Clinical Factors Associated with Low Valsalva Leak Point Pressure Among Women with Stress Urinary Incontinence

Sun-Ouck Kim, Young Jung Kim, Dong Hoon Yoo, In Sang Hwang, Eu Chang Hwang, Seung Il Jung, Taek Won Kang, Dongdeuk Kwon, Kwangsung Park

Department of Urology, Chonnam National University Medical School, Gwangju, Korea

Purpose: The purpose of this study is to determine the predictive factors that are associated with stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD) in women.

Methods: Between January 2008 and December 2009, 185 women with urodynamically proven SUI were included in this study and retrospectively reviewed the medical record. Preoperative SUI symptoms were classified by Stamey grade. Valsalva leak point pressure (VLPP) determination series was repeated two times in each subject after finishing one series of VLPP measurement. The patients were classified into three groups according to VLPP; 1) ISD: VLPP ≤ 60 cm H2O, 2) equivocal: 60 < VLPP ≤ 90 cm H2O, 3) anatomical incontinence (AI): VLPP > 90 cm H2O. Chi-square test and multivariate (logistic regression test) analyses were performed to determine the factors associated with ISD.

Results: The mean patient age was 54.2 years (range, 44.5 to 68.4 years). Seventy-one women (38.3%) were in the ISD group and 70 (37.8%) in the AI group. The results of univariate and multivariate analyses found that women with ISD had a higher symptom grade than women with AI (P = 0.001 and 0.0001, respectively). The number of patients in the ISD and AI group in accordance with the symptom grade were 7 (10%) and 44 (62%) in grade I, 50 (54%) and 23 (25%) in grade II, and 14 (63%) and 3 (14%) in grade III respectively. There was no correlation between VLPP and other clinical factors.

Conclusions: High symptom grade was the only independent clinical factor that predicted the presence of ISD. This should be considered when counseling the patients with SUI.

Keywords: Urinary sphincter; Female; Stress urinary incontinence

INTRODUCTION

The International Continence Society (ICS) defined urinary incontinence as a condition in which involuntary loss of urine is a social or hygienic problem and is demonstrable [1]. Stress urinary incontinence (SUI) occurs when the intravesical pressure exceeds the urethral pressure as a result of increased intraabdominal pressure in the absence of detrusor pressure. SUI is a relatively common problem in women that is thought to be induced from two different reason, urethral hypermobility and intrinsic sphincter deficiency (ISD) [2].

ISD is defined by the ICS as an intrinsic malfunction of the urethral sphincter itself and urodynamic stress incontinence as the involuntary loss of urine during increased abdominal pressure in the absence of detrusor contraction [2]. McGuire et al. [3] introduced the concept of type III incontinence, the most severe form of incontinence of ISD. They observed that some patients showed repeated failure from the retropubic suspension operation, and they found the patients with failed surgery had a deficient sphincter mechanism characterized by open bladder neck and proximal urethra at rest with minimal or no urethral descent during stress [3]. Surgical procedures for the correction of SUI having ISD have shown relative high incidence of failure rate because of the underlying problem of severe urethral dysfunction and poor coaptation. Guerette et al. [4] reported that the low success rate of the transobturator tape...
(TOT) procedure in women with low leak point pressure (LPP) (54.5%) compared to those normal urethra (95.8%). Knowing women with SUI has ISD or not is an important clinical factor, especially before making surgical decision, because it can change operative outcome.

Although subjective parameters are important for the diagnosis of ISD, clinicians want to find objective parameters to quantify urethral sphincter function and diagnose ISD. Now a uniform definition of ISD is lacking and test used to diagnose ISD include low Valsalva leak point pressure (VLPP) and low maximal urethral closure pressure (MUCP). However, at present no single factor can accurately predicts this condition of ISD, the diagnosis of ISD must be based on the individualized clinical features besides VLPP or MUCP [5]. The purpose of this study is to determine the predictive clinical factors that are associated with SUI having ISD in women.

**MATERIALS AND METHODS**

**Subjects and the Study Design**

Between June 2008 and June 2009, 185 women with SUI who underwent the TOT procedure for clinical and urodynamic study (UDS) proven SUI and the medical record of these subjects were retrospectively analyzed. All of the patients underwent urological evaluation before treatment taking a comprehensive medical history including obstetric and gynecologic history, physical and neurologic examinations, and urine analysis. Additional parameters of evaluation included a body mass index, stress cough test, and urodynamic study that included determination of the VLPP. Preoperative SUI symptoms were classified by Stamey grade [6]. We divided the patients into three groups by VLPP measurement; ISD: VLPP ≤ 60 cm H₂O, Gray zone: 60 < VLPP ≤ 90 cm H₂O, anatomical incontinence (AI): VLPP > 90 cm H₂O. The stress cough test was performed with the patient in dorsolithotomy position when the patients sensed full bladder. During pelvic examination, the severity of the vaginal wall defect was determined using the pelvic organ prolapse quantification system [7]. The examiners at this institution were two well experienced specialists in urology. Patients were physically examined while in the dorsolithotomy position on a standard gynecologic table.

**Measurement of VLPP**

Multichannel UDS investigations were done according to the ICS protocol [8]. Conventional filling cystometry was performed with patients in the supine position. The bladder was filled at a constant rate of 50 mL per minute using normal saline solution at room temperature for standard UDS. The VLPP was obtained with the subject seated when the total infused volume of sterile water reached 200 mL by asking the patient to perform a Valsalva maneuver until urine loss was directly observed. The VLPP, a measurement of the lowest abdominal pressure required to produce urine leakage, was recorded which was repeated to verify the initial finding. If urine leak was not noted with Valsalva maneuver, the patient was asked to make cough. The VLPP value of less than 60 cm H₂O was used as the urodynamic criterion for the diagnosis of ISD. The procedure for this study complied with the guidelines provided by the Declaration of Helsinki.

**Exclusion Criteria**

Patients were excluded from this analysis according to the following criteria: patients who had undergone previous spine and brain surgery, concomitant high grade pelvic organ prolapsed (over grade III), history of urinary retention with residual urine over 200 mL, active urinary tract infections and other urologic disease or drug treatment that could have an impact on bladder function and urethral function. Patients using alpha adrenergic receptor agonists or antagonists were also excluded. Potential patients who had any possible cause of neurogenic bladder were excluded.

**Statistical Analyses**

SPSS ver. 17 (SPSS Inc., Chicago, IL, USA) was used for statistical analyses. Data were expressed as means ± standard deviations (SDs). Chi-square test and multivariate (logistic regression test) analyses were performed to determine which clinical factors were associated with ISD. P-values < 0.05 were deemed statistically significant.

**RESULTS**

Patient’s demographic data and the comparison of clinical factors between groups are shown in Table 1. The mean patient age was 54.2 years (range, 44.5 to 68.4 years). Seventy-one women (38.3%), 44 (23.9%) and 70 (37.8%) were in the ISD group, equivocal and AI group, respectively. The mean number of the patients who had natural childbirth was 2.8 and the mean symptoms duration was 7.5 years. The mean number of 28 patients took hormonal treatment. When the subjects were divid-
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Table 1. Analysis of clinical parameters in stress urinary incontinence groups

|                                | LPP ≤ 60 (n = 71) | 60 < LPP ≤ 90 (n = 44) | LPP > 90 (n = 70) | Total | P-value |
|--------------------------------|-------------------|------------------------|-------------------|-------|---------|
| Mean age (yr)                 | 53.8 ± 6.5        | 50.2 ± 9.1             | 55.3 ± 4.2        |       | 0.109   |
| BMI (kg/m²)                   | 24.8 ± 2.9        | 23.2 ± 2.3             | 25.1 ± 2.2        |       | 0.731   |
| Symptom duration (yr)         | 8.0 ± 5.4         | 7.5 ± 6.3              | 7.2 ± 6.8         |       | 0.371   |
| Pregnancy (n)                 | 4.1 ± 1.9         | 4.5 ± 2.3              | 4.7 ± 2.8         |       | 0.652   |
| Delivery (n)                  | 2.8 ± 1.1         | 3.0 ± 1.5              | 2.7 ± 1.3         |       | 0.091   |
| Hormonal therapy (n)          | 26 (31)           | 30 (36)                | 28 (33)           |       | 0.163   |
| Predominal SUI                | 57 (38)           | 36 (24)                | 56 (38)           |       | 0.791   |
| Predominal UUI                | 14 (54)           | 8 (31)                 | 14 (55)           |       | 0.536   |
| Previous surgery (n)          |                   |                        |                   |       |         |
| Anti-incontinence             | 7 (47)            | 5 (33)                 | 3 (20)            | 15    | 0.815   |
| Pelvic surgery                | 13 (36)           | 8 (22)                 | 15 (42)           | 36    | 0.752   |
| Radiation therapy (n)         | 2 (100)           | 0 (0)                  | 0 (0)             | 2     |         |
| Stamey grade (n)              |                   |                        |                   |       | 0.001*  |
| I                              | 7 (10)            | 20 (28)                | 44 (62)           | 71    |         |
| II                             | 50 (54)           | 19 (21)                | 23 (25)           | 92    |         |
| III                            | 14 (63)           | 5 (23)                 | 3 (14)            | 22    |         |

Values are presented as mean ± SD or number (%). LPP, leak point pressure; BMI, body mass index; SUI, stress urinary incontinence; UUI, urge urinary incontinence.

*Statistically significant.

Fig. 1. Comparison of symptom grade between stress urinary incontinence groups. Intrinsic sphincter deficiency (ISD): Valsalva leak point pressure (VLPP) ≤ 60 cm H₂O. Gray zone: 60 < VLPP ≤ 90 cm H₂O. Anatomical incontinence (AI): VLPP > 90 cm H₂O.

DISCUSSION

When ISD was defined as VLPP of 60 cm H₂O or less, we found that the only clinical factor that predicted the presence of ISD was the symptom grade in this study. This result suggests that the higher grades of SUI will have a higher chance of ISD. Clinicians should consider this factor when counseling and evaluating incontinence patients.

SUI is known to arise from the two different mechanisms, AI and Predominal symptoms as predominant stress incontinence or predominant urge incontinence, the majority was predominant stress incontinence (49.7%). The patient who has the history of radiation treatment at pelvic cavity was only two in VLPP less than 60 cm H₂O group. The numbers of patients who had hysterectomy and previous anti-incontinence operations were 15 and who had history of any kind of pelvic surgery were 36, respectively. There was no baseline difference between groups in terms of clinical characteristics except for Stamey grade (Table 1).

The results of Chi-square test and multivariate analyses found that women with ISD had a higher symptom grade than women with AI (P = 0.001 and 0.0001, respectively). The number of patients in the ISD and AI group in accordance with the symptom grade were 7 (10%) and 44 (62%) in grade I, 50 (54%) and 23 (25%) in grade II, and 14 (63%) and 3 (14%) in grade III respectively (Fig. 1). There was no correlation between VLPP and other clinical factors.

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and ISD [3,9]. AI is caused by urethral hypermobility and malposition of an intact urethral sphincter during increase of abdominal pressure which can lead to diminished pressure transmission to the proximal urethra and bladder neck. AI usually well treated by traditionally introduced various surgical procedures that try to reposition and support the urethral sphincter [10]. SUI in women is also caused by ISD when the urethra fails to coapt normally independent of its anatomical position [11].

McGuire et al. [3] observed that some patients with no proximal urethral functions as a sphincter showed surgical failure from multiple retropubic operation to treat incontinence. They found that these patients had an opened bladder neck and proximal urethra at even rest or no urethral descent from stress. Several studies about suspension procedures in SUI women have shown a high incidence of failure rate in this condition [9]. From these reason, the concept of SUI related with ISD has been grown from an attempt to further understand the exact pathophysiology of SUI and curious about the result of surgical of this condition. Raz et al. [10] reported that some patients with anatomical incontinence was not cured by bladder neck suspension showing the failure rate of 90% shortly after the operation despite adequate bladder neck support and anatomical repositioning. They found there could be a component of ISD in association with SUI in those patients and reported high failure rate of 35% from the surgery in those with severe subjective symptoms of incontinence [10].

Since the observation of ISD related different feature of surgical outcome, much work has been devoted to exact definition, recognition, objective diagnosis and proper management. The selection and diagnosis of ISD among the SUI would be extremely important in counseling the patient before surgery and in predicting the outcome of surgical treatment. Although ISD is from the subjective symptom based demonstration, clinicians are still trying to find objective parameters to diagnose this condition. Although there is no single, definite criteria for the presence of ISD until now, the most frequently used objective measure are the LPP and the MUCP. McGuire [12] retrospectively determined the relationship of high surgical failure with low MUCP of 20 cm water or less. And in his later study, he determined that VLPP of 60 cm water or less correlated well with ISD and suggested that LPP correlate well with severity of incontinence [13]. However, both of these methods also lack of general consensus of exact measurement and often cannot discriminate ISD. Thereby, it is not considered that we can accurately diagnose ISD by LPP and it is difficult to use LPP to help in surgical decision because of non-standardization. Several technical factors like catheter size, patient position and bladder volume at Valsalva maneuver may influence the VLPP measurement. Several reports represented the cumulative association of severity of symptoms with previous low LPP in SUI patients which is the same result from our present study [14,15]. They also reported that the majority of patients with severe symptoms and previous surgery had low LPP values.

Many factors are related with the development of ISD that is commonly associated with old age and previous pelvic surgery. The etiologies associated with ISD could predict the presence of ISD. Advanced age greater than 50 years and prolonged menopausal status with estrogen withdrawl which can cause loss of urethral vascularity and insufficient urethral mucosal coaptation, are considered to be the risk factors for the presence of ISD [16,17]. Previous hysterectomy, prolapse surgery, radical pelvic surgery may have an impact on the urethral function due to the denervation and devascularization of the urethra after extensive urethral dissection [18]. Extensive urethral fibrosis and scarring of adjacent suburethral tissue from pelvic radiation can cause this condition. ISD should be suspected based on the patient history taking and the severity of urinary incontinence. From the study of meta-analysis of the literature, Jensen et al. [19] reported that patient history is useful screening tool for those requiring further evaluation. Nitti and Combs [20] investigated the correlation between symptoms of SUI with urethral function measured by VLPP in women with ISD. They reported that the subjective degree of SUI can predict IDS and high grades of SUI have a high probability of low VLPP measurement. Considering invasiveness and discomfort of patient during performing UDS to diagnose ISD and economic burden of this study, predicting the ISD in patients with SUI would be very helpful from the clinical factors.

In this study, we investigated the preoperative clinical factors that can predict the severity of SUI and the presence of ISD to reduce the inconvenience of this methodologic tool of UDS. We found only subjective symptom was the independent factor that can predict the low VLPP (60 cm water or less) in SUI women. Knowing of the factors that can predict ISD from the clinical features in women with SUI, it could help the clinician exact counsel the patients before surgery about the high possibility of variable surgical result and may influence the choice of other operative procedure in these patients. As a limitation, we could not see the correlation of various clinical factors with MUCP which may provide additional result, and neither correlation
between MUCP and VLPP. In conclusion, high symptom grade was the only independent clinical factor that predicted the presence of ISD. This should be considered when counseling the patients with SUI.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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