Preliminary Report

A Role of Intravesical Capsaicin Instillation in Benign Prostatic Hyperplasia with Overactive Bladder Symptoms: The First Reported Study in the Literature

Phitsanu Mahawong MD*, Bansithi Chaiyaprasithi MD*,
Suchai Soontrapa MD*, Pimolvan Tappayuthapijarn MS**

** Division of Urology, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok*
*** Department of Pharmacology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok*

Objective: *To study the treatment efficacy of capsaicin, in the cases of benign prostatic hyperplasia with overactive bladder symptoms.*

Material and Method: *A prospective study of 20 benign prostatic hyperplasia patients whose overactive bladder symptoms were not improved by alpha1 blockers. All of them underwent intravesical capsaicin instillation at the Faculty of Medicine Siriraj Hospital, Bangkok, between 2004 and 2006. Both clinical and urodynamic data were evaluated before and after treatment.*

Results: *Mean urgency decreased from 6.7 $\pm$ 5.1 at baseline to 2.0 $\pm$ 2.3 ($p < 0.005$), 1.4 $\pm$ 2.4 ($p < 0.005$), and 1.3 $\pm$ 2.2 ($p < 0.005$) at 1, 3, and 6 months. Mean urge incontinence decreased from 1.7 $\pm$ 3.5 at baseline to 0.5 $\pm$ 1.3 ($p = 0.148$), 0.4 $\pm$ 1.2 ($p = 0.114$), and 0.3 $\pm$ 1.1 ($p = 0.085$) at 1, 3, and 6 months. Mean urinary frequency decreased from 13.7 $\pm$ 3.3 at baseline to 10.5 $\pm$ 2.8 ($p < 0.005$), 9.6 $\pm$ 2.0 ($p < 0.005$), and 9.5 $\pm$ 2.6 ($p < 0.005$) at 1, 3, and 6 months. Mean nocturia decreased from 4.7 $\pm$ 2.4 at baseline to 3.1 $\pm$ 2.2 ($p < 0.005$), 2.7 $\pm$ 1.2 ($p < 0.005$), and 2.9 $\pm$ 1.6 ($p < 0.005$) at 1, 3, and 6 months. Mean first desire to void increased from 172.5 $\pm$ 100.4 ml at baseline to 210.6 $\pm$ 99.5 ml ($p = 0.016$) at 1 month. Mean maximal cystometric capacity increased from 350.3 $\pm$ 165.9 ml at baseline to 397.4 $\pm$ 165.7 ml ($p = 0.012$) at 1 month. Peak flow rate, detrusor pressure, and post void residual urine were not affected. No serious adverse effect occurred in this study.*

Conclusion: *Intravesical capsaicin instillation is an effective treatment for overactive bladder symptoms in benign prostatic hyperplasia patients.*

Keywords: *Capsaicin, Benign prostatic hyperplasia, Overactive bladder*

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The overactive bladder (OAB) is commonly found in urological practice and causes a much disabling condition affecting heath-related quality of life. The overall prevalence is 16-29.9% in men[1,2]. In the fact that benign prostatic hyperplasia (BPH) patients may have various degrees of lower urinary tract symptoms (LUTS) consisting of storage, voiding and post micturition symptoms. The storage symptoms are a common reason of BPH patients to look for medical treatment[3]. OAB represents a recently defined constellation of storage LUTS that includes urinary urgency with or without urge incontinence, frequency and nocturia[4]. Although OAB is undoubtedly associated with bladder outlet obstruction (BOO), the pathophysiological mechanism has not exactly been proposed[5]. Detrusor overactivity (DO) is highly prevalent (52%) in patients with BOO and usually produces OAB

Correspondence to : Mahawong P, Division of Urology, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkoknoi, Bangkok 10700, Thailand. Phone: 0-2419-8010, Fax: 0-2411-2011, E-mail: phitsanumahawong @yahoo.com

symptoms[6]. Many reports have demonstrated the pathophysiology of DO in BPH and abnormally activated c-afferent fiber pathway which seemed to be the one of primary etiology[7-9].

Although alpha1 blocker reduces obstructive symptoms till satisfaction in the majority of BPH patients, their OAB symptoms have been found persistently about 65% after treatment[10]. Capsaicin, 8-methyl-N-6-nonenamide, is extracted from hot pepper chili, available in many countries, and has been widely used in clinical practice[11-13]. Intravesical capsaicin instillation is an effective treatment for OAB, specifically targets on vanilloids receptor1 in urinary bladder wall in order to desensitize afferent c-fiber [14,15]. The authors prospectively studied the efficacy of capsaicin in treating OAB symptoms in BPH patients.

Material and Method

Twenty-five BPH patients treated with optimum dose alpha1 blocker for at least 1 month, whose OAB symptoms persisted, were recruited. They were enrolled during 2004-2006 at the Division of Urology, Department of Surgery, Siriraj Hospital, Mahidol University, Bangkok, Thailand. All of them were informed, and the consent form had been approved by the Ethics Committee of Siriraj Hospital institute. None of them had been received any drugs that influenced the bladder function at least 2 weeks prior to the present study. The exclusion criteria were patients with neuropathic bladder, urinary tract infection, bladder tumor, post surgery, or radiation of prostate and/or bladder, bladder outlet obstruction from other conditions such as prostate cancer, urethral stricture or contracture bladder neck, and finally a plan for prostate surgery. Patients with International Prostate Symptoms Score (IPSS) less than 9, maximal flow rate (Qmax) from uroflowmetry (UFM) less than 10 ml/s and prostate volume less than 20 ml were excluded from the present study. Before intravesical capsaicin instillation, complete history taking for OAB symptoms, physical examination and digital rectal examination, blood for serum BUN, creatinine, FBS and prostate specific antigen (PSA), urine analysis, IPSS score, three-days voiding diary, transrectal ultrasound (TRUS) prostate, urethrocystoscopy, UFM and post void residual urine (PVR), urodynamic study (UDS) (Dantec instrument) were completed.

Capsaicin for the present study was obtained from the Department of Pharmacology, Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand. The 14 F Foley catheter was inserted and the bladder filled with 2% xylocaine solution without adrenaline 40 ml for 30 minutes, and then evacuated out. Intravenous fentanyl 0.05-0.1 mg injection and oral etoricoxib 120 mg were given together to relieve pain during the instillation process. The bladder was filled with capsaicin solution 100 ml (concentration 1 m M/L in 30% ethanol) for 30 minutes and then washed out with normal saline. In addition to vital sign and side effect recording, the patients were asked to estimate the pain score during capsaicin instillation in a visual analogue scale (0 was no discomfort and 10 was an intense pain requiring either more analgesic treatment or bladder emptying). The Foley catheter was removed at the end of the study and 5-days of oral antibiotics were given to all patients.

Alpha1 blockers were continued throughout the present study. 1, 3, and 6 months after treatment, the patients were reevaluated for OAB symptoms and UFM with PVR. UDS was performed at least one time after treatment in the first 3 months follow up. First desire to void (FDV), maximal cystometric capacity (MCC), detrusor pressure at MCC (PdetMCC) and detrusor pressure at Qmax (PdetQmax) were recorded for later analysis. DO was defined as an urodynamic observation characterized by involuntary detrusor contractions during the filling phase which may be spontaneous or provoked[4]. Pre and post therapy data were presented as the mean value with standard deviation and compared for statistical purpose by two-tailed ANOVA with repeated measurement and paired *t*-test for means. The p-value < 0.05 was considered statistically significant.

Results

Twenty out of twenty-five patients had been completely followed up data and analyzed in the present study. 50% (10/20) of them received anticholinergical treatment and experienced any degree of adverse drug reaction such as dry mouth, headache, blurred vision, and dizziness. The patients' characteristics are demonstrated in Table 1 and 2. All of the complications spontaneously resolved themselves with symptomatic treatment. None of them had acute urinary retention in the present study (Table 3). Mean pain score was 8.8 ± 1.2 and no patients needed regional or general anesthesia to relieve pain during instillation.

OAB symptoms

Urgency symptoms decreased in 90% (18/20) of the patients after instillation. Mean urgency decreased from 6.7 ± 5.1 at baseline to 2.0 ± 2.3 ($p < 0.005$)

Table 1. Characteristics of 20 patients before treatment

	Mean ± SD (range)
Age (years)	62.3 ± 7.0 (51-74)
IPSS score	18.8 ± 3.4 (13-25)
PSA (ng/mL)	1.3 ± 0.9 (0.2-3.9)
Prostate volume (mL)	30.6 ± 9.1 (20.0-58.9)
Duration of alpha1 blocker treatment (months)	22.9 ± 17.2 (3-60)

Table 2. Type of alpha1 blocker treatment

	Number of patients (%)
Alfuzosin	6 (30)
Doxazosin	7 (35)
Tamsulosin	7 (35)
Total	20 (100)

Table 3. Side effects from capsaicin instillation at 1 month follow-up

	Number of patients (%)
Dysuria, hematuria, urgency	1 (5)
Dysuria, hematuria	1 (5)
Dysuria	4 (20)
AUR	0 (0)
No	14 (70)
Total	20 (100)

at 1 month, to 1.4 ± 2.4 ($p < 0.005$) at 3 months and to 1.3 ± 2.2 ($p < 0.005$) at 6 months (Fig. 1). Urge incontinence was presented in 40% (8/20) of the patients and mean incontinence was decreased or disappeared in 87% (7/8) of patients. Surprisingly, 5% (1/20) of the patients developed de novo urinary incontinence after capsaicin treatment. Mean incontinence decreased from 1.7 ± 3.5 at baseline to 0.5 ± 1.3 ($p = 0.148$) at 1 month, to 0.4 ± 1.2 ($p = 0.114$) at 3 months and to 0.3 ± 1.1 ($p = 0.085$) at 6 months (Fig. 2). Frequency was demonstrated in all patients, which decreased in 16/20 (80%) patients. Mean frequency decreased from 13.7 ± 3.4 at baseline to 10.5 ± 2.9 ($p < 0.005$) at 1 month, to 9.6 ± 2.1 ($p < 0.005$) at 3 months and to 9.5 ± 2.6 ($p < 0.005$) at 6 months (Fig. 3). Nocturia was found in all patients and their degree decreased in 95% (19/20) of patients. Mean nocturia decreased from 4.7 ± 2.4 at baseline to 3.1 ± 2.2 ($p < 0.005$) at 1 month, to 2.7 ± 1.2 ($p < 0.005$) at 3 months and to 2.9 ± 1.6 ($p < 0.005$) at 6 months (Fig. 4).

Uroflowmetry and post void residual urine

Mean Q_{max} was 13.9 ± 4.1 ml/s at baseline. Post-treatment mean Q_{max} was 15.3 ± 5.8 ml/s ($p = 0.197$) at 1 month, 14.8 ± 5.6 mL/s ($p = 0.490$) at 3 months and 14.6 ± 5.0 mL/s ($p = 0.528$) at 6 months. No significant difference between both results was found. PVR was measured after UFM and 10% (2/20) of patients had high residual urine (100 mL, 110 mL) before treatment. Mean PVR was 19.3 ± 31.8 ml at pre-treatment. Post-treatment mean PVR was 23.3 ± 30.7 mL ($p = 0.675$) at 1 month, 18.4 ± 24.0 mL ($p = 0.923$) at 3 months, and 16.3

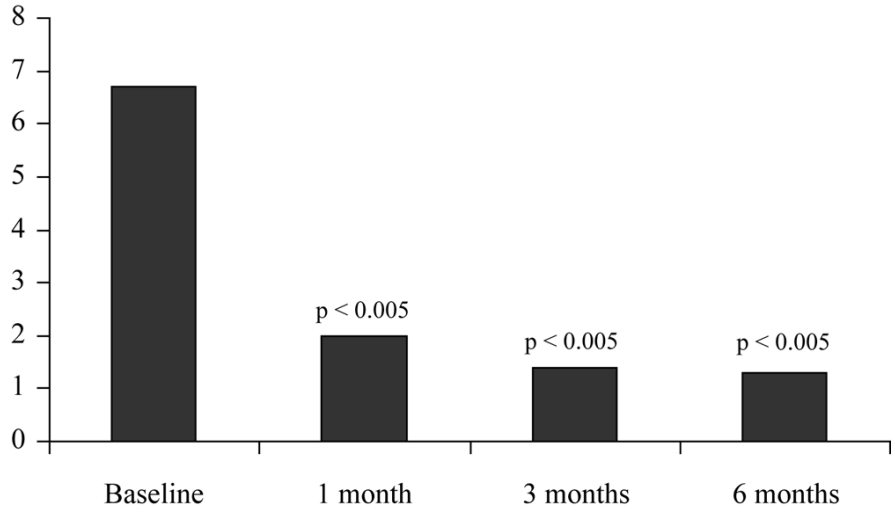

Fig. 1 Mean urgency at before and after treatment (times/day)

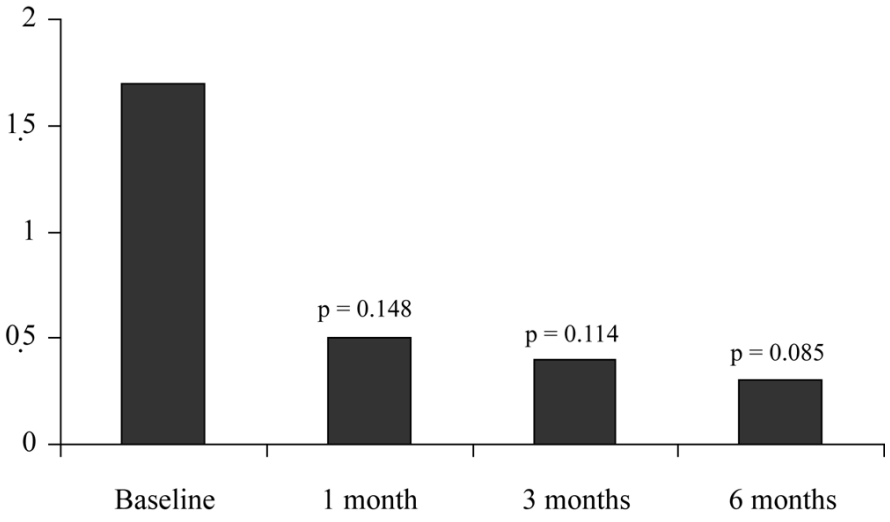

Fig. 2 Mean urge incontinence at before and after treatment (times/day)

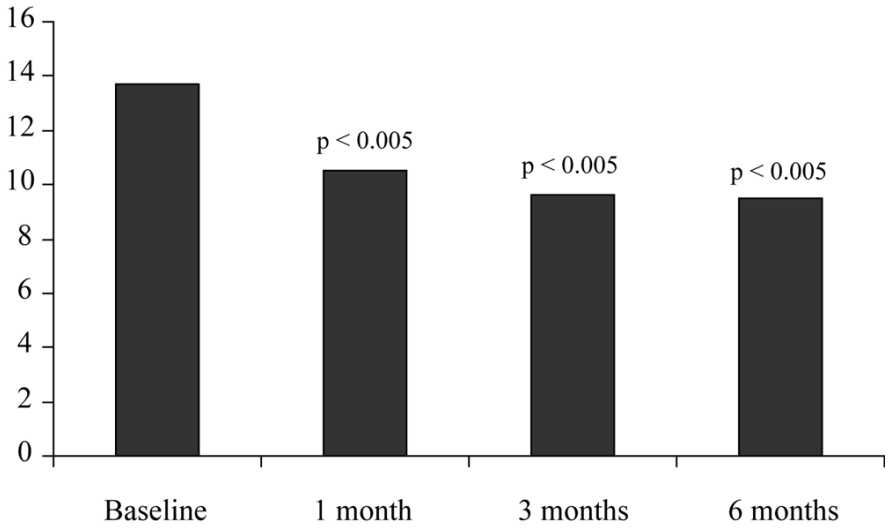

Fig. 3 Mean frequency at before and after treatment (times/day)

± 32.9 mL (p = 0.785) at 6 months. Mean PVR was not altered by capsaicin instillation.

Urodynamic study

FDV increased in 85% (17/20) of patients but decreased in the remaining group. Mean FDV increased from 172.5 ± 100.4 mL to 210.6 ± 99.5 mL (p = 0.016) at 1-3 months. MCC increased in 75% (15/20) of patients and mean MCC increased from 350.3 ± 165.9 mL to 397.4 ± 165.7 mL (p = 0.012) at 1-3 months (Fig. 5). Both FDV and MCC increased, significantly. DO was observed in 15% (3/20) of patients and disappeared in all after capsaicin treatment. Mean PdetMCC was not changed at pre and post treatment (47.9 ± 20.4 cmH_2O vs.48.2 ± 15.8 cmH_2O) (p = 0.873). Mean $PdetQ_{max}$ was 44.7 ± 15.3 cmH_2O and 42.7 ± 12.5 cmH_2O (p = 0.333) at baseline and post instillation, consecutively. There was no difference between both $PdetQ_{max}$ results.

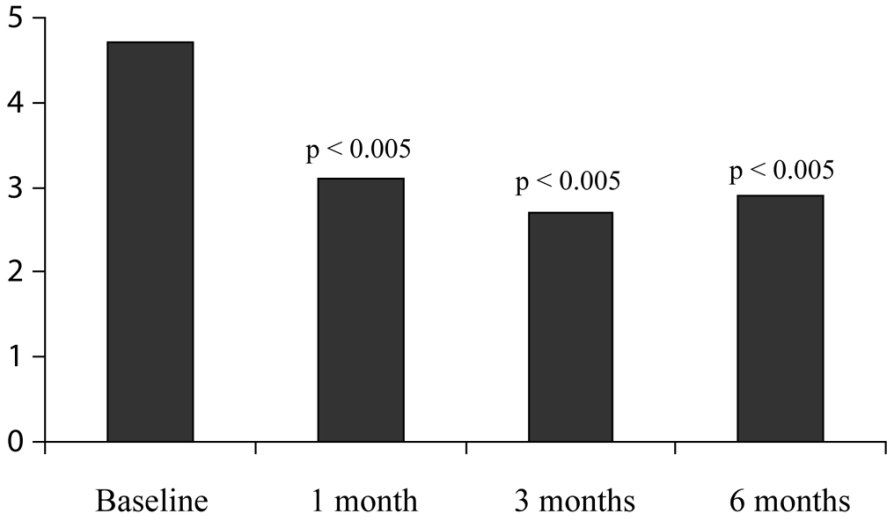

Fig. 4 Mean nocturia at before and after treatment (times/day)

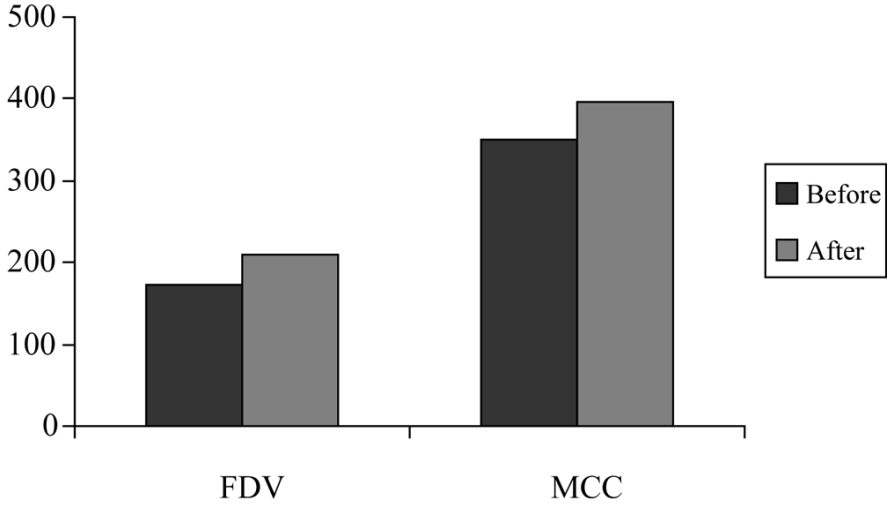

Fig. 5 Mean FDV and MCC at before and after treatment (mL)

Discussion

The estimated total economic cost of OAB in the United States was 12.02 billion USD per year as reported by Hu et al in 2000[16]. They provided the importance of this condition in society. Generally, the accepted causes of OAB include neurological illness or injury, bladder outlet obstruction (BOO), urethral weakness, detrusor hyperactivity and impaired contractility (DHIC), emergence of new voiding reflexes, and so-called idiopathic bladder overactivity[17]. BOO is caused by many etiologies and BPH is the most common among old age males. The exact pathophysiological correlation between BOO and OAB is still unclear.

In 1982, Chalfin A Stuart and William E Bradley studied bladder function in 44 BOO patients by gas cystometry, integrated sphincter electromyography, and UFM. Of these 44 patients, 18 demonstrated DO and prostatic block with lidocaine eliminated DO in 10 of 11 patients. Their study suggested that permanent ablation of sensory stimuli from the prostate in patients

with BOO would be of benefit[18]. A study in 40 patients with BOO from BPH accompanied with DO was performed by Cucchi A in 1988. No significant correlation was found between the severity of obstruction and the degree of DO, but the occurrence of DO did correlate with the degree of obstruction[19]. In 1996, Aton et al studied the correlation existing between prostate morphology and irritative symptoms in 52 BPH patients who underwent transurethral prostatectomy (TURP). They did not find any statistical correlation between these two data and may be indicated that irritative symptoms should rather be attributed to extraprostatic factors such as e.g. bladder reaction[20].

A few studies that supported activated c-afferent fiber pathway as an etiology of DO in BOO were conducted. Ice water test, a c-fiber trigger was evaluated by Chai et al in 1998[7]. A positive ice water test (IWT) was found in 71% of subjects with BOO, which was significantly higher than the 7% positive IWT rate in nonobstructed subjects. 47% of positive bladder cooling reflex in 104 patients with BOO due to BPH was demonstrated by Gotho et al in 1999[8]. Their study confirmed BOO may cause some alteration in the afferent neural function of the bladder, in particular of the c-afferent fibers. 27% positive IWT was observed in 127 BOO patients by Hirayama et al in 2003[9]. Additionally, the patients, who responded to IWT, had higher BOO indexes than did the nonresponders and had a smaller volume at MCC on UDS. The BPH patients clearly showed that DO was mainly due to active c-fiber stimulated by BOO and caused urgency and frequency-related symptoms. An experimental study was done by Schroder et al in 2003[21]. After 7 days of BOO cystometry without anesthesia was performed with female MNRI mice, the majority of which had an overactive voiding pattern with increased nonvoiding DO and without increased bladder weight. This observation suggested that major disturbances caused by BOO might lie on the afferent arm of the signaling pathway.

In medical practice, intravesical capsaicin instillation has been used for neurogenic DO and later introduced to idiopathic DO[11-13]. In 2003, Soontrapa et al tested the efficacy of Thai capsaicin in management of 14 OAB and 11 hypersensitive bladder patients[22]. Mean urinary frequency and incontinence statistically significant decreased after treatment. Bladder capacity increased without alteration in voiding pressure. They concluded that capsaicin efficacy was very high and had reasonable cost effectiveness, especially for developing countries.

To the best of our knowledge, this present study is the first study in the literature about capsaicin treatment for OAB symptoms in BPH patients. The presented patients had medium age and slightly enlarged prostate gland. Mean IPSS ranged in moderate symptoms and was mainly due to storage LUTS. Although the authors tried to use potent analgesic agent before instillation, the mean pain score was still high. General anesthesia is an alternative treatment for patients who cannot tolerate pain. The most common adverse event was dysuria, which was considered due to excitatory effects of capsaicin. The present results show that the blockade of c-fiber sensory input improves storage symptoms as long as 6 months after therapy. All OAB symptoms especially urge incontinence, significantly decreased from baseline after treatment. Statistically insignificant decreasing in incontinence may be due to too small a studied population of patients. Qmax and PVR were not altered after treatment and these findings suggested that capsaicin affects only afferent fiber (sensory) not efferent fibers (motor) pathway. Although two patients had high PVR before therapy, AUR did not occur in any participants after capsaicin instillation. This finding supports the assertion that capsaicin is safe in men with BPH. Increasing of both FDV and MCC in the presented patients improved their OAB symptoms and decreased their problems. Only three patients had pretreatment DO, which was lower than the incidence in other studies[6,10]. All of DO disappeared completely after treatment accompanied with improvement in OAB symptoms. This finding strongly supports the efficacy of capsaicin instillation for OAB in BPH patients. PdetMCC was not decreased, the same as the results from Soontrapa et al. Because PdetQmax was not affected so BOO is not altered by capsaicin instillation.

Resiniferatoxin (RTX), a substance isolated from some species of euphorbia (a cactus-like plant), was studied by Dinis et al in 2004[23]. This non-pungent analogue has the mechanism of action, c-fiber desensitization the same as capsaicin but has fewer excitatory actions. They investigated RTX treatment in12 BPH-associated storage LUTS patients. At 1, 3, and 6 months follow up, mean IPSS score, Quality of Life (QoL) score were significantly decreased. Mean frequency, FDV and MCC increased from baseline after treatment. Urge incontinence, which was present in six cases, disappeared in four patients and decreased to less than half in the others. UFM and PVR were not altered by RTX, the same as with the present results. Mean pain score was 3 during instillation, none asked for any kind

of analgesic medication. DO was not demonstrated in any patients but one case, and the sole patient with DO, maintained his same urodynamic pattern after RTX treatment. Cost and availability are the main disadvantages of RTX.

Combined treatment between alpha1 blocker and anticholinergical for BOO was prospectively studied by Athanasopoulos et al in 2003[24]. Fifty BOO patients concomitant with DO were randomly allocated into two groups. Twenty-five patients were treated with only tamsulosin and the others were treated with tamsulosin plus tolterodine. They concluded that combination treatment improved QOL, no AUR was observed, and tolterodine did not affect UFM and PVR. This combination appears to be an effective and relatively safe treatment option in patients with BOO and DO. At least two systematic reviews were reported and confirmed the role for anticholinergical drugs in BOO patients[25,26]. Dry mouth, the most common side effect of anticholinergical agents, may cause much water intake, which might enhance OAB symptoms. A new generation of this medication with fewer side effects is available but the cost remains high.

Recent data reported by Dinis et al in 2005 are so interesting. Eight prostates were harvested from cadaver transplant donors and immediately immersion fixed. They found that transient receptor potential subfamily vanilloid type 1 receptor (TRPV1) - immunoreactive nerve fibers were distributed throughout the prostatic urethral mucosa, verumontanum, ejaculatory ducts, and periurethral prostatic acini. They concluded that the existence of a rich TRPV1 sensory innervation in human prostate might open new therapeutic perspective for the treatment of pain in patients with chronic prostatitis[27]. In the authors' opinions, pathophysiological correlation between OAB in men and chronic prostatitis may coexist. Some effect from capsaicin instillation could be modulating prostatic urethral function and causes alteration in OAB symptoms.

Why did not all of the patients get symptoms improvement in the present study? Because abnormal activated c-afferent fiber pathway is not the sole pathophysiology for OAB symptoms in BPH patients, so the authors have to search for other etiologies and new treatment targets for a better outcome. A randomized controlled trial would be arranged later for the most accurate results about this challenging treatment.

Conclusion

In spite of BPH being concomitant with OAB symptoms it is quite common in medical practice, its exact pathophysiology is unclear and has no standard treatment. Bladder c-fiber afferent desensitization seems to be a key for treatment in these disabilitating patients. Based on the present study, intravesical capsaicin instillation is an effective and safe treatment without long-term adverse events. It is cost-effective therapy and generally available in many countries. Because capsaicin has uncomfortable pain during administration, the authors generally recommend it as an option for patients who have refractory symptoms after anticholinergical combination and do not give indication for prostate surgery.

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ประสิทธิภาพของแคพไซซินในการรักษาอาการกระเพาะปัสสาวะบีบตัวไวเกินในผู้ป่วยต่อมลูกหมากโต

พิษณุ มหาวงศ์, บรรณสิทธิ์ ไชยประสิทธิ์, สุชาย สุนทราภา, พิมลวรรณ ทัพยุทธพิจารณ์

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพของแคพไซซินในการรักษาอาการกระเพาะปัสสาวะบีบตัวไวเกินในผู้ป่วยต่อมลูกหมากโต*

วัสดุและวิธีการ: *ผู้ป่วยต่อมลูกหมากโตจำนวน 20 ราย ที่มีอาการกระเพาะปัสสาวะบีบตัวไวเกิน ไม่ดีขึ้นหลังจากได้รับยากิน alpha1 blocker ในขนาดที่เหมาะสม ผู้ป่วยทุกคนจะได้รับการรักษาด้วยการใส่สารละลายแคพไซซินความเข้มข้น 1 มิลลิโมลต่อลิตร ละลายใน 30% เอธานอล 100 มิลลิลิตร เป็นเวลาครึ่งชั่วโมง ผู้ป่วยทุกคนจะได้รับการตรวจติดตามผล ของการรักษาในแง่ของอาการและการตรวจทางยูโรพลศาสตร์ที่เวลา 1, 3 และ 6 เดือนหลังการรักษา*

ผลการศึกษา: *ค่าเฉลี่ยของอาการปัสสาวะรีบเร่งลดลงจาก 6.7 $\pm$ 5.1 ครั้งต่อวัน เหลือ 2.0 $\pm$ 2.5, 1.4 $\pm$ 2.4 และ 1.3 $\pm$ 2.2 ครั้งต่อวัน ที่เวลา 1, 3 และ 6 เดือนหลังการรักษาตามลำดับ ค่าเฉลี่ยของอาการปัสสาวะเล็ดราดลดลงจาก 1.7 $\pm$ 3.5 ครั้งต่อวัน เหลือ 0.5 $\pm$ 1.3, 0.4 $\pm$ 1.2 และ 0.3 $\pm$ 1.1ครั้งต่อวัน ที่เวลา 1, 3 และ 6 เดือนหลังการรักษาตามลำดับ ค่าเฉลี่ยของอาการปัสสาวะบ่อยลดลงจาก 13.7 $\pm$ 3.3 ครั้งต่อวัน เหลือ 10.5 $\pm$ 2.8, 9.6 $\pm$ 2.0 และ 9.5 $\pm$ 2.6 ครั้ง ต่อวัน ที่เวลา1, 3 และ 6 เดือนหลังการรักษาตามลำดับ ค่าเฉลี่ยของอาการปัสสาวะกลางคืนลดลงจาก 4.7 $\pm$ 2.4 ครั้ง ต่อวัน เหลือ 3.1 $\pm$ 2.2, 2.7 $\pm$ 1.2 และ 2.9 $\pm$ 1.6 ครั้งต่อวัน ที่เวลา1, 3 และ 6 เดือนหลังการรักษาตามลำดับ ผลการตรวจทางยูโรพลศาสตร์พบว่า ค่าเฉลี่ยความจุของกระเพาะปัสสาวะเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติ โดยไม่มีผลต่อค่าเฉลี่ยความเร็วสูงสุดของการปัสสาวะ ค่าเฉลี่ยปริมาณปัสสาวะเหลือค้างและความดันในกระเพาะ ปัสสาวะ*

สรุป: *แคพไซซินมีประสิทธิภาพในการรักษาอาการกระเพาะปัสสาวะบีบตัวไวเกินในผู้ป่วยต่อมลูกหมากโต*