

# Effect of *Baenong Ickki San* on Chronic Prostatitis/Chronic Pelvic Pain Syndrome: A Case Series

Yung-chan Kim, So-hyun Keum  
Cheungchoon Haniwon (Oriental Medicine Clinic)

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### ABSTRACT

**Objectives:** This case series reports the efficacy of *Baenong Ickki San*, a *Bojungikki-tang*-modified formula, in treating chronic prostatitis/chronic pelvic pain syndrome.

**Methods:** Patients diagnosed with chronic prostatitis/chronic pelvic pain syndrome (n=11) were treated with *Baenong Ickki San*. Changes in their condition were measured using the National Institutes of Health Chronic Prostatitis Symptoms Index (NIH-CPSI).

**Results:** NIH-CPSI scores showed a significant improvement in the disease. The mean NIH-CPSI total score significantly decreased from 37.6±5.8 at baseline to 7.5±3.9 at end point (p<0.001), i.e., a 30.2±7.3 mean decrease was noted.

**Conclusions:** *Baenong Ickki San* may be a potential new medicine for chronic prostatitis/chronic pelvic pain syndrome.

**Key words:** chronic pelvic pain syndrome (CPPS), *Bojungikki-tang*, Korean medicine, *Baenong Ickki San*

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## I. Introduction

Prostatitis is a common disease that about 10% of men suffer from once in their life time<sup>1</sup>. Among the four types of prostatitis classified by the National Institutes of Health (NIH), Chronic Prostatitis /Chronic Pelvic Pain Syndrome (CP/CPPS) which

belongs to category III takes 90~95% of prostatitis at clinically<sup>2</sup>. However, the causes and mechanisms of CP/CPPS are not yet fully understood<sup>3</sup>. CP/CPPS is diagnosed by its symptoms, such as pelvic pain, urinary symptoms lasting over 3 months without evidence of acute bacterial prostatitis or urinary tract infection during past 6 months<sup>4</sup>. CP/CPPS shows a variety of symptoms such as urinary frequency, urinary urgency, residual urine and weak urinary stream; pain in the pelvis, lower abdomen, perineum, or penis; sexual dysfunction<sup>3</sup>. Deterioration in the quality of life due to CP/CPPS can be

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· Corresponding author: Yung-chan Kim Cheungchoon Haniwon,  
1158-33 Jegi-dong, Dongdaemun-gu, Seoul,  
South Korea  
TEL: 82-02-966-1177 FAX: 82-02-964-2277  
E-mail: docy6921@hanmail.net

comparable with myocardial infarction, angina pectoris, Crohn's disease and diabetes mellitus<sup>5,6</sup>. CP/CPPS is known as a inflammatory disease, but its cause is unknown. Furthermore, it is hard for medicine to pass throughout prostate because of it's distinctive structural feature<sup>7</sup>. Despite lots of studies and hypothesis, suitable treatment for CP/CPPS is not yet exist<sup>5,8</sup>.

We have an effective result in treatment of CP/CPPS by regarding it as 'noh-rim (勞淋)<sup>9</sup>'. 'Noh-rim (勞淋)' is a name of disease from Treasured Mirror of Eastern Medicine (東醫寶鑑). It is one of the five subtypes of 'im-jeung (淋證)' in Korean Medicine (KM). Major symptoms of 'im-jeung (淋證)' are urinary symptoms<sup>9</sup>. Noh-rim (勞淋) has pelvic pain and sexual dysfunction as well as urinary symptoms which are accordance with diagnostic criteria of CP/CPPS. Also a cause of noh-rim (勞淋) is exhaustion of energies. Most of CP/CPPS patients who visit clinic for it do not show evidence of infection or disease related to it, but they have overwork, fatigue and acute stress. Therefore we assumed that treatment method of noh-rim (勞淋) can be applied on CP/CPPS.

We developed a new medicine called Baenong Ickki San (BIS), a powder preparation by adding Supplement A (Supp. A), a herb, on a decoction called *bojungikki-tang* which has been used on noh-rim (勞淋). *Bojungikki-tang* can raise exhausted energies, a cause of noh-rim (勞淋). Supp. A can penetrate into lipid membrane of prostatic epithelial cell which makes it hard for drugs to go through and treat prostatitis. Supp. A makes inflammation of CP/CPPS excreted through urine. (Supp. A cannot

be revealed due to it is patent of Cheoungchoon Haniwon.) This kind of mechanisms on treatment of CP/CPPS has never been attempted before. We obtained a significant treatment effect on CP/CPPS with BIS.

CP/CPPS is a very common disease. However, it does not have appropriate treatment due to its causes and mechanisms are not yet clearly known. We tried to diagnose and treat CP/CPPS with KM and developed a new medicine BIS. We report a significant result on CP/CPPS treatment with our new medicine BIS.

## I . Materials and Methods

### 1. Patients

All of patients (n=11) have been diagnosed CP/CPPS at other hospitals. They all have been prescribed western medicine but their condition did not respond. They visited our clinic for KM treatment from May 2014 to March 2015. Their age was from 34 to 63 years and average age was 48.9±10.1 years. Each patients' age, duration of CPPS (years), treatment period (months) and symptoms are as follows (Table 1).

We excluded patients of tumor, heart failure, liver failure patients for this case report. Also We excluded patients of critical high blood pressure, diabetes who are in high-risk group. CP/CPPS Patients with prostatic hypertrophy were excluded for experimental accuracy. Therefore patients aged over 70 were excluded because most of them show prostatic hypertrophy. Mental patients and emotionally unstable patients were excluded.

Table 1. Histories of Patients

Patients	Age	Histories of patient		
		Duration of CPPS (Years)	Treatment periods (Months)	Symptoms
P1	41	17	5	Pain in perineum, residual urine, didymalgia and painful ejaculation.
P2	59		5	Fatigue, hyposexuality and erectile dysfunction.
P3	55	16	8	Backache, weak urinary stream, erectile dysfunction, residual urine, nocturnal enuresis, urethralgia and pain in perineum.
P4	34	2	3	Pain in lower abdomen, residual urine, nocturnal enuresis, epididymitis and backache.
P5	48	9	5	Pain in the pelvis, disesthesia in perineum, nocturnal enuresis and erectile dysfunction.
P6	51		11	Pain in perineum, urethralgia, residual urine, nocturnal enuresis and didymalgia during urination.
P7	53	2	3	Nocturnal enuresis and disesthesia in perineum, residual urine.
P8	40	2	9	Dysuria, disesthesia in perineum, residual urine and painful ejaculation.
P9	63	20	7	Disesthesia in perineum, urethralgia, erectile dysfunction, residual urine and nocturnal enuresis.
P10	59	3	4	Pain in perineum after defecation during 10 minutes, urethralgia, weak urinary stream and nocturnal enuresis.
P11	35	7	3	Urinary frequency, residual urine, weak urinary stream, nocturnal enuresis, hyposexuality and erectile dysfunction.

## 2. Materials

All of the patients received BIS. BIS is a modified formula of *Bojungikki-tang* which is used for boosting immunity and recovering from weakness. BIS is consisted of *bojungikki-tang* (*Astragali Radix* (6 g), *Ginseng Radix*, *Glycyrrhizae Radix*, *Atractylodis Macrocephalae Rhizoma* (4 g), *Fraxini Cortex*, *Angelicae Gigantis Radix* (2 g), *Cimicifugae Rhizoma* and *Bupleuri Radix* (1.2 g)) from Treasured Mirror of Eastern Medicine (東醫寶鑑), *Massa Medicata Fermentata*, *Hordei Fructus Germinatus*, *Crataegi Fructus* and Supp. A (x g). Supp. A can penetrate into lipid membrane of prostatic epithelial cell and excrete inflammation in there. (Supp. A cannot be revealed due to it is patent of Cheoungchoon Haniwon) It is a powder preparation (Table 2).

Table 2. Composition of Baenong Ickki San

Composition of Baenong Ickki San
Herb (g)
<i>Bojungikki-tang</i>
<i>Astragali Radix</i> (6 g)
<i>Ginseng Radix</i> (4 g)
<i>Glycyrrhizae Radix</i> (4 g)
<i>Atractylodis Macrocephalae Rhizoma</i> (4 g)
<i>Fraxini Cortex</i> (2 g)
<i>Angelicae Gigantis Radix</i> (2 g)
<i>Cimicifugae Rhizoma</i> (1.2 g)
<i>Bupleuri Radix</i> (1.2 g)
Addition
<i>Massa Medicata Fermentata</i> (x g)
<i>Hordei Fructus Germinatus</i> (x g)
<i>Crataegi Fructus</i> (x g)
Supp. A(x g)

A recipe of BIS is similar as recipes for common powder preparations. First, herbs are cleaned and completely dried. Next, Supp. A is stir-baked alone. Lastly, all herbs are mixed and ground into powder. This procedures were executed at our clinic. All of the herbs were purchased Daechang-saengyak (82-02-969-2728). All of herbs have a permission from Ministry of Food and Drug Safety.

### 3. Korean Traditional Medicine Diagnosis

We diagnosed major symptoms of CP/CPPS such as urinary symptoms, pelvic pain and sexual dysfunction as noh-rim (勞淋) in KM.

### 4. Measures

We used on the National Institutes of Health Chronic Prostatitis Symptoms Index (NIH-CPSI) as a criteria to measure improvement of CP/CPPS. The NIH-CPSI measures aspects of the three most important symptom domains of CP/CPPS: pain (location, frequency, and severity; score range, 0 to 21), voiding problems (irritative and obstructive symptoms; score range, 0 to 10), and negative effects on the quality of life (score range, 0 to 12), with a total score ranging from 0 to 43<sup>10</sup>. Higher scores indicate more severe symptoms<sup>11</sup>. 4-point decrease in the NIH-CPSI score is the minimal clinically significant difference perceived by patients as beneficial<sup>12</sup>.

### 5. Procedures

Every patients filled out NIH-CPSI questionnaires at their first visit (baseline). Patients received BIS. Treatment periods are different from patients because they had different time to full recovery. Treatment periods are from 3 to 11 month and average 5.7±2.7 month. We took picture of excreted

inflammation during treatment periods. When patient 2 (P2) and patient 9 (P9) visited clinic, they were middle of pain and urinary frequency by BIS and excreting a lot of inflammation mass in urine. We decided to take unplanned picture. We made P2 and P9 urinate on a white plate and took picture of inflammation mass with a digital camera (DSC-T77). We did not record the shooting date. After full recovery, patients filled out NIH-CPSI questionnaires again and this is end point.

The daily dose of BIS is 6 g. Patients took a dose of BIS 2 g, 3 times a day after meals. It is necessary to have more than 4 hours of intervals for taking medicine. It is prohibited to take medicine on an empty stomach. Patients did not take any remedies or medicine for CP/CPPS.

### 6. Statistical Analysis

We used statistical analysis to measure results. We used t-test,  $p < 0.001$  to show statistical differences at baseline and end point in NIH-CPSI score and indicate it as  $x \pm s$ . (SPSS Statistics v22.0 2013 IBM)

## II. Results

We used NIH-CPSI to measure patients improvement. All of the scores showed significant decrease.

The mean NIH-CPSI total score of patients decreased from 37.6±5.8 at baseline to 7.5±3.9 at end point ( $p < 0.001$ ). There was 30.2±7.3 mean decrease in the total score for NIH-CPSI. The mean NIH-CPSI pain score of patients decreased from 17.5±3.9 at baseline to 3.1±2.3 at end point ( $p < 0.001$ ). There was 14.5±4.4 mean decrease in the pain score for NIH-CPSI. The mean NIH-CPSI urinary score of patients decreased from 9.2±1.0 at baseline

to  $1.5 \pm 0.9$  at end point ( $p < 0.001$ ). There was  $7.6 \pm 1.4$  mean decrease in the urinary score for NIH-CPSI. The mean NIH-CPSI quality-of-life score of patients decreased from  $10.9 \pm 1.4$  at baseline to  $2.8 \pm 1.3$  at end point ( $p < 0.001$ ). There was  $8.1 \pm 2.0$  mean decrease in quality-of-life score for NIH-CPSI.

There were significant differences in the decrease from baseline to end point in the NIH-CPSI total score, pain score, urinary score and quality-of-life score (Table 3).

	NIH-CPSI Score			
	Baseline	End point	Mean decrease	P value
Total score	$37.6 \pm 5.8$	$7.5 \pm 3.9$	$30.2 \pm 7.3$	$p < 0.001$
Pain score	$17.5 \pm 3.9$	$3.1 \pm 2.3$	$14.5 \pm 4.4$	$p < 0.001$
Urinary score	$9.2 \pm 1.0$	$1.5 \pm 0.9$	$7.6 \pm 1.4$	$p < 0.001$
Quality-of-life score	$10.9 \pm 1.4$	$2.8 \pm 1.3$	$8.1 \pm 2.0$	$p < 0.001$

\* Plus-minus values are means  $S \pm D$ . For the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI), higher scores indicate more severe symptoms (except the quality-of-life score, higher quality-of-life scores indicate a more negative effect). Score ranges are as follows: total score, 0 to 43; pain score, 0 to 21; urinary score, 0 to 10, quality-of-life score, 0 to 12. Mean decrease stands average changes between baseline and end point.  $P < 0.001$  for the statistical significance of difference in between baseline and end point.

After taking BIS, inflammation is excreted via urethra with urine (Fig. 1). Inflammation is ivory yellow or light yellow sometimes it has blood on it. Inflammation is excreted in mass form. Because of the pressure caused by inflammation mass, there can be severe pain in lower abdomen and prostate. Also stimulations owing to inflammation

mass cause frequent urination. The intensity of pain and frequency of urine depend on size of inflammation mass. There are various size of inflammation mass ranging from relatively large visible masses to invisible small particles. Large visible masses mostly bring intense pain. Invisible small particles mixed in urine mostly do not bring intense pain and patients rarely recognize that it is being excreted. After inflammation excretion is repeated many times, all inflammations are eliminated and symptoms of CP/CPPS are disappeared.

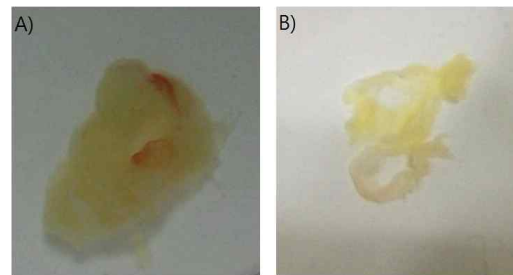


Fig. 1. Inflammation excreted with urine.

- A) Inflammation from patient 2 (P2)  
B) Inflammation from patient 9 (P9)

There are no adverse event in patients.

### III. Discussion

CP/CPPS is a very common disease that 10%~15% of men experience<sup>13</sup>. CP/CPPS has a so evil effect on patients' quality of life that it becomes reason of sociopsychological symptoms such as depression<sup>14</sup>. There is not enough explanations for causes and mechanisms of CP/CPPS. Due to its uncertain etiology, CP/CPPS dose not have a certain treatment. Most of remedies or medications of CP/CPPS are only for symptomatic treatments<sup>15</sup>.

Traditional medicine in East Asia owns methodical

pathology, pharmacology and lots of clinical cases because it has been used and studied a long time. Traditional medicine in East Asia has been presented successful results on treatment of CP/CPSP by using herbal medicine according to its indigenous pattern identification, pharmacology or western medicine. There are researches using traditional indigenous pattern identification to prescribe existing herbal medicine such as 'Bazhengsan'<sup>16</sup>, 'Tiaoshen Tonglin Decoction'<sup>17</sup>, '*Bojungikki-tang*'<sup>18</sup> and 'Yi Guan Jian'<sup>19</sup>, researches which prescribe newly developed herbal medicine aiming at CP/CPSP such as 'Qanliexian decoction'<sup>2</sup> and 'Qiantongding Decoction'<sup>20</sup> and researches which use traditional pattern identification to prescribe newly developed herbal medicine aiming at CP/CPSP such as 'Aike Decoction' and 'Qianliexianyan'<sup>21</sup>. Traditional medicine in East Asia uses traditional herbal medicine and shows clinically meaningful results on CP/CPSP by reducing NIH-CPSI significantly.

We diagnosed CP/CPSP as noh-rim (勞淋)<sup>9</sup> one of the subtypes of im-jeung (淋證) in Treasured Mirror of Eastern Medicine. Major symptoms of im-jeung (淋證) are urinary symptoms such as 'there are something like millet in urine and severe pains and stiffness in lower abdomen', 'im-jeung (淋證) means dippy urine including pain or difficulty in passing urine'<sup>9</sup>. Noh-rim (勞淋), one of the subtypes of im-jeung (淋證), indicates symptoms which are corresponded to diagnostic criteria of CP/CPSP. Noh-rim (勞淋) shows pain in lower abdomen and pelvic area and sexual dysfunction in company with urinary symptoms of im-jeung (淋證) such as 'noh-rim (勞淋) means difficulty in passing urine and pain in lower abdomen from severe fatigue and exhaustion of energies', 'When having sex, feeling tight in the groin region and pain in coccyx' and 'If qi of bladder damaged by over drinking or

excessive intercourse, im-jeung (淋證) can arise'<sup>9</sup>. Also, it is supportive that many CP/CPSP patients recognize their symptoms after overwork without any other diseases or infections.

It says that noh-rim (勞淋) is caused from exhaustion of qi at Treasured Mirror of Eastern Medicine, so we made BIS, herbal medicine for CP/CPSP by adding Supp. A on *bojungikki-tang* in powder preparation form. There are two mechanisms of BIS in treating CP/CPSP. *Bojungikki-tang* boosts the immune system and improves all of symptoms from fatigue<sup>22-24</sup>. BIS treats exhaustion of qi with *bojungikki-tang*. Supp. A can penetrate into lipid membrane of prostatic epithelial cell which make it hard for drugs to go through and treat prostatitis<sup>7</sup>. In addition, Supp. A drainages inflammation in prostate with urine as mass form. This phenomenon showed a lot of patients who take BIS, but not always. There is a treatment which treats CP/CPSP by reinforcing exhausted qi with herbal medicine already<sup>11</sup>. However, direct excretion of inflammation adding to reinforcing qi is attempted at first time by BIS. The result of this study verifies the theory of KM about pathological mechanisms of CP/CPSP and suggests a new treatment of CP/CPSP.

This case series report dose not have a control group. Also there are too small group of patients (n=11). Durations of taking medicine were different from each patients. There were not measurement NIH-CPSI score middle of treatment periods but baseline and end point. There was not measurement of sexual dysfunction, one of the major symptoms of CP/CPSP. BIS does not have GMP. Also, this case series report dose not have explanation about ingredient, size and information of inflammation mass. Later experiments of CP/CPSP recommend

to have a bigger experimental group, a control group, same treatment periods, measurement of NIH-CPSI score for regular periods, standardized medicines and measurement of sexual dysfunction. Additionally, our theory of CP/CPPS is limited to noh-rim (勞淋) of im-jeung (淋證). Later researches about traditional medicine in East Asia recommended to make an effort to place more traditional medical diagnosis and treatment in clinical circles by more systematic consideration on literatures of traditional medicine.

This case series report measured effect of BIS on CP/CPPS treatment. CP/CPPS is known as it has not a effective treatment until now. So we report the effective result of BIS on treatment of CP/CPPS. BIS reduced all of NIH-CPSI total score, pain score, urinary score and quality-of-life

score greatly. And BIS showed no adverse events. BIS showed a very effective result on CP/CPPS.

#### IV. Conclusions

BIS showed statistically significant decreases in CP/CPPS NIH-CPSI total score, pain score, urinary score and quality-of-life score. BIS has a superior effect to other treatments of CP/CPPS so that it has a clinically important meaning. BIS has not a side effect. BIS is an effective new treatment for CP/CPPS.

#### V. Disclosure Statement

No competing financial interests exist.

## 배농익기산의 만성전립선염/만성 골반동통 증후군의 치료 효과에 대한 증례 보고

김영찬, 금소현  
청춘 한의원

### ABSTRACT

**목적:** 본 증례 보고에서는 보중익기탕 가감방인 배농익기산의 만성 전립선염/만성 골반 동통 증후군의 치료효과를 보고한다.

**방법:** 본 원(청춘 한의원)에 내원한 만성 전립선염/만성 골반 동통 증후군 11명 환자에게 배농익기산을 처방한 효과적인 증례를 보고한다. 증상의 변화는 미국 국립보건원 만성전립선염 증상 점수표(NIH-CPSI)로 측정하였다.

**결과:** 배농익기산 처방 후 NIH-CPSI에서 통계학적으로 유의미한 감소가 나타났다. NIH-CPSI 총점의 평균은 치료 전  $37.6 \pm 5.8$ 점에서 치료 후  $7.5 \pm 3.9$  점으로 감소하였다( $p < 0.001$ ). NIH-CPSI 총점은 평균  $30.2 \pm 7.3$  점 감소하였다. 배농익기산 처방 후 NIH-CPSI의 총점, 통증 점수, 배뇨증상 점수, 삶의 질 점수에서 모두 유의미한 감소가 나타났다.

**결론:** 배농익기산은 만성 전립선염/만성 골반 동통 증후군을 치료하는 매우 효과적인 한약이다.

**중심단어:** 만성전립선염/만성골반동통증후군(CPPS), 보중익기탕, 한의학, 배농익기산

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