

Effectiveness of Baclofen Plus Terazosin Treatment in Patients with Lower Urinary Tract Symptoms Caused by Spastic Urethral Sphincter

Hann-Chorng Kuo

Department of Urology, Buddhist Tzu Chi General Hospital, Hualien, Taiwan

ABSTRACT

Objective: To compare the effectiveness of treatment with baclofen alone or baclofen combined with terazosin in patients with spastic urethral sphincter. **Materials and Methods:** In a consecutive series of 580 patients with lower urinary tract symptoms (LUTS), spastic urethral sphincter was diagnosed as the cause of voiding symptoms in 137 patients (61 men and 76 women). These 137 patients were treated with baclofen 10mg t.i.d alone or in combination with terazosin 2 mg q.d. for at least 3 months. Baseline and post-treatment international prostate symptom score (IPSS), maximal flow rate (Q_{max}), and residual urine amount were assessed and compared. **Results:** Among the 137 patients, improvement in both IPSS and Q_{max} at the end of 3 months was found in 68 (49.6%), and in IPSS alone in 25 (18.2%). The total success rate was 67.9%. There was no significant difference in the total success rate between men (67.2%) and women (68.5%). However, a significantly higher success rate was found in the patients treated with combined baclofen and terazosin (82.8%) compared to those treated with baclofen alone (52.7%). **Conclusions:** In this series, spastic urethral sphincter was the most common cause of LUTS in non-obstructive men (54.5%) and was also highly prevalent in women with frequency urgency syndrome (29.7%). Treatment of spastic urethral sphincter disease with combined baclofen and terazosin is effective and has a higher success rate than baclofen alone in both men and women. (*Tzu Chi Med J* 2000; 12:141-148)

Key words: spastic urethral sphincter, lower urinary tract symptoms, voiding dysfunction

INTRODUCTION

Lower urinary tract symptoms (LUTS) are a frequent complaint in patients visiting urological clinics. Bladder outlet obstruction (BOO), stress urinary incontinence (SUI), and detrusor instability, sensory urgency, and detrusor underactivity are the most common causes of LUTS in neurologically intact men and women [1,2]. In addition to these causes, spastic urethral sphincter contributes in part to LUTS [3]. Previous studies have shown that repetitive discharges of the external striated sphincter may result in chronic urethral obstruction in women [4]. Although this disease might be a learned

habit from early childhood, it could also be a somatic response to psychological effect [5]. Identification of urethral spincteric spasticity is important. It can coexist with benign prostatic hyperplasia (BPH) or bladder neck dysfunction in men. If this pathology is not diagnosed accurately, surgery for BPH or bladder neck dysfunction will not be as effective as in those patients with true BOO. In women, spastic urethral sphincter can result in recurrent cystitis and severe frequency and dysuria which are refractory to treatment. Identification of this disease and proper medication can effectively alleviate recurrent urinary tract infection and LUTS.

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Address reprint requests and correspondence to: Dr. Hann-Chorng Kuo, Department of Urology, Buddhist Tzu Chi General Hospital, 707, Section 3, Chung Yang Road, Hualien, Taiwan



However, diagnosis of spastic urethral sphincter is not easy since the results of uroflowmetry, cystometry, cystoscopy, pressure flow study, or electromyography (EMG) alone are inconclusive [2]. Videourodynamic study, by combining voiding cystourethrography (VCUG) and pressure flow study, can effectively reveal the underlying pathology [6]. Through analysis of the pressure, flow, EMG, and urethral opening during the voiding phase, poor relaxation of the external sphincter can be clearly delineated.

A variety of treatments for spastic urethral sphincter have been reported with varying degrees of success including oral skeletal muscle relaxants such as diazepam [1,7] and baclofen [8], estrogen and urethral dilatation [9], and biofeedback. However, because previous reports of treatment using these methods were not based on the results of videourodynamic studies, it is not certain whether all of the patients treated actually had spastic urethral sphincter. This study prospectively determined the VCUG and pressure flow characteristics in a group of men and women with spastic urethral sphincter. These patients were treated according to the presenting abnormalities in the bladder and urethral conditions indicated by these studies.

MATERIALS AND METHODS

From October 1997 to August 1999, 580 neurologically normal patients were referred to the videourodynamic laboratory for diagnostic assessment of LUTS. None of these patients had frank neuropathy, urinary retention, and diabetes mellitus. Over active urinary tract infection. All of the patients underwent a standard videourodynamic study and a diagnosis was made according to the VCUG and pressure flow results.

During the videourodynamic study, fluid containing contrast media was infused via a double lumen transurethral catheter. In the women, the intravesical pressure was recorded by an 18G epidural catheter placed transurethral throughout the entire study. In the men, the intravesical pressure was recorded initially by the transurethral catheter during the filling phase and was shifted to a suprapubic 18G epidural catheter placed by suprapubic puncture during the voiding phase. Intra-abdominal pressure was recorded by a 10 Fr rectal balloon catheter. External sphincteric EMG was recorded by two perianal surface electrodes. A C-arm X-ray was used for image recordings of the filling and voiding phases.

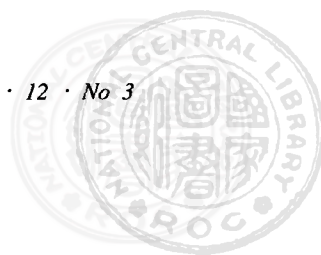
Definition of BOO in men was based on the provisional International Continence Society definition of obstruction [10]. In patients with equivocal low pressure and low flow results, the features of the bladder

neck, prostatic urethra, and sphincteric EMG activity during videourodynamic study were used for diagnosis of detrusor and urethral conditions. When the external sphincteric EMG was silent during the voiding phase in combination with a low voiding pressure, a low flow rate was regarded as due to detrusor underactivity in the non-obstructive bladder outlet. However, if the sphincteric EMG showed intermittent activity during the voiding phase and VCUG showed a narrow membranous urethra, the low flow rate was regarded as due to low detrusor contractility caused by a spastic urethral sphincter [11]. (Fig. 1)

In women, BOO was defined as a high voiding pressure (P_{det}) of ≥ 50 cmH₂O and a low maximum flow rate (Q_{max}) of <12 mL/s [9]. External sphincter EMG was carefully monitored to assess the coordinated response to bladder filling and emptying. If the EMG activity showed no relaxation in combination with a sustained low P_{det} and low Q_{max} during the voiding phase, spastic urethral sphincter was diagnosed (Fig. 2). In patients with a high P_{det} and a narrow distal urethra on VCUG, but no definite endoscopic evidence of urethral stricture, pseudodyssynergia of the urethral sphincter was diagnosed [1,9,11].

After the videourodynamic study, all patients with a diagnosis of spastic urethral sphincter were treated with oral baclofen 10 mg three times daily. Regular urethral dilatation was performed in addition to medication for women with a diagnosis of pseudodyssynergia [9]. Among all 137 patients with a diagnosis of spastic urethral sphincter, 64 were randomly assigned to receive terazosin 2 mg once daily in addition to baclofen. No other medication was added to the treatment regimen for those presenting with hypersensitive bladder.

Patients were educated about the possible underlying pathophysiology of their LUTS and reassured that the disorder posed no risk to their general health. The therapeutic results were reassessed at least 3 months after the initial treatment. Patients were requested to report therapeutic results. The International Prostatic Symptom Score (IPSS), Q_{max} , and residual urine amount were assessed. Improvement of IPSS and Q_{max} was defined as more than a 50% improvement in IPSS and an increase in Q_{max} by at least 1.5 mL/s. If the improvement was less, the change was considered stationary. IPSS, Q_{max} , and residual urine were compared at baseline and post-treatment. The results for patients who were treated with baclofen alone and those treated with combined baclofen and terazosin were also compared. The therapeutic result was considered successful if patient had improvement in both IPSS and Q_{max} (objective improvement) and improvement in IPSS alone



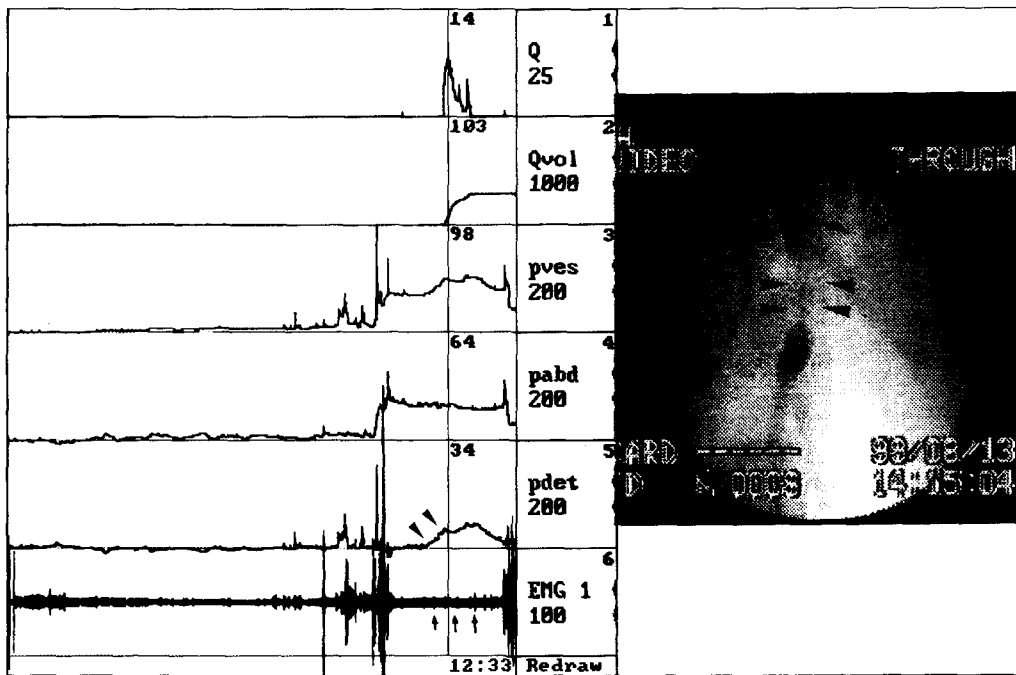


Fig. 1. Spastic urethral sphincter and low detrusor contractility in a 65-year old man. Videourodynamic study shows an open bladder neck and prostatic urethra (small arrows), but narrowing of the membranous urethra (large arrow heads) during voiding. A gradual elevation of Pdet (small arrow heads) and a poorly relaxed urethral sphincter are noted before urine started to flow. (small arrows)

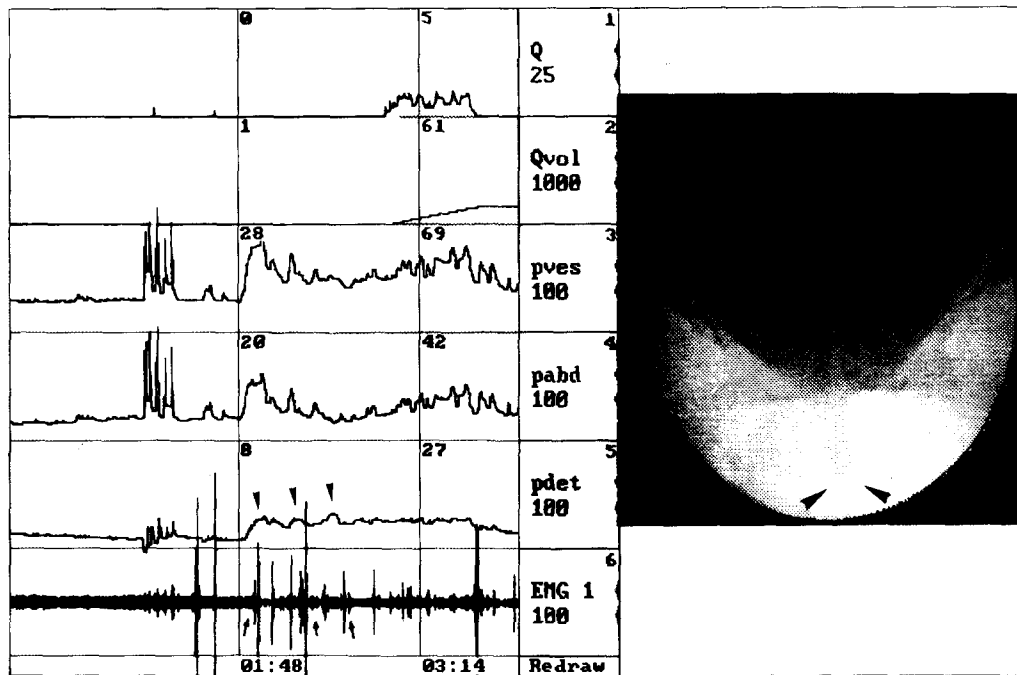


Fig. 2. Spastic urethral sphincter resulted in a normal pressure low flow tracing in a 45-year old woman presenting with hesitancy, frequency, dysuria, and residual urine sensation. When voiding is attempted, intermittent sphincteric EMG activities are persistent (small arrows), causing a low detrusor pressure (small arrow heads). A low Qmax is noted during the voiding phase due to incomplete sphincteric relaxation as shown in VCUG throughout the voiding phase (large arrow heads).



(subjective improvement). Paired t-test and Student's t-test were used to determine the significance of differences between groups. A p value of <0.05 was considered statistically significant.

RESULTS

A total of 580 consecutive patients with LUTS were studied. There were 324 men (48 to 86 years old, mean 68.0 ± 7.5 years) and 256 women (10 to 92 years old, mean 56.1 ± 13.9 years).

After videourodynamic studies, BOO was diagnosed in 212 men whereas 112 men had no evidence of urodynamic obstruction. Spastic urethral sphincter was diagnosed in 61 men (18.8% of all men with LUTS, and 54.5% of non-obstructive men) who exhibited a low pressure and low flow tracing and typical narrow membranous urethra on VCUG. Of the 256 women, spastic urethral sphincter was found in 76 (29.7%) and 25 women were demonstrated to have BOO. Among the 25 women with BOO, 9 (36%) were considered to have pseudodyssynergia of the external sphincter. These 9 patients were not included in the final analysis because they had BOO and were treated both medically and with urethral dilatation.

At the end of the study, IPSS was determined by questioning all patients and investigating with uroflowmetry. As shown in the Table 1, the post-treatment val-

ues of IPSS, Qmax, and residual urine showed significant improvement in both men and women compared with baseline values. Comparison of the results between the patients treated with baclofen alone ($n=73$) and the patients treated with combined baclofen and terazosin ($n=64$) showed that the latter group had significantly greater improvement in IPSS and Qmax after treatment (Table 2). However, no significant difference was found in reduction of residual urine between the two treatment groups. The combination treatment group had a significantly higher objective success rate in improvement of IPSS and Qmax (67.2% v 32.2% , $p<0.05$) and higher total success rate (82.8% v 52.7% , $p<0.05$) than the baclofen group.

Analysis of the results for the 137 patients with spastic urethral sphincter revealed that 68 (49.6%, 26 men and 42 women) showed an improvement in voiding symptoms as measured by both IPSS and uroflow. There were 25 patients (18.2%, 15 men and 10 women) who had a stationary uroflow but an improvement in IPSS. The remaining 44 patients (32.1%, 20 men and 24 women) had no change in either IPSS or uroflow. The overall success rate was 67.9%. There were 17 patients (12.4%) who experienced side effects of dizziness and asthenia, however, after explanation all of them could tolerate and continue taking the medications. There was no significant difference in the success rate between male (67.2%) and female patient (68.5%) groups.

Table 1. Comparison of IPSS, Qmax and residual urine before and after medical treatment in all patients*

	IPSS		Qmax		Residual urine	
	Baseline	Treated	Baseline	Treated	Baseline	Treated
Men (61)	17.5 \pm 7.1	9.9 \pm 3.7	13.3 \pm 11.5	17.7 \pm 8.3	71.7 \pm 23.5	33.5 \pm 31.9
p value	<0.05		<0.05		<0.05	
Women (76)	11.3 \pm 7.4	7.2 \pm 6.3	15.5 \pm 10.3	20.7 \pm 7.4	54.5 \pm 32.1	35.3 \pm 21.5
p value	<0.05		<0.05		<0.05	

*: Paired t test

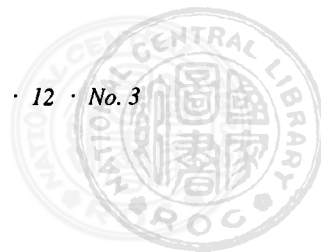
IPSS: International Prostatic Symptom Score; Qmax: maximal flow rate

Table 2. Comparison of IPSS, Qmax and residual urine before and after medical treatment in the two treatment groups

	IPSS		Qmax		Residual urine	
	Baseline	Treated	Baseline	Treated	Baseline	Treated
Baclofen ($n=73$)	15.2 \pm 6.7	10.4 \pm 5.7	14.3 \pm 9.7	16.7 \pm 8.1	65.7 \pm 33.9	37.5 \pm 21.7
% of change	31.6 \pm 21.5		16.8 \pm 12.7		42.9 \pm 34.1	
Baclofen plus Terazosin ($n=64$)	12.7 \pm 7.9	6.1 \pm 4.5	14.8 \pm 11.0	22.6 \pm 7.5	58.1 \pm 21.8	31.1 \pm 31.2
% of change	51.9 \pm 27.4		52.7 \pm 31.1		46.5 \pm 29.3	
Statistics*	$p < 0.05$		$p < 0.05$		NS	

*: Student's t-test

IPSS: International Prostatic Symptom Score; Qmax: maximal flow rate



DISCUSSION

This study demonstrates that spastic urethral sphincter is the most common cause of LUTS in non-obstructive men, and also is highly prevalent in women with LUTS. Treatment of this disease with combined skeletal muscle relaxants and alpha-1 adrenergic blockers had a high success rate (82.8%) both in men and women.

Abnormalities in the bladder and urethra frequently occur in combination. Urination is a synchronized action of urethral sphincteric relaxation and detrusor contraction. Voluntary coordinated external sphincter relaxation completes the voiding process [11]. A poorly relaxed external sphincter can inhibit a forceful detrusor contraction through inhibiting the detrusor nucleus in the micturition center at the sacral cords [12]. Psychogenic factors can also affect sphincteric relaxation. Women with urinary retention may have multiple somatic complaints [13]. A surprising elevation of the hysteria and hypochondriasis scales has also been reported among the women with urethral syndrome, indicating the importance of emotional effects on the external sphincter [14].

Spastic urethral sphincter comprises 54.5% of cases of non-obstructive LUTS in men in this study. An incidence of pseudodyssynergia has been reported in 24% of the population younger than 50 years old with LUTS [15]. This condition may coexist with BPH or bladder neck dysfunction. If this pathology is not treated properly, surgery for BPH or bladder neck dysfunction is not as effective as in those with benign prostatic obstruction [16].

Low detrusor contractility in women might result from true detrusor underactivity or reflect the influence of spastic urethral sphincter. In this study, 29.7% of women with LUTS had spastic urethral sphincter. Although dysuria may not be the predominant complaint in women with LUTS, spastic urethral sphincter may be a contributing factor in their symptoms. Interestingly, in the 25 women who had both high pressure and low flow BOO, 9 cases were considered to have resulted from pseudodyssynergia of the external sphincter. Chronic abnormal activities of the urethral sphincter may lead to sphincter contraction during voiding and cause urethral obstruction. Long-term sphincteric spasm can cause the voiding pressure to increase gradually and result in high-pressure voiding and secondary bladder changes [5-7,17]. Without awareness of this underlying pathology, medication for the treatment of LUTS is unlikely to be effective.

To prevent confusion between obstructive and non-obstructive urethral sphincteric conditions, in this study, the term "pseudodyssynergia" was used only for chronic

urethral sphincteric hyperactivity that resulted in high voiding pressure and BOO. Spastic urethral sphincter referred to a condition with low voiding pressure, low flow and a non-relaxing urethral sphincter.

A diagnosis of spastic urethral sphincter should not be made based on any single conventional urodynamic study. Combined cystometry and sphincteric EMG or combined uroflowmetry with EMG have been reported to achieve a diagnosis of spastic urethral sphincter [1,7]. However, diagnosis by combined uroflowmetry and EMG might not be possible because there is often a disparity between the response in the EMG signals that makes interpretation difficult [18]. Because of this problem, a combination of pressure, flow, EMG, and VCUG provides the most accurate diagnostic method for this disease.

Surface EMG measures electrical activity in groups of perineal muscles that may or may not be indicative of the activity of the external urethral sphincter. Disparity has been reported between the EMG findings in the different perineal muscles [17]. However, it is unclear whether the external urethral sphincter is composed of only the periurethral and intraurethral striated muscles or whether the entire group of perineal muscles acts as the sphincter. Except in instances of perineal injury or selected neuropathy, an electrode placed near the external anal sphincter may be assured to provide a similar response to that taking place in the external urethral sphincter [19].

During videourodynamic study, intraurethral catheterization might induce poor relaxation in the external sphincter and impede urinary flow [20]. To reduce this interference to a minimum, in the present study, a small suprapubic catheter was used in men and a transurethral 18G catheter was used in women during the voiding phase. Surface EMG electrodes should be carefully applied to prevent urine contamination. Disconnection of the electrodes, or improper positioning of the electrodes that can make the results unreliable during the voiding phase, especially in women with LUTS [21]. To eliminate artifacts resulting from improper placement, testing and re-testing should be done prior to videourodynamic study. The cine-fluoroscopic feature can further provide clear information about spastic urethral sphincter.

The satisfactory success rate (67.9%) in treating spastic urethral sphincter in this study indicates that accurate diagnosis is of the utmost importance for effective treatment of this disease. Baclofen is a skeletal muscle relaxant that has been shown to have both a central and peripheral effect on the skeletal muscles [8,22]. Intra-theal incision of baclofen in paraplegics has been



shown to successfully reduce spasticity of the extremities and voiding dysfunction [23]. However, the therapeutic effectiveness of oral baclofen has been considered doubtful because of its unpredictable absorption and systemic side effects. Although the response to baclofen is controversial because of its polysynaptic inhibitory effect, it has been successfully used in treating both sphincter spasticity and bladder hyperactivity [24]. The results of this study show that baclofen is effective in the treatment of spastic urethral sphincter. Baclofen treatment was found to be significantly more effective when combined with an alpha-adrenergic blocker. The effectiveness of an alpha-adrenergic blocker in treating women with prostatism-like symptoms remains controversial [25]. However, women with prostatism-like symptoms may include a large portion of patients without spastic urethral sphincter. Previous investigations have also revealed that the external sphincter is partially innervated by sympathetic nerves [12]. These theories support the therapeutic regimen using baclofen and an alpha-adrenergic blocker in treating a spastic urethral sphincter. The high success rate in this study suggests this combination treatment is rational and is better than a single medication.

CONCLUSIONS

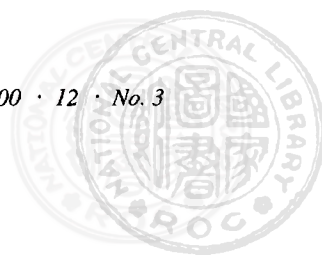
The role of the external urethral sphincter is essential to normal micturition. This sphincter has been considered the "on-off" switch for voiding [26]. Although spastic urethral sphincter might not result in obstructive uropathy in the short term, its effects on quality of life might be equal to that of BOO. Urologists often ignore non-obstructive diseases and treat them arbitrarily without understanding the underlying pathophysiology of LUTS. This study has demonstrated that the external sphincter plays an important role in LUTS and any abnormalities should be carefully diagnosed and treated. In this regard, videourodynamic study offers a good diagnostic tool for this often overlooked disease. The results of this study suggest effective treatment for spastic urethral sphincter should involve a combination of a skeletal muscle relaxant and an alpha-adrenergic blocker.

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以Baclofen及Terazosin治療因尿道括約肌痙攣造成之下尿路症狀之效果

郭漢崇

佛教慈濟綜合醫院 泌尿科

摘要

目的：比較使用baclofen與合併使用baclofen及terazosin對於治療尿道括約肌痙攣之效果。**材料與方法：**在一系列有下尿路症狀之580位病人中，有137位(61為男性、76為女性)診斷為尿道括約肌痙攣。這些病人隨機分為單獨以baclofen 10 mg t.i.d.治療，以及合併使用terazosin 2 mg q.d.及baclofen 10 mg t.i.d.治療兩組，治療時間至少3個月。以治療前及治療後之國際前列腺症狀積分(IPSS)，最大尿流速(Qmax)，以及殘尿量作評估及比較兩組治療效果。**結果：**在所有137位病人中，在治療3個月後有68位(49.6%)IPSS及Qmax均有進步，25位(18.2%)只有IPSS單獨進步，全部治療成功率為67.9%。男性(67.2%)與女性(68.5%)的成功率並無統計上之意義。然而，使用baclofen及terazosin合併治療的病人，其成功率比單獨使用baclofen治療的病人為有意義的高(82.8% vs 52.7%， $p<0.05$)。**結論：**本研究顯示，尿道括約肌痙攣是男性非尿道阻塞之下尿路症狀最常見的原因(佔54.5%)，而且也是造成女性下尿路症狀常見的原因(29.7%)。合併使用baclofen及terazosin在男性及女性均可以得到有效的治療成功率。(慈濟醫學 2000; 12:141-148)

關鍵語：尿道括約肌痙攣，下尿路症狀，排尿困難

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抽印本索取及聯絡地址：花蓮市中央路3段707號 佛教慈濟綜合醫院泌尿科 郭漢崇醫師

