



Clinical Efficacy of 1-Year Intensive Systematic Dietary Manipulation as Complementary and Alternative Medicine Therapies on Female Patients With Interstitial Cystitis/Bladder Pain Syndrome

Hitoshi Oh-oka

OBJECTIVE	To evaluate the clinical efficacy of intensive systematic dietary manipulation (ISDM) for female patients with interstitial cystitis (IC)/bladder pain syndrome (BPS) in stable condition who were followed up in our hospital.
MATERIALS AND METHODS	In cooperation with the nutrition control team, we created a basic IC/BPS diet menu for 1 month. Data regarding daily food intake and food-related symptoms were collected by conducting a detailed interview of each patient, and we set meal menu to control IC/BPS symptoms and advised the patients to reduce the intake of specific food items to the maximum possible extent. The following food items were removed from or restricted in the diet of patients: tomatoes, tomato products, soybean, tofu product, spices, excessive potassium, citrus, high-acidity-inducing substances, etc. We evaluated the following factors 3 months and 1 year after the start of the intervention: O'Leary-Sant symptom index, O'Leary-Sant problem index, urgency visual analogue scale score, bladder or pelvic pain visual analogue scale score, and numerical patient-reported quality of life index.
RESULTS	All evaluated factors improved statistically significantly when the intensive group was compared with the nonintensive group (baseline to 3 months and 3 months to 1 year ISDM, $P < .05$, respectively).
CONCLUSION	ISDM was found to alleviate the symptoms of IC/BPS in almost 3 months and continued clinical efficacy for at least 1 year. ISDM as one of the conservative treatment modality for IC/BPS should be attempted more strictly because of its noninvasiveness, without alterations to the other treatments. UROLOGY 106: 50–54, 2017. © 2017 Elsevier Inc.

Interstitial cystitis/bladder pain syndrome (IC/BPS) is a clinical syndrome characterized by urinary frequency, increased micturition frequency, urinary urgency, and bladder and pelvic pain. The causes of IC/BPS are not fully understood, and the condition is often difficult to treat.¹ There are no established diagnostic criteria for IC/BPS, and this has hampered the understanding of the underlying

mechanisms and the development of diagnostic and treatment methods. The treatment options for IC/BPS include conservative therapy, internal medication (pain management), intravesical instillation, and electrical stimulation therapy. Bladder hydrodistention and resection or coagulation of Hunner's lesion should be considered after treatment failure of multimodal conservative treatments.² However, there is currently no established treatment for IC/BPS.³ Given the situation, complementary and alternative medicine (CAM) therapies such as behavioral therapy, physical therapy, stress reduction, and dietary manipulation (DM) can be potential treatment options.^{4,6} This study investigated the effectiveness of intensive systematic DM (ISDM) in women with stable IC/BPS.

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From the Department of Urology, National Hospital Organization, Kobe Medical Center, Kobe, Hyogo, Japan

Address correspondence to: Hitoshi Oh-oka, Ph.D., M.D., Department of urology, Kobe Medical Center, 3-1-1, Nishiochiai, Suma-ku, Kobe-shi, Hyogo 654-0155, Japan. E-mail: bighill@zeus.eonet.ne.jp

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MATERIALS AND METHODS

The study period was between June 1, 2015 and May 31, 2016. Forty patients with a diagnosis of IC/BPS and who were being followed up at our hospital were selected for the study. The inclusion criteria were as follows:

- (1) age 20 years or older;
- (2) 1-year minimum duration of IC/BPS considered eligible for trial entry;
- (3) presence of bladder pain and storage symptoms, such as urinary frequency and urgency, that are stable at least for 8 weeks, in the absence of bacterial or fungal infections in the urinary tract, uterus, adnexa of the uterus, and vagina; and
- (4) diagnosis of IC/BPS based on findings such as punctate bleeding, rainfall bleeding, and ulceration of the bladder mucosa on mild bladder hydrodistention followed by bladder biopsies, in addition to the above symptoms. The patient's condition has been stable for at least 6 months after mild bladder hydrodistention.⁷

Patients who met any of the following criteria were excluded:

- (1) Patients with untreated parenchymal disorders of the lower urinary tract (bladder neck contracture, stricture of the urethra, bladder tumor, bladder stone, etc.);
- (2) Patients with bacterial or fungal infections in the urinary tract or gynecologic systems;
- (3) Patients who have no desire to urinate;
- (4) Patients with cognitive impairment who have difficulty in understanding the study objective and the content of questionnaire; and
- (5) Patients who were judged objectively inappropriate for the study.

Forty patients with IC/BPS were randomly assigned to 2 groups: 30 patients who received intensive systematic DM (ISDM group; details are described below) and 10 patients who did not receive ISDM (nonintensive DM [NIDM] group).

We developed an IC/BPS diet for the above 30 patients in collaboration with dietitians at our hospital. The diet contained 1500 kcal energy, 65 g protein, 40 g fat, 220 g carbohydrates, 1000 mL moisture, and 7 g salt. Each patient had an in-depth interview by a physician, nurse, and registered dietitian to obtain information about the relationship between foods and symptoms. We developed a diet for inpatients with IC/BPS by using the reference values for basal metabolism in women aged 30-49 years based on the Dietary Reference Intakes for Japanese (2010 edition). The physical activity was scored as 1.3. The standard diet contained 55%-60% of energy as carbohydrate, 24%-25% of energy as fat, and 1.2 g/kg protein.⁸ When patients were treated in the outpatient setting, modifications were made considering the patient characteristics, including sex, age, height, and lifestyle. As certain foods were eliminated, suitable alternative foods were suggested to prevent deficiency of nutrients. According to

the IC/BPS guidelines (GL), the grade of recommendation of conservative therapies including DM is high (Japanese GL: grade b,² American Urological Association [AUA] GL: first-line treatment,⁹ European Association of Urology [EAU] GL: grade C,¹⁰ Canadian Urological Association [CUA] GL: grade B),¹¹ and it is reported that DM can reduce the symptoms of IC/BPS.¹²⁻¹⁴ However, the effects of foods on the symptoms differ, depending on patients. Therefore, strict dietary restriction should not be imposed on all patients without evaluating their individual characteristics.⁵ An IC/BPS diet that is flexible in terms of food selection needs to be developed. We found that the following procedures were particularly challenging in the development of the ISDM program.

Cumbersome Procedures in Food Service

The ISDM program included the following procedures: information sharing (about foods to avoid) among physicians and other health-care professionals in the inpatient and outpatient settings, creation of a special menu, instruction to the cooking staff, monitoring in the kitchen, regular outpatient dietary counseling, and considerations of the burden placed on the staff associated with the administration of the ISDM program.

Individualized Nutrition Management

The foods for patients with IC/BPS tend to be limited to those that do not trigger symptoms (eg, carbohydrate-based foods). Creating a menu that is nutritionally balanced and appeals to and satisfies each person is demanding and time-consuming.

Development of a Basic Menu and Dietary Guidance Material

We developed the basic menu and dietary guidance material while eliminating foods that may exacerbate symptoms as much as possible. We tried to make the basic menu easy, adaptable, nutritionally balanced, and attractive.

ISDM was performed on the basis of the abovementioned principle for the ISDM group. After developing the basic menu and dietary guidance material (Table 1) by using the dietary guidance material (booklet) involving food lists based on information about the food preference of patients, we created 1-month menus after interviewing patients about their food preferences. During ISDM, the patients were free to consult with dietitians in both the inpatient and the outpatient settings. We created a system in which the information obtained by dietitians is conveyed to physicians and other health-care professionals. They were instructed to comply with the diet and also advised to avoid certain foods (listed below) as much as possible.

Evaluation was performed at baseline, 3 months, and 1 year. The evaluation items included the O'Leary-Sant symptom index (OSS)/O'Leary-Sant problem index (OSPI), urinary urgency (U) (0, none; 9, extremely high), bladder and pelvic pain (P) (0, none; 9, extremely high), and subjective measure of quality of life (QOL) (0, very satisfied; 6, very unsatisfied).

Table 1. Development of dietary guidance

Low-Risk Foods	Food Category	Foods That Should Be Avoided
Rice, wheat, oatmeal	Grain	Rye, sourdough bread
Beef, pork, chicken, mutton	Meat	Meat products containing spices (wiener, bacon, etc.)
Cod, flatfish, salmon, shellfish, crab, shrimp	Seafood	Canned food, seafood products containing spices
Chicken egg	Egg	
Milk, cheese (mozzarella, cheddar)	Dairy products	Yogurt, cheese containing spices, aged cheese

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