

## Kampo Formula Developed in Japan (1)

*Otsujito* (“B”Character Decoction)

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*Otsujito* (“B”Character Decoction) was a formula invented about 200 years ago in Japan by Nan-yo Hara (1752-1820). He created several new formulae and four of them have names starting with Chinese Zodiac, Ko(A), Otsu(B), Hei(C), and Tei(D). *Otsujito* is the most well known formula of them all. After this, Sohaku Asada (1815-1894) modified the *otsujito* and the modified formula is now called *otsujito*.

The formula is now available in the extract form and often used as a specialized prescription for hemorrhoids (piles) in clinical sites. The constituents of the prescription are as follows:

*Angelicae Acutilobae* Radix 6 g

*Bupleuri* Radix 5 g

*Scutellariae* Radix 3 g

*Glycyrrhizae* Radix 3 g

*Cimicifugae* Rhizoma 1 g

*Rhei* Rhizoma 1 g

(In the original prescription made by Nan-yo Hara, Japanese angelica Root was not used but instead Chinese Date and Fresh Ginger were contained.)

[Efficacy] Cooling and activating the blood and elevating qi

[Indications] Blood heat, blood stasis, falling qi

[Drug actions] *Angelicae Acutilobae* Radix activates the blood and its circulation. *Bupleuri* Radix frees qi movement in the triple energizers and *Cimicifugae* Rhizoma enhances sunken qi. Combined use of these three kinds of drugs resolves obstructed network vessels (meridian) caused by qi binding in the lower energizer. *Scutellariae* Radix clears heat generated by qi stagnation and blood stasis. *Rhei* Rhizoma enters

the qi system and the blood system, clears the heat and purge the fire and cool the blood and then expels toxins. *Glycyrrhizae* Radix has the actions of harmonizing various drugs as well as clearing heat and resolving toxins.

### Clinical application

*Otsujito* is used for various types of hemorrhoids and its use is especially suitable for the relatively acute condition in which there are constipation, pain and small amounts of bleeding. *Otsujito* is also used for prolapsed hemorrhoids in the initial stage.

#### 1. Hemorrhoids

Yoshio, et al. administered *otsujito* 6.0g to 98 patients with hemorrhoids for 8 weeks to compare subjective symptoms (pain, bleeding, prolapse) and objective symptoms (bloating, size of hemorrhoid) before and after the administration. They report the results of the overall improvement rate that markedly improved accounted for 28.6%, improved 39.6%, and slightly improved 23.5%. For the rate of usefulness, extremely useful accounted for 22.4%, quite useful 41.8%, and slightly useful 21.5% with the recurrence rate of 15.2% after the discontinuation of administration. The recurrence timing was after 2.5 to 7 months after the discontinuation of administration<sup>1)</sup>.

When this prescription is clinically used for hemorrhoids, generally it is not used by itself but it is often used in combination with other prescriptions. For example, *keishibukuryogan* (*Cassia Twig and Tuckahoe Pill*) is combined if blood stasis is complicated; *hochuekkito* (*Middle-Reinforcing and Qi-Benefiting Decoction*) if there is distinguished qi deficiency; *yokukansan* (*Liver-Inhibiting Powder*) if there is marked liver qi depression; and *orengedokuto* (*Coptis Detoxifying Decoction*) if there is an excess heat toxin.

### Case 1: Hemorrhoid

The patient was a male of 27 years old. He had been suffering hemorrhoids since his school days. Recently, an anal fissure (bleeding hemorrhoid) and internal hemorrhoids of a finger-tip size became inflamed like attacks several times a year so that the patient was somewhat neurotic. Although his doctor recommended a surgery, he could not be away from work for hospitalization for as many as a week. So he did everything he did but the condition did not improve at all. He felt like using “Kampo Medicine” and visited the clinic.

He was quite healthy except for the affected area although there was the sho of blood stasis. Therefore, the decoction of *otsujito* was administered for continuous two months without effects. Since there were no reasonable conditions for changing the prescription and the patient said that it took a lot of trouble to prepare the decoction, I decided to use the extract tablet of *otsujito* and *keishibukuryogan* as a drug for dispelling blood stasis.

Three weeks later, the bleeding stopped and pain was also relieved. After continuous use for six months, an examination indicated that the internal hemorrhoids reduced to the size of a piece of soybean and the symptom of blood stasis of the face and the lower abdomen disappeared. Two years passed without the medication. However, there has been no recurrence. (Akira Ishihara, Two Cases in Clinical Trial on *Otsujito*, The Association of East-Asia Medicine Vol.12 3-go p61, 1965)

### Case 2: Hemorrhoidal bleeding

Patient: Female of 34 years old

Chief complaint: Bleeding

Current medical history: When constipated, she had bleeding and the toilet bowl became bright red, which began to happen several years ago. Whenever bleeding occurred, the patient used

over-the-counter suppositories. As bleeding became severe four days ago and did not stop with suppositories, she visited our clinic.

Findings at the initial visit: There were three internal hemorrhoids in the 3 o'clock, 7 o'clock, and 11 o'clock positions. From the internal hemorrhoid in the 7 o'clock position, ruptures and bleeding were observed. The internal hemorrhoid was positioned in the 1 o'clock direction.

Treatment: *otsujito* (Tsumura & Co., Ltd., Tokyo, Japan) were used with *orengedokuto* (Tsumura & Co., Ltd., Tokyo, Japan) Extract Granules (for ethical use). On the 2<sup>nd</sup> day of the administration, the bleeding disappeared. After one month of administration, a proctoscopic examination showed the bleeding stopped and the internal hemorrhoids changed in color from bright red to dark red.

(Tomonori Kawai, Jishitu ni taisuru Kampo Seizai Heiyo Ryoho, Kampo Shinryo Vol.7, 2-go, p50, 1988)

### Case 3: Bleeding hemorrhoids and pain

Patient: Female of 59 years old

Chief complaints: Bleeding and pain

The patient had a medium physical constitution and no anemia with slightly dark complexion. Appetite and sleep were normal. Bowel movements were diarrhea-constipation. She was sensitive to cold (+) with no dry mouth, and no sweat. The abdominal sho was shown in Figure 1. There were two hemorrhoids with the size of a piece of soybean in the 7 o'clock position.

After three months of administration of *otsujito* 8.0 + *hochuekkito* 6.0 (per day), no bleeding was observed. After five months, the patient complained pain only sometimes. A cure was achieved within eight months.

(Shigeru Tanaka, Jishitu to Kampo Chiryō, Kampo Shinryo Vol.5, 1-go, p42, 1986)

### 1. Prolapsed hemorrhoid

*Otsujito* works to recover the qi movement bound in the lower energizer. So this formula is also used for prolapsed hemorrhoids. Bupleurum Root and Cimicifuga Rhizome contained in the prescription enhance stagnant qi movement by their action of raising qi and drooped organs caused in conjunction with lowering qi. The prolapsed hemorrhoids which are the symptom of deficiency are often accompanied by spleen deficiency, in which case *hochuekkito*, for example, is used in combination.

#### Case 4: Prolapsed hemorrhoid and pain

Patient: Female of 45 years old

Chief complaints: Prolapsed hemorrhoid and pain

Sometimes hemorrhoid prolapsed during a bowel movement, which began to happen several years ago. Pain was added and became persistent from two months ago.

The patient face was pale but did not have anemia. The lower half of her body was cold. Appetite and sleep were normal. Bowel movements were once/day with one slightly soft stool. The dry mouth condition was (+) with sweat (-). The overall abdomen was weak and soft without resistance. The affected area: The hemorrhoid with a size of a finger tip was in the state of an everted flower and the surrounding tissues were congested and swollen. Intense pain was felt intense in palpation. “*shiunko*” was applied and then the hemorrhoid was pushed back. *Shiunko* was used as an external medication.

I judged that an intense sensation of cold with normal appetite was the symptom of deficiency of qi and blood. On the basis of this, Prepared Aconiti Radix Processa 1.5g + *shikunshito* 8.0g (per day) were administered for two months. Then the prolapsed hemorrhoid became able to retract somehow. Therefore, the medications

were changed to *otsujito* 7.0g + *hochuekkito* 7.0g (per day). For constipation the patient complained of, *mashiningan* 4.0g (as needed) was used after dinner. Further two months later, prolapsing was reduced to only a little during a bowel movement. Further three months later, subjective symptoms relieved. The medications were suspended again for further two months. (Shigeru Tanaka, *Jishitu to Kampo Chiryō*, Kampo Shinryō, Kampo Shinryō Vol. 5, 1-go, P39, 1986)

### 1. Itching around the anus

Anal itching is often caused by damp-heat in the lower energizer. This prescription has the action of recovering qi movement in the lower energizer and concurrently dispelling damp-heat, by which the itchy sensation in the anus and the anterior pubic region can be relieved.

#### Case 5: Bleeding hemorrhoids and itching around the anus

Patient: Male of 38 years old.

Initial visit: July 30, 1983

Present medical history: The patient had been complaining of bleeding from the anus and itching around the anus for about two years.

Present condition: The patient was of large build, fatigable, and unable to have sufficient sleep with pale complexion. The patient was a heavy sweater (whole body). The anus felt no pain but there were bleeding and an itchy sensation around the anus. Bowel movements were once a day with one stool and there was a sensation of residual stool. Appetite was good.

The tongue was covered with thin white furs and moist. Pulse was floating with strength. The abdomen was generally soft with a slight bloating feeling in the chest and hypochondrium on right and left sides, and there was a slight tension over the abdominal muscles in palpation.

[Treatment and course]

During the administration of *otsujito*(without *Rei Rhizoma*), subjective symptoms gradually improved. By the end of the 100 day administration, they become resolved.

(Genpo Ogata, Kampo Chiryō Shorei-Senshu (1) P236, Gendai Shuppan Planning Co., Ltd. 1988)

- 3) Akagi K, et al.: *Ninshin/Sanjyoku no Komon Shojyo eno Otsujito no Toyo Koka*, Kampo Shinryo Vol. 15 No. 3, P41-42, 1986

#### 1. Hemorrhoidal disease during puerperium

Pregnancy and child birth delivery have adverse influences on the development of hemorrhoids and its worsening. There is a documentation reporting that *otsujito* was successfully applied to these problems.

Honda said that 58% of puerperal women become affected with hemorrhoids, 30% of the women develop hemorrhoids after delivery although they did not have hemorrhoids during pregnancy, and 60% of the women who had hemorrhoids during pregnancy do not have relief within one month after delivery and rather tend to have exacerbated symptoms such as bleeding, prolapse, and pain during the period of one-month-after delivery. He administered *otsujito* to 30 patients with hemorrhoids observed on the 1<sup>st</sup> day of the puerperium, reporting the results of significant improvements in four symptoms of “painful bowel movements,” “bleeding,” “prolapse,” and “swelling,” slightly effective in 11 patients (36.7%), and quite effective (36.7%) with the overall effectiveness rate of 73.3%<sup>2)</sup>. Akagi, et al. also administered *otsujito* for anal symptoms during pregnancy/puerperium and obtained mostly similar results<sup>3)</sup>.

- 1) Yoshio T, Yanagida K, Sumiyama Y, et al.: *Naijikaku ni taisuru Otsujito no Rinsho Koka*, Journal of New Remedies and Clinics 40:2087-2096, 1991
- 2) Honda T, et al.: *Fujin to Ji-shikkan-sono 4 – Kampo (Otsujito) no Koka – Bosei-Eisei*, Vol. 31 No. 1, 1990