

**2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)****References**

Aoe H, Matsuo T, Ebisutani M, et al. Efficacy of using juzentaihoto to augment preoperative autologous blood donation in cancer patients\*. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2000; 17: 67-71 (in Japanese)

Aoe H, Ota M, Kawahara N, et al. Efficacy of using juzentaihoto to augment preoperative autologous blood donation\*. *Rinsho Kensa (Journal of Medical Technology)* 2003; 47: 395-9 (in Japanese). Ichushi Web ID: 2003251978

**Aoe H. Effect of Juzen-taiho-to on haematological recovery from predeposit autologous blood donation. *Pharma Medica* 2007; 25: 11-4. Ichushi Web ID: 2008070612 [MOL](#), [MOL-Lib](#)**

**1. Objectives**

To evaluate the efficacy of using juzentaihoto (十全大補湯) to augment preoperative autologous blood donation in cancer patients.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Not identified (but the abstractor infers a Department of Obstetrics and Gynecology in each of the following three facilities: Japanese Red Cross Society Himeji Hospital, Fukuyama City Hospital, and Chugoku Central Hospital), Japan.

**4. Participants**

One-hundred and twenty patients who visited the above institutions within the past 5 years and 2 months and donated 800 mL or more autologous blood before undergoing surgery for gynecologic malignant tumors. Patients receiving preoperative chemotherapy and patients with collagen disease were excluded.

**5. Intervention**

Arm 1: intravenous administration of an iron preparation (240 mg weekly) + intravenous drip infusion of 6000 units of EPO three times weekly, from the day of the first donation through the day before the operation in patients with pre-donation Hb value of < 14 g/dL, n=52.

Arm 2: intravenous administration of an iron preparation (240 mg weekly) + intravenous drip infusion of 6000 units of EPO three times weekly + oral administration of a sachet (2.5 g) of TSUMURA Juzentaihoto (十全大補湯) Extract Granules t.i.d (before meals), from the day of the first donation through the day before the operation in patients with pre-donation Hb value of < 14 g/dL, n=51.

Arm 3: intravenous administration of an iron preparation (240 mg weekly), n=17.

**6. Main outcome measures**

Hematological profile: RBC count, hemoglobin, hematocrit, reticulocyte count, etc., measured before donation (before administration) and preoperatively (immediately after completion of administration).

Serum biochemical profile: total protein, albumin, and iron concentrations, determined before donation (before administration) and preoperatively (immediately after completion of administration).

Hemoglobin increment: pre-donation hemoglobin concentration × volume of donation blood/volume of circulating blood – (pre-donation hemoglobin concentration – preoperative hemoglobin concentration).

**7. Main results**

Decrements in RBC count and hematocrit after donation were significantly smaller in the EPO combination groups than in the iron monotherapy group, and significantly smaller in the juzentaihoto and EPO combination group than in the EPO combination group ( $P<0.05$ ). There was also a significant difference in hemoglobin increment between arms ( $P<0.05$ ).

**8. Conclusions**

An iron preparation combined with EPO and additionally with juzentaihoto enhances the clinical efficacy of preoperatively donated autologous blood.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

None.

**11. Abstractor's comments**

This study demonstrated that adding juzentaihoto to the preoperative donation management protocol successfully suppresses reductions in RBC count and hematocrit after donation and enhances the increase in blood hemoglobin concentration. This suggests that the hematological profile of donated autologous blood is better after use of this combination than after use of only an iron preparation plus EPO. Thus, this finding is clinically significant. With the accumulation of more cases, a safety study, including an examination of the possibility that complementary medicines promote cancer cell growth, is expected.

**12. Abstractor and date**

Ushiroyama T, 1 April 2008, 19 December 2008, 31 December 2013.