

## 9. Cardiovascular Diseases

**Reference**

Kato N, Kato K, Hosoi Y. Effects of Otsuji-to in patients with hemorrhoid using ALTA and LE combined therapy. *Igaku to Yakugaku (Journal of Medicine and Pharmaceutical Science)* 2008; 60: 747-53 (in Japanese). Ichushi Web ID: 2009068979 [MOL](#), [MOL-Lib](#)

**1. Objectives**

To evaluate the clinical efficacy of otsujito (乙字湯) combined with aluminum potassium sulfate/tannic acid (ALTA) sclerotherapy, the latest treatment for hemorrhoids.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Two institutions: Furudate Kato Proctology & Surgery Clinic and Hosoi Surgery Clinic, Japan.

**4. Participants**

Twenty patients with hemorrhoids (stage III or IV according to the Goligher classification) who underwent ALTA alone or ALTA-LE (ligation and excision) at the above-mentioned two institutions between March and September 2008.

**5. Intervention**

Arm 1: ALTA alone or ALTA-LE, followed by treatment with Kanebo Otsujito (乙字湯) Extract Fine Granules 3 g b.i.d. orally before meals from postoperative day 1 for 4 weeks (n=10).

Arm 2: ALTA alone or ALTA-LE (n=10).

Non-steroidal anti-inflammatory drugs (NSAIDs) were used as needed for pain relief in both arms.

**6. Main outcome measures**

Spontaneous pain, pain during defecation, and blood C-reactive protein (CRP) level at weeks 1, 2, and 4 of the otsujito treatment; and usage of analgesics up to postoperative week 2.

**7. Main results**

The effects on blood CRP level at week 1, pain during defecation at week 2, and spontaneous pain at weeks 1 and 2 were significantly greater in arm 1 than in arm 2 ( $P<0.05$ ). The usage of analgesics tended to be reduced in arm 1 than in arm 2 (median, 2 vs. 10 tablets;  $P=0.09$ ). Although the incidence of induration and hemorrhoid shrinkage after ALTA was similar between arms, the period of induration-persistence (time to disappearance of induration) was significantly reduced in arm 1 (11.3 weeks) than in arm 2 (15.3 weeks;  $P<0.05$ ).

**8. Conclusions**

Otsujito relieves postoperative spontaneous pain, pain during defecation, and persistent induration in patients who undergo ALTA with or without LE.

**9. From Kampo medicine perspective**

This study revealed that otsujito (unlike common Kampo medicines) has a rapid onset of action. The prevention of constipation seemed to mainly result from the purging effect of daio (大黃) and the intestine-moistening effect of toki (当帰). Unfortunately, postoperative pain relief from the perspective of Kampo medicine was not discussed in this paper.

**10. Safety assessment in the article**

Adverse reactions to otsujito were not reported in this study.

**11. Abstractor's comments**

Hemorrhoids are highly prevalent in the general population and can sometimes cause great discomfort and social embarrassment. This study demonstrated that otsujito, a traditional treatment for hemorrhoids, combined with ALTA sclerotherapy, the latest Western medical treatment for hemorrhoids, relieves pain after surgery and reduces the period of induration persistence. This study indicates the integration of modern Western therapy with oriental therapy (i.e., otsujito, long known, by itself, to be effective treatment for hemorrhoids) can enhance efficacy. The findings of this study have important implications for the future direction of hemorrhoids treatment. Otsujito may enhance the effects of tannic acid, such as inhibition of sterile inflammation and reduction of tissue damage. Further studies are expected to elucidate the mechanism of action of otsujito.

**12. Abstractor and date**

Ushiroyama T, 1 June 2010, 31 December 2013.