients without

BOO. with statistical significance (P<0.05); The incidence of intermittent urination also increased (P=0.009), but the incidence of urinary incontinence decreased (P=0.064). The incidence of urinary retention in the two groups was similar (P>0.05) (Table 3.2).

Table 3.2 Comparison of symptom incidence rates between 41 female patients with BOO and 230 female patients with LUTS without BOO

LUTS	BOO (n, %)	Without BOO (n, %)	χ^2	p
Urinary incontinence	11 (26.8)	97 (42.2)	3.418	0.064
frequent urination	28 (68.3)	87 (37.8)	13.222	0.000
urgent urination	23 (56.1)	55 (23.9)	17.584	0.000
increased nocturia	19 (46.3)	60 (26.0)	6.912	0.009
dysuria	24 (58.5)	28 (26.1)	48.236	0.000
insufficient urination	12 (29.2)	32 (13.9)	6.033	0.014
urinary retention	6 (14.6)	29 (12.6)	0.127	0.722
intermittent urination	5 (12.2)	12 (5.2)	2.892	0.090

Among the 41 female patients with BOO, of which 10 (24.4%) were under 50 years old, and 31 (75.6%) were over 50 years old. Therefore, the proportion of BOO in patients <50 years old was (10/89.11.2%), while in patients \ge 50 years old it was

(31/182, 17.0%), with no significant difference between the two age groups (P>0.05). The incidence of LUTS was similar in both age groups, with no significant difference (P>0.05) (Table 3.3).

Table 3.3 Comparison of the incidence of LUTS in patients with BOO of different ages

LUTS	<50 (n, %)	≥50 (n, %)	χ^2	p
Frequent urination	7 (70.0)	21 (67.7)	0.000	1.000
Dysuria	7 (70.0)	17 (54.8)	0.228	0.633
Urgent urination	6 (60.0)	17 (48.9)	0.000	1.000
Increased nocturia	6 (60.0)	23 (54.8)	0.399	0.528
Insufficient urination	4 (40.0)	8 (25.8)	0.210	0.647
Intermittent urination	3 (30.0)	2 (6.5)	2.478	0.115
Urinary retention	2 (20.0)	4 (12.9)	0.001	0.970
Urinary incontinence	1 (10.0)	10 (32.3)	0.943	0.332

The incidence of symptoms in the urine storage phase was higher in female patients with BOO than in the urination phase, and the incidence of symptoms during the urine storage phase was also higher in patients \geq 50 years old than during the urination phase, with a statistically significant difference (P<0.05); however, there was no similar situation in patients <50 years old (P>0.05) (Table 3.4).

Table 3.4 Comparison of symptoms between the urine storage phase and the urination phase in patients with BOO

group	cases	urine storage phase	urination phase	и	\boldsymbol{P}
BOO	41	1.0 (1.0 - 3.0)	2.0 (0.5 - 2.0)	4.059	< 0.001
< 50	10	2.0 (1.0 - 2.0)	2.0 (0.75 - 1.5)	0.541	0.684
≥50	31	2.0 (1.5 - 3.5)	0.0 (0.0 - 2.0)	4.469	< 0.01

DISCUSSIONS

The normal urination process in the human body relies on the regulation of complex neural network, which is coordinated and controlled by the detrusor of bladder and the external urethral sphincter. When the bladder volume reaches a certain threshold, the bladder sensory signal is transmitted to the spinal cord and enters the pontine micturition center located in the pons. The pontine micturition center sends a signal to induce the contraction of the detrusor of bladder, and the relaxation of the urethral smooth muscle and urethral sphincter muscle to complete urination [9]. Any damage to one of these pathways may lead to the occurrence of lower urinary tract symptoms, including the symptoms in the urine storage phase, urination phase, and post urination phase, female patients with LUTS is mainly

characterized by the first two. Chinese researches showed that [10] the incidence of lower urinary tract symptoms between men and women is roughly similar, but the international researches showed that [11] the incidence of lower urinary tract symptoms in women is higher than that in men. Considering that the risk factors of lower urinary tract symptoms may be related to pregnancy, childbirth, obesity, constipation, age, diabetes, cardiovascular disease and pressure of life [12-14]. With the application of urodynamic studies, the incidence of female BOO in lower urinary tract symptoms has increased year by year. This study reviewed female patients who examined for lower urinary tract symptoms in Shaoyang Hospital Affiliated to University of South China, to understand their medical history, clinical symptoms, pelvic floor ultrasound, and urodynamic parameters. The study identified causes of

female patients with BOO and analyzed their characteristics of lower urinary tract symptoms, providing bases for the diagnosis of BOO.

In this study, 271 cases were collected, including 89 cases (32.8%) in the <50 years age group and 182 cases (67.2%) in the \geq 50 years age group. This suggests that among female patients who underwent urodynamic examination for lower urinary tract symptoms, patients who aged ≥ 50 years old accounted for the majority, indicating that lower urinary tract symptoms may increase with age. Similar to this study, the epidemiological study of LUTS in China was carried out in 2018 [15], which included the largest number of study population (4136 cases) so far, and found that the incidence of LUTS increased with age. Previous studies have suggested that multiple factors contribute to this phenomenon, with changes in estrogen levels in female patients being one of the main reasons [16]. Studies have found that estrogen can affect bladder function and structure. The animal experiment found that the experimental group of rats with bilateral ovaries removed (experimental group), the normal group of rats without bilateral ovaries removed (normal group), and the control group of rats supplemented with estrogen after ovaries removal (control group) showed significant reductions in bladder weight, maximum bladder volume, bladder compliance, and maximum bladder contraction function (P<0.05); However, there was no significant difference in the above observation indicators between the normal group and the control group (P>0.05) [17]. Therefore, this study suggests that the occurrence of LUTS in postmenopausal female patients is related to a decrease in estrogen levels in the body. Adequate supplementation of estrogen may improve LUTS, but further research is needed to confirm this. In addition, the Parkinson's incidence diabetes, disease, cerebrovascular accident and other diseases increases with age, and these diseases will also affect the lower urinary tract function to varying degrees, leading to the increase of LUTS with age [18-20]. Therefore, as the aging population intensifies, women's lower urinary tract problems will face more challenges.

However, in this study, patients with diseases that may lead to neurogenic bladder, such as spinal injury, radical pelvic organ resection, pelvic malignant tumor radiotherapy, urinary tract infection, long-term diabetes, Parkinson's disease, multiple sclerosis and cerebrovascular accident, were not included in the study population. Moreover, urodynamic examination is an invasive and costly examination, and is not recommended for patients with mild symptoms or good outcomes of initial treatment. Therefore, this study has excluded patients who may have neurogenic bladder complications, and most cases of LUTS are more severe, which cannot represent the overall situation of LUTS in women in the region.

In this study, the incidence of symptoms during the urine storage phase was higher in female LUTS patients, with the most common symptoms being frequent urination (42.4%), urinary incontinence (39.9%), increased nocturia (29.2%) and urgent urination (28.8%). Furthermore, the symptoms in the urine storage phase accounted for a higher proportion of LUTS (72.1%), with frequent urination, urinary incontinence, urgent urination and increased nocturia accounting for 21.8%, 20.5%, 14.8% and 15.0% of all lower urinary tract symptoms, respectively. However, Zhang Wei et al., analyzed the symptoms in the urine storage phases and urination phases in 656 female patients with LUTS in the local area and found that no significant difference in the incidence among different age groups [21]. The reason for this may be that different studies included different populations, which affected the analysis of female LUTS.

In addition, by comparing the incidence of different LUTS in the two age groups, it was found that the incidence of urinary retention (P=0.04), urinary incontinence (P=0.087) and increased nocturia (P=0.091) increased in the ≥ 50 years age group, while the incidence of frequent urination, urgent urination, insufficient urination, dysuria and intermittent urination was similar in the two age groups. The incidence of urinary retention is considered to be related to female BOO and detrusor unactive (DU) as age increases [22]. Some studies have found that DU is more common in elderly people, with the incidence of up to 45% [23]. Because the symptoms of female BOO in the early stage are similar to those of patients with DU, most of them are characterized by frequent urination, urgent urination, dysuria and insufficient urination, and the symptoms are insidious. If effective diagnosis and treatment cannot be obtained for a long time, the detrusor contraction function may be reduced, which may develop into DU, resulting in increasing of the post-voiding residual urine (PVR), or even urinary retention. This study found that the incidence of urinary incontinence shows an increasing trend with age, which may be related to hormonal changes during menopause, Pelvic organ prolapse. constipation, obesity, pregnancy, and childbirth in patients. The research has found that various anti urinary incontinence mechanisms in female patients gradually weaken with age. When the pressure of urethral closure during the urine storage phase is lower than the pressure generated by the contraction of the detrusor, any factors cause the abdominal pressure increase which transmit to the bladder can lead to urinary incontinence, resulting in a total incidence of stress urinary incontinence (SUI) of 5% \sim 69% [24]. At the same time, the research has found that obesity increases the risk of stress urinary incontinence [25]. Local application of estrogen has a certain effect on improving female urinary incontinence, which also confirms that the occurrence of urinary incontinence is closely related to age. In 2002, the definition of Overactive bladder (OAB) by the International Continence Society (ICS) pointed out that in addition to frequent urination, it is usually accompanied by the occurrence of increased nocturia [26]. The research has found that the incidences of OAB and increased nocturia increase with age [27].

Therefore, this study found that among female patients who underwent urodynamic examinations due to LUTS, the symptoms in the urine storage phase were more obvious, and the incidence of urinary retention, urinary incontinence and increased nocturia in female patients might increase with age.

The female patients with bladder outlet obstruction (BOO) lack the specific clinical symptoms, which are similar to the lower urinary tract symptoms (LUTS), the manifestations are frequent urination, urgent urination, and increased nocturia. It is difficult to identify female BOO only by clinical manifestations. The symptoms of male patients with BOO are mainly in the urination phase, such as dysuria, insufficient urination, intermittent urination, and even urinary retention [28]. However, it is different from male BOO, this study found that 41 female patients with BOO were mainly characterized by the symptoms in the urine storage phase, with the most common symptoms was frequent urination (68.3%), followed by dysuria (58.5%), urgent urination (56.1%), increased nocturia (46.3%), and insufficient urination (29.2%), urinary incontinence (26.8%), urinary retention (14.6%), and intermittent urination (12.2%). In the comparison of symptoms in the urine storage phase and urination phase, it was found that female patients with BOO tended to have symptoms in the urine storage phase, and patients in the \geq 50 years age group also showed the same trend, while patients in the <50 years age group showed no difference. Considering that there were fewer cases included in the <50 years age group.

It is generally believed that the symptoms of urination phase will occur in most cases of BOO, but this study found that symptoms of female BOO mostly occur in the urine storage phase. The reasons for this are that: (1) Female patients with BOO lead to compensatory hyperplasia and sensitive sensation of the detrusor, which can cause overactive bladder; (2) Among the female patients, the urethra is short and straight, and women without BOO do not need strong contraction of the detrusor during urination, sometimes it is only rely on the relaxation of pelvic floor to complete urination. The contraction strength of the detrusor muscle is lower than that of men, and the symptoms in the urination phase are not as obvious as those in male BOO. Previous studies have confirmed that BOO patients with overactive bladder caused by compensatory hypertrophy and sensitive sensation of the detrusor are also prone to showing symptoms in the urine storage phase (such as increased nocturia, frequent urination, urgent urination, and urinary

incontinence) [29, 30]. The prevalence of OAB in the general population is $12\% \sim 53\%$ [31]. The incidence of female BOO in this study was 15.1% (41/271), which is similar to previous studies, indicating that female patients with BOO may not increase the chance of undergoing urodynamic examination for LUTS. Therefore, it is not simple to identify whether a female patient has BOO based on the clinical symptoms, and the urodynamic examination is required for identification.

Although the LUTS of female patients with BOO are mainly in the urine storage phase, this study found that compared with the LUTS of female patients without BOO, the frequent urination, urgent urination, increased nocturia, insufficient urination, and dysuria of female patients with BOO were significantly higher than those of female patients without BOO. Urinary incontinence, intermittent urination, and urinary retention did not show significant difference between the two groups. Therefore, due to compensatory hypertrophy of the detrusor leading to excessive activity of bladder, not only do female patients with BOO experience higher symptoms in the urine storage phase compared to patients without BOO, but the incidence of symptoms in urination phase such as insufficient urination and dysuria are also increased. Therefore, in daily clinical diagnosis, if we can identify and score the symptoms in more detail, it may be possible to identify LUTS in female patients with BOO. which also suggests that we need to explore the effectiveness of using more detailed symptom scoring tables to identify LUTS in female patients with BOO in the future research.

By analyzing the LUTS characteristics of female BOO patients in different age groups (one is <50 years old while other is ≥ 50 years old), this study found that the incidence of LUTS in different age groups was similar, suggesting that age factors may not have an obvious impact on LUTS of female BOO. However, there were only 10 female patients with BOO in the <50 years age group in this study, if more cases were included, the results might be different. However, this study found that among 271 female patients who underwent SVUDS with LUTS, the incidence of urinary retention in the \geq 50 years age group was higher than that in the <50 years age group, and urinary incontinence and increased nocturia also tended to increase, which also suggested that LUTS of female BOO was different from that of general female patients, and it is still needs further research.

Although this study found that the incidence of urinary retention in female BOO patients was similar to that in patients without BOO, it did not mean that for female BOO patients with LUTS, the use of M-receptor blockers would not lead to detrusor unactive (DU) while improving the symptoms in the urine storage phase, the increase of post-voiding residual urine (PVR) and even

urinary retention. Although the intensity of detrusor contraction required for female urination was lower than that of male, and the degree of female BOO was not as serious as that of male BOO, long-term chronic BOO would also lead to fibrosis of female detrusor, causing damage of detrusor contractility. Therefore, the process of damage of detrusor contractility caused by female BOO might be longer and more insidious than that of male BOO. the clinicians may pay more attention to the treatment of symptoms of female BOO patients in the urine storage phase, while ignoring the adverse effects of M-receptor blockers on the contractility of the detrusor. Therefore, for female BOO patients, it is necessary to fully understand the medical history, analyze the duration and cause of disease, and select M-receptor blockers carefully to treat LUTS of female BOO according to the urodynamic results.

This study has the following limitations: ① There are few cases collected and there is a lack of follow-up after treatment; ② Urodynamic examination requires the placement of a bladder pressure tube through the urethra, which can cause discomfort to the patient, as well as changes in urination patterns during the examination, such as sitting to urinate, which may affect normal urination; ③ During the examination, the operator is a male physician, which may increase the tension of female patients and cause errors in examination data. In future studies, we will explore more effective indicators without invasive to diagnose female patients with BOO.

CONCLUSIONS

Among the female patients with LUTS, the main symptoms are in the urine storage phase, and the frequency can be mostly seen. Besides, women ≥50 years of age are more likely have LUTS. and their incidence of urinary retention is increasing. LUTS of female patients with BOO were mainly characterized by symptoms in the urine storage phase. Compared with the control group (female patients with LUTS without BOO), the incidence of frequent urination, urgent urination, nocturia, insufficient urination, and dysuria were higher.

Conflicts of Interest: All authors have no conflicts of interest to declare.

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