

Investigation Report by an EBM Work Team of Japanese Association of Oriental
Psychosomatic Medicine

Evidence of Kampo Therapy for Psychosomatic Diseases and Stress-related Diseases

3) Eating Disorders

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Introduction

Eating disorder (ED) is the collective term of diseases centering on abnormal eating behaviors, and includes anorexia nervosa (AN) and bulimia nervosa (BN).

Drug therapy with western medicines for ED has been attempted in many cases especially of AN and BN. Consequently, the following three hypothetical results have been derived:¹⁾ [1] drug therapy is useful in some ED patients, but it is not the only treatment method and drug therapy should be combined with nutritional recovery and education or psychotherapy, [2] the action mechanism of drug therapy with antipsychotic drugs in ED patients is as yet not well known, and [3] it is wrong to define the psychopathology of ED based on good responsiveness of ED patients to drug therapy with a certain group of drugs and information on the function of the drug therapy. Specifically, there is no report on effective drug therapy, though there are some reports on the usefulness of psychotherapy, such as cognitive behavioral therapy, for “a desire to be thin” and “a fear of obesity,” which are the core of the psychopathology in AN patients.^{2,3)}

Drug therapy for AN merely has effect as supportive care on neurological symptoms such as depressed mood and anxiety and supplementary usefulness such as improvement in gastrointestinal function.¹⁾

As for BN patients, although it is reported that anti-depressive drugs are useful in reducing binge eating and vomiting, they are less effective than cognitive behavioral therapy, and it is suggested that anti-depressive drugs and cognitive behavioral therapy produce moderate additional effect when used concomitantly.¹⁾

This time, we investigated and discussed reports that evaluated usefulness of Kampo formulations for ED patients.

1. Investigation methods

We searched for Kampo articles (both in Japanese and English) released after 1986 at PubMed, Japan Medical Abstracts Society website, and Tsumura's website Kampo Square. In order to understand the whole picture of clinical studies with Kampo formulations, some records of academic conferences and seminars as well as articles in academic journals were included as target articles. We included reports regarding Kampo extract products that comply with the new formulation standards established after 1986, and in principle excluded those regarding drug solutions of crude drug pieces for decoction, powdered crude drugs, and OTC products. In principle, reports that involve at least 10 cases were included, but case reports were also included for (5) Refractory cases and (8) Psychosomatic study.

2. Results

1) Current situation

As of February 2008, there is no article on a double-blind randomized controlled trial (DB-RCT) or a randomized controlled trial (RCT) that evaluated the efficacy of Kampo therapy for ED, and there are two articles on case-series studies that evaluated efficacy in at least 10 cases. These are both regarding studies evaluating the effect of rikkunshito on physical symptoms in AN patients.

2) Usefulness

Matsubayashi et al.⁴ administered rikkunshito to 17 AN patients at 5 g/day for 4 weeks and then investigated changes in the scores of abdominal symptom and psychological symptom and body weight. Furthermore, they evaluated correlation between improvements in symptom scores and 2-year outcomes. Four-week treatment with rikkunshito significantly improved anorexia and general malaise ($p < 0.05$), and body weights also increased significantly ($P < 0.01$). There was no correlation between improvements in symptom scores and 2-year outcomes, but in patients for whom treatment was terminated after 2 years there was a trend towards larger increases in body weights during treatment with rikkunshito ($p = 0.0621$).

Suzuki⁵ administered rikkunshito to 52 AN patients, and reported that 33 patients (63%) experienced improvement in unpleasant gastrointestinal symptoms such as better condition of the upper abdomen as a result of an improved heavy stomach feeling, a decreased sense of fullness after meals, etc., and 30 of them requested continued prescription of rikkunshito. In addition, she reported that there were some AN patients who remarked they are afraid of their good appetites.

3) Effect on QOL

There is no report evaluating the effect of Kampo prescriptions on QOL in ED patients.

4) Comparison with western medicines

There is no report comparing western medicines and Kampo medicines in terms of effect of treatment for ED patients.

5) Effect on refractory cases

It is difficult to define patients refractory to drug therapy because the role of drug therapy for ED patients is of a supplementary character.

6) Study of concomitant use with western medicines

There is no report on combination of western medicines and Kampo prescriptions in treatment for ED patients.

7) Study of Sho

Matsubayashi et al.⁴⁾ administered rikkunshito to 17 AN patients, in whom findings were scored from the aspect of Kampo medicine. As a result, 14 patients showed Kyosho with their scores not more than 4 points; 3 patients showed Chukansho; and there was no patient with Jissho. They did not evaluate whether the effect of rikkunshito is different according to the difference in Sho.

8) Psychosomatic study

What lie at the center of problems with AN patients are “a fear of obesity” and “a desire to be thin,” and it is therapeutically important whether patients can correct this way of thinking and accept an increase in their body weights. Uehara et al.⁶⁾ reported that rikkunshito is ineffective in improving physical appearance. However, since the administration of rikkunshito to AN patients at an early treatment stage reduce psychological and gastrointestinal symptoms which the patients complain of, rikkunshito may indirectly (supplementarily) help form a favorable relationship between healthcare professionals and patients.

9) Mechanism of action

The use of rikkunshito is allowed when a patient shows Kyosho in Shoyo, in other words, the patient is paler, has no appetite due to a heavy feeling in the epigastrium, has a feeble pulse and abdomen, and sometimes complains of a stomachache.⁷⁾ The action mechanism of rikkunshito for improvement in gastrointestinal symptoms is gradually becoming clear in recent years, and the involvement of 5-HT₂ receptor and ghrelin is suggested.⁸⁾

10) Grades of recommendation

Not determinable.

11) Future problems and consideration

There is no article on a DB-RCT or RCT evaluating the usefulness of Kampo prescriptions in ED patients. Thus it is desirable to establish evidence by DB-RCTs and RCTs in the future.

The following are issues to be considered in the future. Psychotherapy, such as cognitive behavioral therapy, is effective against “a desire to be thin” and “a fear of obesity,” which are the core of the psychopathology in AN patients, and currently psychotherapy is given in most of specialized institutions. Therefore, it is very difficult to evaluate the effect of Kampo prescriptions on the core of the psychopathology in AN patients because the evaluation is conducted during concomitant treatment with psychotherapy. Thus it is desirable that the usefulness of Kampo prescriptions for AN patients should be evaluated through the evaluation of the effect on psychological symptoms (e.g. depressed mood and anxiety) and concomitant physical symptoms such as improvement in gastrointestinal function. As for BN patients, it is reported that anti-depressive drugs are useful in reducing binge eating and vomiting,¹⁾ and thus it is desirable that the usefulness of Kampo formulations should be evaluated through the evaluation of the effect in reducing the frequency of binge eating and vomiting.