

**Evidence Reports of Kampo Treatment
(EKAT)
Appendix 2012**

**Edited by
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**Task Force for Evidence Reports / Clinical Practice Guidelines
(ER/CPG-TF)
Committee for Evidence-based Medicine (EBM)
The Japan Society for Oriental Medicine (JSOM)**

31 December 2012

History of the versions of EKAT

- 31 Dec. 2012: Kampo Chiryō Ebidensu Repoto Appendix 2012 (Evidence Reports of Kampo Treatment Appendix 2012)
- 1 Oct. 2011: Kampo Chiryō Ebidensu Repoto Appendix 2011 (Evidence Reports of Kampo Treatment Appendix 2011)
- 1 Jun. 2010: Kampo Chiryō Ebidensu Repoto 2010 - 345 no RCT (Evidence Reports of Kampo Treatment 2010: 345 Randomized Controlled Trials)
- 1 Jun. 2009: Kampo Chiryō Ebidensu Repoto 2009 - 320 no RCT (Evidence Reports of Kampo Treatment 2009: 320 Randomized Controlled Trials)
- 1 Apr. 2008: Kampo Chiryō Ebidensu Repoto Dai 2-han - RCT wo Shu ni Shite - Chukan Hokoku 2007 ver 1.1 (Evidence Reports of Kampo Treatment 2nd edition - Focusing on RCTs - Interim Report 2007 ver.1.1)
- 15 Jun. 2007: Kampo Chiryō Ebidensu Repoto Dai 2-han -RCT wo Shu ni Shite - Chukan Hokoku 2007 (Evidence Reports of Kampo Treatment 2nd edition - Focusing on RCTs - Interim Report 2007)
- 20 Jul. 2005: Kampo Chiryō niokeru Ebidensu Repoto (Evidence Reports of Kampo Treatment) (*Nihon Toyo Igaku Zasshi [Kampo Medicine]* 2005: 56, EBM supplementary issue)
- 20 Sept. 2002: Kampo Chiryō niokeru EBM - 2002 nen Chukan Hokoku (EBM in Kampo 2002, Interim Report) (*Nihon Toyo Igaku Zasshi [Japanese Journal of Oriental Medicine]* 2002: 53 [5], supplementary issue)

Notes to the EKAT Appendix 2012

The Task Force for Evidence Reports/Clinical Practice Guidelines (ER/CPG-TF) of the Japan Society for Oriental Medicine (JSOM) Evidence-based Medicine (EBM) Committee gathers comprehensive data on the randomized controlled trials (RCTs) of Kampo formulations in Japan, and compiles structured abstracts (SAs) and publishes them as “Kampo Chiryō Ebidensu Repoto (Evidence Reports of Kampo Treatment [EKAT])”.

As the version history on the previous page shows, the “Kampo Chiryō Ebidensu Repoto 2010 - 345 no RCT - (Evidence Reports of Kampo Treatment: 345 Randomized Controlled Trials [EKAT 2010])” was published on June 1, 2010, and included 345 RCTs and 1 meta-analysis published between 1986, when the specifications for the quality of Kampo formulations for prescription became as they are today, and the first half of 2009. On 1 October 2011, SAs only for the references published in the subsequent year were published as the EKAT 2011 Appendix.

The EKAT 2012 Appendix includes the SAs for RCTs published in the preceding year. Although the website itself has not been updated from EKAT 2010, the custom Google search engine allows readers to search all SAs in EKAT 2010, EKAT Appendix 2011, and EKAT Appendix 2012. EKAT’s aims and production methods have remained essentially unchanged since EKAT 2010. Please see EKAT 2010 for those details.

EKAT 2010 included 345 SAs, EKAT Appendix 2011 added 14 SAs, and this year’s EKAT Appendix 2012 added a further 20 SAs. It has been ascertained that a study for which a SA was included in EKAT 2010 (Ito K, Yamamoto H, Saibara T, et al. The usefulness of Kanebo Hachimijogan in patients with hypertension or cerebrovascular disease [excluding acute phase symptoms] and their concomitant symptoms: a multicenter, double-blind, crossover study. *Shindan to Chiryō [Diagnosis and Treatment]* 1988; 76: 1096–114 [in Japanese]) used products that predated and failed to meet current Kampo product quality standards. This study has therefore been removed. Furthermore, while EKAT Appendix 2011 did not include a list of excluded studies for which no SAs were written, EKAT Appendix 2012 does include a list of studies excluded from both EKAT Appendix 2011 and EKAT Appendix 2012. The above study by Ito et al. appears on the list of excluded studies.

The following table shows the current standing for references and SAs in this EKAT Appendix 2012.

Version/date	15-Jun-07	1-Apr-08	1-Jun-09	1-Jun-10	1-Oct-11	31-Dec-12
Title	Evidence Reports of Kampo Treatment, 2nd edition - Focusing on RCTs - Interim Report 2007	Evidence Reports of Kampo Treatment, 2nd edition - Focusing on RCTs - Interim Report 2007 ver. 1.1	Evidence Reports of Kampo Treatment, 2009 - 320 Randomized Controlled Trials (EKAT 2009)	Evidence Reports of Kampo Treatment, 2010 - 345 Randomized Controlled Trials (EKAT 2010)	Evidence Reports of Kampo Treatment, Appendix 2011 (EKAT Appendix 2011) ²⁾	Evidence Reports of Kampo Treatment, Appendix 2012 (EKAT Appendix 2012)
Year of publication of targeted references	1999–2005	1999–2005	1986–Jun 2008	1986–Jun 2009	1986–Jun 2010	1986–Jun 2011
No. of references	104	116	385	416	432	457
No. of structured abstracts (SAs)	102	98	321 ¹⁾	346 ¹⁾	360 ¹⁾	379 ¹⁾
No. of excluded references	42	32	111	133	–	150

¹⁾ Including 1 meta-analysis

²⁾ The numbers of references and structured abstracts in EKAT Appendix 2011 are the numbers of references and structured abstracts in EKAT 2010 plus those added in EKAT Appendix 2011.

³⁾ The numbers of references and structured abstracts in EKAT Appendix 2012 are the numbers of references and structured abstracts in EKAT 2010 plus those added, minus those deleted, in EKAT Appendix 2011 and EKAT Appendix 2012.

In addition, RCT references, which had been included in EKAT 2010 but not in the Cochrane Library (CENTRAL), were uploaded to CENTRAL in October 2011, and are now linked to the EKAT SAs. In future, EKAT references will continue to be uploaded to CENTRAL.

Lastly, it is anticipated that the next complete revision will be published during 2013 and will appear on the website.

Third Phase (June 2009 -)
Task Force for Evidence Reports / Clinical Practice Guidelines (ER/CPG-TF)
Committee for Evidence-based Medicine (EBM)*
The Japan Society for Oriental Medicine (JSOM)

Organization

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Pharmaceutical Sciences, University of Tokyo

(29 June 2012 -)

* The Special Committee for EBM became a standing committee in 2012, thus the change of name.

Lists of Structured Abstracts

<<EKAT Appendix 2012: Structured Abstracts describing RCTs and the References Reporting Them>>

Note: Original English titles assigned by authors were used in these lists and the structured abstracts. When references had no English titles, the Task Force translated the original Japanese titles into English ones (〃).

Abbreviations: C, The Cochrane Library (CENTRAL); I, *Igaku Chuo Zasshi (Japana Centra Revuo Medicana, Ichushi)*; N, Database Offered by Nikkankyo (the Japan Kampo Medicines Manufacturers Association)

ICD-10	Research Question	Kampo Formula	References	Study Design	Source	Page No.
A09.0	To evaluate the effectiveness of Kampo therapy for infectious diarrhea.	goreisan (五苓散), goreisan (五苓散)+ shakuyakukanzoto (芍薬甘草湯)	Miura Y, Yamagishi Y, Mikamo H, et al. Investigation into the effects of Kampo therapy for infectious diarrhea*. <i>Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)</i> 2011; 28: 102-4 (in Japanese).	RCT-envelope	I	8
G62.9	To clarify the efficacy and adverse effects of goshajinkigan (牛車腎気丸) for peripheral neuropathy induced by oxaliplatin therapy for advanced or recurrent colorectal cancer.	goshajinkigan (牛車腎気丸)	Nishioka M, Shimada M, Kurita N, et al. The Kampo medicine, Goshajinkigan, prevents neuropathy in patients treated by FOLFOX regimen. <i>International Clinical Journal of Oncology</i> 2011; 16: 322-7.	RCT	N	9
H90.5	To compare the effectiveness of saireito (柴苓湯) and isosorbide for low-frequency sensorineural hearing loss.	saireito (柴苓湯)	Kaneko T. Comparison of saireito and isosorbide in efficacy against low-frequency sensorineural hearing loss. <i>Kampo to Saishin Chiryō (Kampo and the Newest Therapy)</i> 2010; 19: 233-9 (in Japanese with English abstract).	quasi-RCT	I	10
I62.0	To evaluate the effectiveness and safety of goreisan (五苓散) after chronic subdural hematoma surgery in elderly people.	goreisan (五苓散)	Yoshikawa T, Munakata S, Okuma H. Effectiveness of Goreisan for recurrence prevention in elderly cases of chronic subdural hematoma surgery— Interim report on a comparative trial*. <i>Noshinkei Geka to Kampo (Neurosurgery and Kampo)</i> 2010; 16 (in Japanese).	RCT	N	11
J44.9	To evaluate the effect of bakumondoto (麦門冬湯) on cough in patients with chronic obstructive pulmonary disease (COPD).	Bakumondoto (麦門冬湯)	Mukaiida K, Hattori N, Kondo K, et al. A pilot study of the multiherb Kampo medicine bakumondoto for cough in patients with chronic obstructive pulmonary disease. <i>Phytomedicine</i> 2011; 18: 625-9.	RCT-cross over	N	12
			Hattori N, Mukaiida K, Haruta Y, et al. A pilot study of the effects of Bakumondoto (TJ-29) on cough in chronic obstructive pulmonary disease (COPD)*. <i>Kampo to Meneki - Arerugi (Kampo and Immuno-Allergy)</i> 2011; 24: 38-45 (in Japanese with English abstract).		N	
K21.9	To evaluate the effectiveness of rikkunshito (六君子湯) for patients with proton pump inhibitor (PPI)-resistant gastroesophageal reflux disease (GERD, and especially non-erosive reflux disease [NERD]).	rikkunshito (六君子湯)	Tominaga K, Fujiwara Y, Shimoyama Y, et al. Rikkunshito improves PPI-refractory NERD: a prospective randomized multi-center trial in Japan. <i>Gastroenterology</i> 2010; 138: S655-6.	RCT	N	13
			Tominaga K, Fujiwara Y, Arakawa T, et al. GERD — Rikkunshito*. <i>Shindan to Chiryō (Diagnosis and Treatment)</i> 2011; 99: 771-6 (in Japanese).		N	
K21.9	To evaluate the effects of rikkunshito (六君子湯) on esophageal motor function and gastroesophageal reflux.	rikkunshito (六君子湯)	Morita T. Effects of rikkunshito (TJ-43) on gastroesophageal reflux, esophageal motor functions and salivary secretion: placebo-controlled double-blind study. <i>Nikkei Medical (Supplement)</i> 2010; 8: 27 (in Japanese).	RCT-cross over	N	14
K21.9	To evaluate the effects of rikkunshito (六君子湯) on esophageal motor function and gastroesophageal reflux.	rikkunshito (六君子湯)	Morita T. Effects of rikkunshito (TJ-43) on gastroesophageal reflux, esophageal motor functions and salivary secretion: placebo-controlled double-blind study. <i>Nikkei Medical (Supplement)</i> 2010; 8: 27 (in Japanese).	RCT-cross over	N	15

ICD-10	Research Question	Kampo Formula	References	Study Design	Source	Page No.
K30.0	To evaluate the effects of rikkunshito (六君子湯) on gastric contraction and expansion.	rikkunshito (六君子湯)	Shiratori M, Shoji T, Kanazawa M, et al. Effect of rikkunshito on gastric sensorimotor function under distention. <i>Neurogastroenterology & Motility</i> 2011; 23: 323-9, e155-6.	RCT-cross over	N	16
K31.9	Comparative evaluation of the regulatory effects of thermal stimulation to the abdomen and Daikenchuto (大建中湯) on superior mesenteric artery (SMA) blood flow in healthy people.	rikkunshito (六君子湯)	Takayama S, Seki M, Watanabe M, et al. The effect of warming of the abdomen and of herbal medicine on superior mesenteric artery blood flow - a pilot study. <i>Forschende Komplementärmedizin</i> 2010; 17: 195-201.	RCT	N	17
K59.0	To evaluate the effects of daikenchuto (大建中湯) in combination for chronic constipation patients taking sennoside.	daikenchuto (大建中湯)	Horiuchi A, Nakayama Y, Tanaka N. Effect of traditional Japanese medicine, daikenchuto (TJ-100) in patients with chronic constipation. <i>Gastroenterology Research</i> 2010; 3: 151-5.	RCT	N	18
K91.8	To evaluate the effectiveness and safety of daikenchuto (大建中湯) soon after colorectal cancer surgery.	daikenchuto (大建中湯)	Watanabe K. Effects of Daikenchuto on early bowel movement after colorectal cancer surgery*. <i>Kampo Igaku (Science of Kampo Medicine)</i> 2010; 34: 346-7 (in Japanese).	quasi-RCT	N	19
			Fujii S. Effects of Daikenchuto on early bowel movement after colorectal cancer surgery*. <i>Progress in Medicine</i> 2011; 31: 468-9 (in Japanese).		N	
N95.1	To evaluate the clinical effects of keishibukuryogan (桂枝茯苓丸) for hot flashes in menopausal American women.	keishibukuryogan (桂枝茯苓丸)	Plotnikoff GA, Watanabe K, Torkelson C, et al. The TU-025 keishibukuryogan clinical trial for hot flash management in postmenopausal women: result and lessons for future research. <i>Menopause</i> 2011; 18: 886-92.	RCT	N	20
N95.1	To evaluate the effects of keishibukuryogan (桂枝茯苓丸) and kamishoyosan (加味逍遙散) on levels of circulating cytokines in patients with hot flashes.	keishibukuryogan (桂枝茯苓丸), kamishoyosan (加味逍遙散)	Yasui T, Matsui S, Yamamoto S, et al. Effects of Japanese traditional medicines on circulating cytokine levels in women with hot flashes. <i>Menopause</i> 2011; 18: 85-92.	quasi-RCT	N	21
O12.0	To evaluate the effectiveness of saireito (柴苓湯) combined with either sojutsu (蒼朮, <i>Atractylodes Lancea</i> Rhizome) or byakujutsu (白朮, <i>Atractylodes Rhizome</i>) as constituent crude drugs for lower limb edema and functional dyspepsia-like gastrointestinal symptoms.	saireito (柴苓湯)	Takushima Y, Michigami F. Clinical study of Saireito on gestational edema and upper gastrointestinal symptoms. <i>Igaku to Yakugaku (Japanese Journal of Medicine and Pharmaceutical Science)</i> 2010; 64: 709-15 (in Japanese).	quasi-RCT	I	22
R05.0	To evaluate the combined effects of bakumondoto (麥門冬湯) and a bronchodilator for prolonged cough following common cold.	bakumondoto (麥門冬湯)	Irifune K, Hamada H, Ito R, et al. Antitussive effect of bakumondoto a fixed kampo medicine (six herbal components) for treatment of post-infectious prolonged cough: controlled clinical pilot study with 19 patients. <i>Phytomedicine</i> 2011; 18: 630-3.	RCT-envelope	C	23
R35.0	To evaluate the effectiveness of goshajinkigan (牛車腎氣丸) for nocturnal polyuria with elevated B-type natriuretic peptide.	goshajinkigan (牛車腎氣丸)	Shimizu Y, Yoshimura K, Soda T, et al. The effects of Gosha-Jinki-Gan, a blended herbal medicine, and furosemide for nocturnal polyuria with elevated B-type natriuretic peptide: a crossover trial. <i>Neurology and Urodynamics</i> 2010; 29: 833-4.	RCT-cross over	C	24
R53.0	To evaluate the effectiveness of hochuekkito (補中益氣湯) for cancer-related fatigue.	hochuekkito (補中益氣湯)	Jeong JS, Ryu BH, Kim JS, et al. Bojungikki-tang for cancer-related fatigue: A pilot randomized clinical trial. <i>Integrative cancer therapies</i> 2010; 9: 331-8.	RCT	N	25

ICD-10	Research Question	Kampo Formula	References	Study Design	Source	Page No.
Z03.8	To evaluate the effectiveness of shakuyakukanzoto (芍薬甘草湯) as premedication for ERCP in suppressing duodenal peristalsis.	shakuyakukanzoto (芍薬甘草湯)	Fujinami H. Assessment of diminished peristalsis using shakuyakukanzoto (TJ-68) as premedication for endoscopic retrograde cholangiopancreatography (ERCP): randomized placebo-controlled trial. <i>Nikkei Medical (Supplement)</i> 2010; 8: 34 (in Japanese).	RCT	N	26
			Fujinami H, Kudo T, Nakayama Y, et al. Assessment of diminished peristalsis using shakuyakukanzoto (TJ-68) as premedication for endoscopic retrograde cholangiopancreatography (ERCP): a randomized, placebo-controlled trial. <i>Gastrointestinal Endoscopy</i> 2010; 71: AB227.		N	
Z04.8	To assess whether differences in ethical Kampo extract formulation dosage and dosing frequency have an effect on compliance and patient satisfaction.	Not described	Kita T, Sumino M. The effect of dosage frequency of ethical Kampo extract formulations on drug compliance – a comparison of twice a day and three times a day prescriptions. <i>Igaku to Yakugaku (Japanese Journal of Medicine and Pharmaceutical Science)</i> 2011; 66: 117–22 (in Japanese).	RCT-cross over	I	27

Revisions of structured abstracts previously published in EKAT 2010

ICD-10	Research Question	Kampo Formula	References	Study Design	Source	Page No.
J69.0	To evaluate whether hangekobokuto prevents aspiration pneumonia and pneumonia-related mortality in elderly people with dementia.	hangekobokuto (半夏厚朴湯)	Iwasaki K, Kato S, Monma Y, et al. A pilot study of banxia houpu tang, a traditional Chinese medicine, for reducing pneumonia risk in older adults with dementia. <i>Journal of the American Geriatrics Society</i> 2007; 55: 2035-40.	RCT	C	28
			Iwasaki K, Kato S, Monma Y, et al. A pilot study of banxia houpu tang, a traditional Chinese medicine, for reducing pneumonia risk in brain-damaged elderly. <i>International Journal of Stroke</i> 2010; 5 suppl 2: 38-9.		C	
K30	To clarify the effect of rikkunshito (六君子湯) on increasing ghrelin secretion and improving symptoms and its mechanism of action in patients with functional dyspepsia (FD).	rikkunshito (六君子湯)	Arai M. Rikkunshito significantly enhances the secretion of ghrelin in patients with functional dyspepsia*. <i>Kampo Igaku (Kampo Medicine)</i> 2009; 33: 405-6.	RCT	N	29
			Matsumura T, Arai M, Suzuki T, et al. The traditional Japanese medicine rikkunshito improves upper gastrointestinal symptoms in patients with functional dyspepsia. <i>Gastroenterology</i> 2010; 138: S471.		C	
			Arai M, Matsumura T, Yoshikawa M, et al. Analysis of the Rikkunshito efficacy on patients with functional dyspepsia*. <i>Nihon Yakurigaku Zasshi (Folia Pharmacologica Japonica)</i> 2011; 137: 18–21. (in Japanese).		N	
Z03.8	Efficacy of shakuyakukanzoto for relieving pain and complaints during preparation for barium enema.	shakuyakukanzoto (芍薬甘草湯)	Imazato S, Kai S, Koizumi K, et al. A clinical study of Shakuyaku-Kanzo-to (Kampo) as a preparation for double contrast barium enema. <i>Therapeutic Research</i> 1997; 18: 5505-10 (in Japanese with English abstract).	RCT	N	30
			Imazato S, Kai S, Koizumi K, et al. A Clinical Study of Shakuyaku-Kanzo-to (Kampo) as a Preparation for Double Contrast Barium Enema. <i>Kampo Igaku (Science of Kampo Medicine)</i> 1998; 22: 87–92 (in Japanese).		N	

1. Infections (including Viral Hepatitis)**Reference**

Miura Y, Yamagishi Y, Mikamo H, et al. Investigation into the effects of Kampo therapy for infectious diarrhea*. *Sanfujinka Kampo Kenkyu no Ayumi (Recent Progress of Kampo Medicine in Obstetrics and Gynecology)* 2011; 28: 102–4 (in Japanese). Ichushi Web ID: 2011211647

1. Objectives

To evaluate the effectiveness of Kampo therapy for infectious diarrhea.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT - envelope).

3. Setting

Izumi Ladies' Clinic, Japan.

4. Participants

Thirty-three patients who presented with watery diarrhea between September 2007 and March 2009 and were diagnosed with infectious gastroenteritis caused by norovirus, identified from stool samples using a rapid testing method.

5. Intervention

Arm 1: goreisan (五苓散) (manufacturer not identified) 2.5 g t.i.d. (n=11).

Arm 2: goreisan (五苓散) (manufacturer not identified) 2.5 g t.i.d. + shakuyakukanzoto (芍薬甘草湯) (manufacturer not identified) 2.5 g t.i.d. (n=11).

Arm 3: no Kampo therapy (n=11).

6. Main outcome measures

Time to dissipation of vomiting, diarrhea, and abdominal pain.

7. Main results

Time until vomiting dissipated was 79.1 ± 27.5 minutes in Arm 1 (mean \pm S.D. and the same below), 83.6 ± 20.1 minutes in Arm 2, and 1701.8 ± 377.2 minutes in Arm 3. Time until diarrhea dissipated was 110.0 ± 30.0 minutes in Arm 1, 129.5 ± 28.6 minutes in Arm 2, and 1728.2 ± 352.0 minutes in Arm 3. Time until abdominal pain dissipated was 122.3 ± 26.5 minutes in Arm 1, 105.0 ± 16.0 minutes in Arm 2, and 1813.6 ± 357.1 minutes in Arm 3.

8. Conclusions

Goreisan and shakuyakukanzoto are effective for vomiting, diarrhea, and abdominal pain due to infectious diarrheal disease caused by norovirus.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This clinical trial investigated the therapeutic effects of goreisan and shakuyakukanzoto for infectious diarrheal disease caused by norovirus. It is difficult to assess the therapeutic effects of Kampo medicines on acute-stage diseases, particularly because patients do not return for examination after improvement. In that sense, this is a valuable clinical study as it elucidates the effectiveness of Kampo medicines for an acute-stage disease. Yet, notwithstanding that this written report has the form of an academic article, no mention is made of patient background (age and gender, etc.), the period between onset and examination, and the number (if any) of dropouts. Furthermore, time until dissipation of symptoms are clearly different between the Arms (goreisan, goreisan and shakuyakukanzoto, and no Kampo medicine), but the statistics are not analyzed, meaning there is no mention of significant differences. It is a worthwhile clinical study, so, the authors should have included these details in their article. Yet, the study can rightly be considered excellent because acute-stage disease cannot be easily monitored following therapy, and because it focuses attention on the question of whether Kampo medicines are effective for norovirus infection, a disease without very effective treatment. Hopefully this study will lead to others that examine larger numbers of cases.

12. Abstractor and date

Goto H, 31 December 2012.

6. Nervous System Diseases (including Alzheimer's Disease)**Reference**

Nishioka M, Shimada M, Kurita N, et al. The Kampo medicine, Goshajinkigan, prevents neuropathy in patients treated by FOLFOX regimen. *International Journal of Clinical Oncology* 2011; 16: 322–7. CENTRAL ID: CN-00812737, Pubmed ID: 21258836

1. Objectives

To clarify the efficacy and adverse effects of goshajinkigan (牛車腎気丸) for peripheral neuropathy induced by oxaliplatin therapy for advanced or recurrent colorectal cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

University of Tokushima Hospital, Japan.

4. Participants

Forty-five outpatients who received mFOLFOX6 (oxaliplatin + l-LV + 5FU) therapy for advanced colorectal cancer from Jan. 2007 to Dec. 2009. Each patient had performance status (PS) 0–2, and no patient had bone marrow, hepatic, renal, or cardiac function abnormalities, clinical neuropathy, diabetes, alcohol-related diseases, or brain lesions.

5. Intervention

Arm 1: TSUMURA Goshajinkigan Extract Granules (7.5 g/day, in 2 or 3 divided doses) in combination with mFOLFOX6 therapy (n=22).

Arm 2: mFOLFOX6 therapy alone (n=23).

6. Main outcome measures

Incidence of grade 3 peripheral neuropathy, percentage of patients who developed grade 2 or 3 peripheral neuropathy after each treatment period, grade 3 adverse effects other than peripheral neuropathy, and modification of the effects of mFOLFOX6 therapy. (Peripheral neuropathy was assessed according to DEB-NTC [Neurotoxicity Criteria of Debiopharm]).

7. Main results

There were no significant differences in background factors between groups (age, gender, PS, proportion of rectal/colon cancer, site of metastasis, proportion of previously treated patients, proportion of patients taking bevacizumab in combination, number of completed courses, and cumulative oxaliplatin dose). Grade 3 peripheral neuropathy incidence was significantly lower in arm 1 than arm 2 ($P < 0.01$) and percentage of patients with grade 2 and 3 peripheral neuropathy at the beginning of each course was lower in arm 1. However, goshajinkigan did not modify the incidence of other adverse effects (grade 3) or therapeutic effects of mFOLFOX6 therapy.

8. Conclusions

Goshajinkigan decreased the incidence of severe peripheral neuropathy induced by mFOLFOX6 therapy (oxaliplatin + l-LV + 5FU) in patients treated for non-resectable or recurrent colon cancer.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse effects mentioned.

11. Abstractor's comments

The recent advent of oxaliplatin has been a major advance in the chemotherapy of colorectal cancer. Because peripheral neuropathy is the main dose-limiting toxicity of the therapy, its prevention is vital to improve the effectiveness of chemotherapy. Varieties of options have so far been tested in vain. The present trial suggested that goshajinkigan effectively decreased the incidence of severe peripheral neuropathy induced by mFOLFOX6. But it did not improve the prognosis of the patients, because it did not extend the treatment period of mFOLFOX6. We look forward to the investigations of the mechanisms of action of goshajinkigan for peripheral neuropathy as well as the establishment of the measures to increase the courses of mFOLFOX6 for colorectal cancer.

12. Abstractor and date

Hoshino E, 31 December 2012.

8. Ear Diseases

Reference

Kaneko T. Comparison of saireito and isosorbide in efficacy against low-frequency sensorineural hearing loss. *Kampo to Saishin Chiryō (Kampo and the Newest Therapy)* 2010; 19: 233–9 (in Japanese with English abstract). Ichushi Web ID: 2010304850

1. Objectives

To compare the effectiveness of saireito (柴苓湯) and isosorbide for low-frequency sensorineural hearing loss.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

An otorhinolaryngology clinic (Tochigi prefecture), Japan

4. Participants

One hundred and fifty-five patients with low-frequency sensorineural hearing loss who presented with ear blockage sensation as chief complaint between June 2008 and October 2009.

5. Intervention

Arm 1: TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. (n= 76).

Arm 2: isosorbide (Kowa Pharmaceutical Co., Ltd., Isobide) 30 mL t.i.d. (n=75).

6. Main outcome measures

Two measures: pure tone audiometry and subjective symptoms. Assessment by pure tone audiometry was divided into four stages: recovered (hearing threshold levels for three low frequencies [125, 250, and 500 Hz] all found within 20 dB, or no left/right difference detected), improvement (restored to 10 dB or more, but not full recovery), no change (less than 10 dB), and worsening. Four-stage subjective assessment: improved, somewhat improved, no change, worsened.

7. Main results

The number of tested patients was 51 in arm 1 (10 males and 41 females; ages 19–76; mean age 47.8 years) and 53 in arm 2 (16 males and 37 females; ages 11–78; mean age 47.1 years). Arm 1 showed a slightly stronger tendency for improvement in the hearing test compared to arm 2, but no statistically significant difference was observed. The subjective measures “no change” and “worsened” tended to be more common in arm 2, but no significant difference was observed. Comparison of initial occurrences with recurrences showed that improvement tended to be more difficult after recurrence in both groups, but no significant difference was observed. Recovery tended to be poor in subjects with dizziness symptoms in both groups, but no significant difference was observed.

8. Conclusions

Saireito and isosorbide are similarly effective for low-frequency sensorineural hearing loss.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor’s comments

Low-frequency sensorineural hearing loss is frequently encountered in daily practice, nevertheless, its causes remain unknown. A finding of the study that is significant in clinical and pathological terms is that Saireito and isosorbide have equal effectiveness. Unfortunately, the trial amounted to a quasi-RCT because allocation of participants to receive one of the treatments was in the order of diagnosis. The reliability of the results could have been improved if patients who did not return to the clinic for determination of the effects of treatment could have been followed up. Participants might not have returned because their symptoms improved or because they visited another clinic. This greatly affected the results. Hopefully the researcher will properly randomize the trial and improve the follow-up rate in the next stage of his research. In this study a doctor at the frontline of community health care has attempted an RCT to verify a medical practice that has concerned him in the clinic. It is praiseworthy for its contribution to the development of Kampo medicine.

12. Abstractor and date

Tsuruoka K, 31 December 2012.

9. Cardiovascular Diseases

Reference

Yoshikawa T, Munakata S, Okuma H. Effectiveness of Goreisan for recurrence prevention in elderly cases of chronic subdural hematoma surgery— Interim report on a comparative trial*. *Noshinkei Geka to Kampo (Neurosurgery and Kampo)* 2010; 16 (in Japanese).

1. Objectives

To evaluate the effectiveness and safety of goreisan (五苓散) after chronic subdural hematoma surgery in elderly people.

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Neurosurgery, Kuroishi General Hospital, Japan.

4. Participants

Forty-three elderly people over 70 years who underwent surgery (trephining) for symptomatic chronic subdural hematoma between January and August 2009.

5. Intervention

Administration continued for 1 month from the day after surgery.

Arm 1: goreisan (五苓散) (manufacturer not identified) 7.5 g/day (administration frequency not indicated) (n=22).

Arm 2: no treatment (n=21).

Steroids, glyceol, or hemostatics were not used in combination.

6. Main outcome measures

Changes in the hematoma were compared using CT scan 7, 14, and 28 days after surgery.

7. Main results

The age range was 73–89 years, and the between-group differences in gender or age were insignificant. The rate of hematoma shrinkage was greater in arm 1 than arm 2, especially between the 7th and 14th days (statistical significance not specified). Repeat surgery was required for 2 of the 22 participants in arm 1 (9%) and 5 of the 21 participants in arm 2 (24%), however, there was no significant between-group difference.

8. Conclusions

Goreisan is potentially effective for prevention of recurrence following chronic subdural hematoma surgery.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No complications from goreisan were observed.

11. Abstractor's comments

This is a novel clinical study that investigated the effects of goreisan in preventing recurrence in elderly after chronic subdural hematoma surgery. The study was conducted to investigate goreisan's effects in preventing recurrence of postoperative chronic subdural hematoma, because it had been suggested that goreisan was effective for non-surgical cases of the condition. However, the study was presented as an abstract at a seminar, so unfortunately no details of the methods and results are included. In addition, it is an interim report, as the title indicates, so at the time it was written, it could report no significant difference recurrence rate between the goreisan group and the control group. The authors will hopefully continue with their research because the possibility remains that enlarging the sample groups will elucidate the effectiveness of goreisan, as the authors mention in their abstract. Goreisan has few adverse effects, so once it is established that it is effective for the prevention of recurrence after surgery in elderly cases of chronic subdural hematoma, a new therapeutic domain will have opened up for Kampo medicines in the field of neurosurgery. This is, therefore, a very important clinical study that holds much interest.

12. Abstractor and date

Goto H, 31 December 2012.

10. Respiratory Diseases (including Influenza and Rhinitis)

References

Mukaida K, Hattori N, Kondo K, et al. A pilot study of the multiherb Kampo medicine bakumondoto for cough in patients with chronic obstructive pulmonary disease. *Phytomedicine* 2011; 18: 625–9. CENTRAL ID: CN-00790726, Pubmed ID: 21177084

Hattori N, Mukaida K, Haruta Y, et al. A pilot study of the effects of Bakumondoto (TJ-29) on cough in chronic obstructive pulmonary disease (COPD)*. *Kampo to Meneki – Arerugi (Kampo and Immuno-Allergy)* 2011; 24: 38–45 (in Japanese with English abstract).

1. Objectives

To evaluate the effect of bakumondoto (麦門冬湯) on cough in patients with chronic obstructive pulmonary disease (COPD).

2. Design

Crossover randomized controlled trial (RCT –cross over).

3. Setting

Hiroshima University Hospital and two general hospitals, Japan.

4. Participants

Twenty-four COPD outpatients aged over 65 who presented between May 2007 and March 2009.

5. Intervention

Treatment with or without bakumondoto (麦門冬湯) for 8 weeks in a cross-over design.

Patients taking any Kampo medicine within the previous 2 weeks were excluded. Treatment with the conventional COPD drugs was continued during the trial.

Arm 1: TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. before meals for 8 weeks, then no bakumondoto (麦門冬湯) for 8 weeks (n=13).

Arm 2: No bakumondoto (麦門冬湯) for 8 weeks, then TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. before meals for 8 weeks (n=11).

One subject in arm 1 was excluded from the efficacy analysis.

6. Main outcome measures

Frequency and intensity of cough assessed on a VAS (visual analogue scale) and changes in severity as recorded in a cough diary. Quality of life (QOL) using St. George's Respiratory Questionnaire (SGRQ). Lung functions.

7. Main results

Twenty-three patients were included in the efficacy analysis. VAS scores showed significant improvement in cough intensity and frequency during the first 8-week period of treatment with bakumondoto in arm 1 ($P=0.004$), but the magnitude of improvement gradually declined after treatment ceased. In arm 2, however, no significant improvement was observed for the latter 8-week period of treatment with bakumondoto. The authors do not mention whether or not there was a significant difference between the bakumondoto treatment and non-treatment groups for arms 1 and 2 combined. Neither QOL nor lung functions were affected by bakumondoto.

8. Conclusions

Bakumondoto is potentially effective for cough in elderly COPD patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Increases in ALP were observed in one participant in each of arms 1 and 2, however, they both completed the course of bakumondoto.

11. Abstractor's comments

The report by Hattori et al. (2011) was presented at a conference, so it includes questions and answers. One person asked whether cough in COPD patients was a common complaint. The presenter replied that there were many cases of exposure to toxic gas among the cases at Hiroshima University, and that some of those who complained of cough symptoms were included in the study. However, there is no mention of patients being exposed to toxic gas in the article by Mukaida et al. (2011). The authors should include such background information in their article.

12. Abstractor and date

Fujisawa M, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

References

Tominaga K, Fujiwara Y, Shimoyama Y, et al. Rikkunshito improves PPI-refractory NERD: a prospective randomized multi-center trial in Japan. *Gastroenterology* 2010; 138: S655–6.

Tominaga K, Fujiwara Y, Arakawa T, et al. GERD — Rikkunshito*. *Shindan to Chiryō (Diagnosis and Treatment)* 2011; 99: 771–6 (in Japanese). [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the effectiveness of rikkunshito (六君子湯) for patients with proton pump inhibitor (PPI)-resistant gastroesophageal reflux disease (GERD, and especially non-erosive reflux disease [NERD]).

2. Design

Randomized controlled trial (RCT).

3. Setting

Department of Gastroenterology, Osaka City University Hospital, and four other hospitals/clinics, Japan.

4. Participants

Seventy-one PPI-resistant GERD patients who showed no improvement despite taking rabeprazole (RPZ 10 mg/day) for more than four weeks.

5. Intervention

Arm 1: combination group: Participants continued taking 10 mg/day of RPZ and also took TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. (n=35).

Arm 2: double-dose group: Participants doubled their RPZ dose to 20 mg/day (n=36).

Assessment after 4 weeks of treatment in both groups.

6. Main outcome measures

Frequency Scale for Symptoms of GERD (FSSG) score and improvement rate.

7. Main results

Thirty-three of the 104 subjects were excluded from the assessment. There were no significant differences between participants in age, gender, body mass index, or endoscopic findings after PPI monotherapy. However, FSSG scores were significantly higher in arm 1 before the trial commenced. FSSG total score (arm 1, $P < 0.001$; arm 2, $P < 0.01$) as well as reflux and indigestion subscores improved significantly in both groups after 4 weeks of treatment. The before/after improvement rate was similar in both groups. Sub-group analysis of males showed significant improvement in arm 1 but not arm 2. Remarkably, the ectomorphic group showed similar trends in both arms.

8. Conclusions

Rikkunshito is effective for patients with PPI-resistant GERD (and especially NERD). The effects of combined treatment with RPZ and Rikkunshito are similar to treatment with double the RPZ dosage.

9. From Kampo medicine perspective

The researchers did not analyze participants' *sho* (証, patterns), but remarkable and significant effects were observed in ectomorphic males.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

There is still no clear definition of PPI-resistant GERD and no treatments have yet been established. Against that background, this RCT holds great clinical significance because it compared combined rikkunshito and RPZ with double-dosage RPZ in GERD patients who did not respond to 10 mg/day of RPZ. Participants showed similar rates of improvement; however, the exacerbation rate was lower in the rikkunshito and RPZ group, which indicates the effectiveness of rikkunshito in combination.

12. Abstractor and date

Kogure T, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Morita T. Effects of rikkunshito (TJ-43) on gastroesophageal reflux, esophageal motor functions and salivary secretion: placebo-controlled double-blind study. *Nikkei Medical (Supplement)* 2010; 8: 27 (in Japanese).

1. Objectives

To evaluate the effects of rikkunshito (六君子湯) on esophageal motor function and gastroesophageal reflux.

2. Design

Randomized controlled crossover trial (RCT - cross over).

3. Setting

No description (the author is from the Second Department of Internal Medicine, Shimane University), Japan.

4. Participants

Ten healthy people.

5. Intervention

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days, then placebo for 7 days (number of participants not specified).

Arm 2: placebo for 7 days then TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days (number of participants not specified).

6. Main outcome measures

Lower esophageal sphincter (LES) resting internal pressure, esophageal peristaltic contraction pressure, gastroesophageal reflux frequency.

7. Main results

Rikkunshito significantly increased LES resting internal pressure ($P<0.05$), but had no effect on esophageal peristaltic contraction pressure and gastroesophageal reflux frequency.

8. Conclusions

Rikkunshito increases LES static internal pressure in healthy people without affecting esophageal peristaltic contraction pressure or gastroesophageal reflux frequency.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Gastroesophageal reflux has been increasing in recent years, particularly among elderly people. Researchers hope rikkunshito will be effective in cases where it cannot be controlled successfully with proton pump inhibitors. This study investigates the effects of rikkunshito on healthy people as the first stage of evidence gathering. Rikkunshito increased LES static pressure, and this study is commendable for having shown that rikkunshito increases that physiological response when a meal is taken. Analysis of the other measures showed no significant difference, however, that result can be accepted for what it is: the outcome of an investigation with healthy subjects. Yet, since the study was randomized, the number of participants in each group should have been indicated. Hopefully, a similar study on gastroesophageal reflux patients will be conducted with reference to these data.

12. Abstractor and date

Motoo Y, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Morita T. Effects of rikkunshito (TJ-43) on gastroesophageal reflux, esophageal motor functions and salivary secretion: placebo-controlled double-blind study. *Nikkei Medical (Supplement)* 2010; 8: 27 (in Japanese).

1. Objectives

To evaluate the effects of rikkunshito (六君子湯) on esophageal motor function and gastroesophageal reflux.

2. Design

Randomized controlled crossover trial (RCT – cross over).

3. Setting

No description (the author is from the Second Department of Internal Medicine, Shimane University), Japan.

4. Participants

Twenty healthy volunteers.

5. Intervention

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days, then placebo for 7 days (number of participants not specified).

Arm 2: placebo for 7 days then TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days (number of participants not specified).

6. Main outcome measures

Saliva amount, salivary epidermal growth factor (EGF), salivary bicarbonate concentration.

7. Main results

Rikkunshito caused no significant change in saliva amount, salivary EGF, or salivary bicarbonate concentration.

8. Conclusions

Rikkunshito increases lower esophageal sphincter (LES) resting internal pressure in healthy people, but does not affect saliva excretion.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Saliva dilutes refluxed acid and neutralizes bicarbonate, while EGF appears to aid repair of esophageal mucous cells. Decreased saliva excretion in conditions including gastroesophageal reflux, Sjogren's syndrome, diabetes, old age, and stress facilitate the onset of reflux esophagitis. This trial was conducted on the assumption that increases in saliva excretion, and therefore in EGF and bicarbonate, by rikkunshito will improve gastroesophageal reflux disease (GERD). But the study found no significant effect on these factors, which at this point suggests that rikkunshito's main mechanism of action is the increase in LES pressure. The subjects in this study were healthy volunteers, so a further study might verify that the improvement of GERD by rikkunshito is due to increased saliva excretion. To confirm the mechanism, participants with reduced saliva excretion (e.g., elderly people, diabetics, or Sjögren's syndrome sufferers) should be compared to participants with normal saliva excretion to find the differences among them.

12. Abstractor and date

Motoo Y, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Shiratori M, Shoji T, Kanazawa M, et al. Effect of rikkunshito on gastric sensorimotor function under distention. *Neurogastroenterology & Motility* 2011; 23: 323-9, e155-6. Pubmed ID: 21175995

1. Objectives

To evaluate the effects of rikkunshito (六君子湯) on gastric contraction and expansion.

2. Design

Crossover randomized controlled trial (RCT-cross over).

3. Setting

Tohoku University Hospital, Japan.

4. Participants

Nine healthy volunteers.

5. Intervention

Participants were randomly assigned to either arm 1 or arm 2.

Arm 1: gastric pressure measured after observation for 2 weeks without administration and then after taking 7.5 g/day of TSUMURA Rikkunshito (六君子湯) Extract Granules for 2 weeks. Number of subjects: not reported.

Arm 2: gastric pressure measured after taking 7.5 g/day of TSUMURA Rikkunshito Extract (六君子湯) Granules for 2 weeks and then after observation for 2 weeks without administration. Number of subjects: not reported.

6. Main outcome measures

Gastric pressure measurements using a gastric barostat before and after imposition of stress.

7. Main results

Reduction in gastric volume due to stress was observed before or after but not during the period of rikkunshito administration. Pressure thresholds for epigastric bloating and for pain were lower during rikkunshito administration, regardless of stress imposition.

8. Conclusions

Rikkunshito may improve changes in gastric wall tonus caused by stress or anxiety.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This article demonstrates the potential of rikkunshito in helping to control overeating when stress is not present, and in preventing appetite reduction when stress is present. Unfortunately, however, the authors did not report the number of subjects in each group. It is significant that the study used the objective measure of gastric pressure to assess the specific effects of rikkunshito on gastric contraction and expansion.

12. Abstractor and date

Nakata H, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Takayama S, Seki T, Watanabe M, et al. The effect of warming of the abdomen and of herbal medicine on superior mesenteric artery blood flow – a pilot study. *Forschende Komplementär Medizin* 2010; 17: 195–201 (in English with German abstract). Pubmed ID: 20829597

1. Objectives

Comparative evaluation of the regulatory effects of thermal stimulation to the abdomen and Daikenchuto (大建中湯) on superior mesenteric artery (SMA) blood flow in healthy people.

2. Design

Randomized controlled trial (RCT).

3. Setting

Five centers, including the Center for Asian Traditional Medicine, Graduate School of Medicine, Tohoku University, Japan.

4. Participants

Forty-two healthy male volunteers with no heart disease.

5. Intervention

Arm 1: participants received 20 minutes of thermal stimulation to the paraumbilical region with a warming device (40°C), and were then observed for 50 minutes.

Arm 2: participants took TSUMURA Daikenchuto (大建中湯) Extract Granules (5.0 g) with distilled water (50 mL, 37°C) and were then observed for 50 minutes.

Arm 3: participants took distilled water (50 mL, 37°C) and were then observed for 50 minutes.

Randomization was performed only in arm 1 and arm 2 (14 subjects per arm).

6. Main outcome measures

Hemodynamic testing: SMA blood flow was measured before taking daikenchuto, before thermal stimulation with a warming device, and before taking distilled water, and then 10, 20, 30, 40, and 50 minutes after the start of each intervention.

7. Main results

SMA blood flow increased significantly between 10 and 50 minutes after daikenchuto administration ($P < 0.01$) and between 10 and 40 minutes after thermal stimulation ($P < 0.05$). There was no significant difference between these arms. SMA blood flow did not change after administration of distilled water.

8. Conclusions

Daikenchuto increases SMA blood flow in healthy people. The increase is equivalent to that generated by thermal stimulation using a warming device.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study employed a physiological evaluation method of verification in its investigation of blood flow increase stimulated by daikenchuto, which is used for *kansho* (寒証, cold pattern). It appears to be either a follow-up of a study in *The Tohoku Journal of Experimental Medicine* (2009; 219: 319–30) or concurrent research, as it compared the effects of thermal stimulation using a warming device (positive control) with administration of distilled water only (negative control). Daikenchuto is well known for its promotion of intestinal movement and is used clinically for sub-ileus conditions regardless of pattern: it is recognized for certain effects. This study found that increases in SMA blood flow induced by daikenchuto were similar to those induced by a thermal stimulation device, which suggests that it would be valuable to practicing clinicians. However, it should be pointed out that the subjects were healthy volunteers and the study did not clarify the question of whether the same phenomenon would be observed in people suffering from ileus conditions or conditions associated with coldness in the pelvic cavity. Based on this study of healthy people, researchers should be encouraged to use the study's protocols to further elucidate the action mechanisms (probably more than one) of Kampo medicines, specifically daikenchuto, in outpatients with cold-pattern sub-ileus conditions or habitual constipation.

12. Abstractor and date

Ushiroyama T, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**Reference**

Horiuchi A, Nakayama Y, Tanaka N. Effect of traditional Japanese medicine, daikenchuto (TJ-100) in patients with chronic constipation. *Gastroenterology Research* 2010; 3: 151–5.

1. Objectives

To evaluate the effects of daikenchuto (大建中湯) in combination for chronic constipation patients taking sennoside.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Twenty-two patients with chronic constipation presenting with abdominal pain and bloating and treated for more than 3 months by taking sennoside (24–60 mg/day). Participants' stool frequency was less than three times a week when not taking sennoside. Colonoscopy revealed no abnormality, and participants had no history of abdominal surgery.

5. Intervention

Arm 1: Sennoside 24 to 60 mg/day with TSUMURA Daikenchuto (大建中湯) Extract Granules 7.5 g/day for 6 weeks (n=14).

Arm 2: Sennoside 24 to 60 mg/day with TSUMURA Daikenchuto (大建中湯) Extract Granules 15 g/day for 6 weeks (n=8).

6. Main outcome measures

Abdominal bloating (visual analogue scale), abdominal pain (visual analogue scale), Gastrointestinal Symptoms Rating Scale (GSRS), Gas Volume Score (GVS).

7. Main results

Abdominal bloating scores decreased significantly in both arms from 55 before intervention to 20 after four weeks of intervention in arm 1 ($P=0.006$) and from 69 to 35 in arm 2 ($P=0.007$). Abdominal pain scores decreased significantly from 32 to 9 after four weeks in arm 2 ($P=0.02$). GSRS scores also decreased significantly in both arms after four weeks, from 2.6 to 2.2 in arm 1 ($P=0.002$), and from 2.8 to 2.3 in arm 2 ($P=0.008$). GVS scores decreased significantly in both arms after six weeks, from 0.049 to 0.040 in arm 1 ($P=0.02$), and from 0.042 to 0.036 ($P=0.016$) in arm 2.

8. Conclusions

Daikenchuto alleviates abdominal pain and bloating in chronic constipation patients taking a stimulant laxative.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There were no adverse reactions.

11. Abstractor's comments

This study suggests that when taken in combination with sennoside, daikenchuto alleviates abdominal pain and bloating in chronic constipation patients. However, the study only makes before/after comparisons, not between-group comparisons. Daikenchuto is a prescription that warms the middle abdominal region and treats *kyosho* (虚証, deficiency patterns) (温中補虚), so it warms the gastrointestinal tract. On the other hand, the active constituent in senna leaf (番泻葉) is sennoside, which resolves heat in the stomach and intestines and promotes intestinal peristalsis. In Kampo medical terms, these drugs are used for the opposing pattern. Hopefully, researchers will conduct a trial that compares sennoside + daikenchuto to control groups including placebo and daikenchuto alone. Lastly, if each participant's *sho* (証, pattern) had been identified in this comparative study, light might have been shed on the pathological conditions for which daikenchuto is indicated.

12. Abstractor and date

Okabe T, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**References**

Watanabe K. Effects of Daikenchuto on early bowel movement after colorectal cancer surgery*. *Kampo Igaku (Science of Kampo Medicine)* 2010; 34: 346–7 (in Japanese).

Fujii S. Effects of Daikenchuto on early bowel movement after colorectal cancer surgery*. *Progress in Medicine* 2011; 31: 468–9 (in Japanese). [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the effectiveness and safety of daikenchuto (大建中湯) soon after colorectal cancer surgery.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Center for Gastroenterological Disease, Yokohama City University, Japan.

4. Participants

Participants received surgery (cur A resection) for colon cancer or sigmoid colon cancer between September 2009 and August 2010 (n=151). They were all over 20 years old, with performance status 0 or 1, and ability to eat and drink 2 days after surgery. No participants were asked for their laparotomy history or type of abdominal surgery (laparotomy or laparoscopic surgery). Participants with a history of emergency surgery, double cancer, or colostomy were excluded.

5. Intervention

Arm 1: daikenchuto (大建中湯) group (manufacturer not identified): 5 g t.i.d. (n=57).

Arm 2: mosapride (Gasmotin[®]) group: 5 g t.i.d. (n=54).

Arm 3: control group: no treatment (n=40).

6. Main outcome measures

Recovery of intestinal movement after surgery (period until both gas and stool passed), number of days in hospital after surgery, anti-inflammatory action (leucocytes, C-reactive protein [CRP] level), intestinal obstruction incidence, adverse events.

7. Main results

The period until gas was passed was significantly shorter in arm 1 and arm 2 than in arm 3 (2.6 days in arm 1 [$P=0.001$], 2.8 days in arm 2 [$P=0.036$], and 3.4 days in arm 3). No significant difference in the period until stool was passed was evident among the groups (arm 1, 3.4 days; arm 2, 3.8 days; arm 3, 3.8 days). The incidence of intestinal obstruction was lower but not significantly lower in arm 1 (arm 1, 1.8%; arm 2, 5.8%; arm 3, 10%). No among-group difference was observed in the leucocyte count, but the decrease in CRP in arm 1 was significant from the third day ($P<0.05$), suggesting that daikenchuto had anti-inflammatory effect. The number of days spent in the hospital after surgery was 8.7 in arm 1, 10.8 in arm 2, and 10.1 in arm 3, so hospital stay was the shortest for arm 1, and significantly shorter than that of arm 2 ($P=0.045$). Comparison with arm 3 yielded a P -value of 0.061.

8. Conclusions

Patients treated with daikenchuto soon after colorectal cancer surgery recover intestinal movement more rapidly. The results may lead to the idea that daikenchuto shortens post-surgery hospital stay or decreases the incidence of intestinal obstruction.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Rash was observed in one participant in the daikenchuto group, and liver dysfunction in one participant in the mosapride group, however, the causal relation to the medications remains unclear.

11. Abstractor's comments

This abstract summarizes the article by Fujii (2011). The trial is clinically significant for suggesting the effectiveness of Daikenchuto. The two references listed above reported on the same study. Watanabe's article (2010) appears to be an interim paper. This trial is not an RCT in the strict sense of the word because treatment was assigned on an alternate month basis. The study seems to offer the possibility of subanalysis, so further work is anticipated.

12. Abstractor and date

Tsuruoka K, 31 December 2012.

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Plotnikoff GA, Watanabe K, Torkelson C, et al. The TU-025 keishibukuryogan clinical trial for hot flash management in postmenopausal women: result and lessons for future research. *Menopause* 2011; 18: 886–92. CENTRAL ID: CN-00810843, Pubmed ID: 21738077

1. Objectives

To evaluate the clinical effects of keishibukuryogan (桂枝茯苓丸) for hot flashes in menopausal American women.

2. Design

Randomized controlled trial (RCT).

3. Setting

Allina Center for Health Care Innovation (Minneapolis, MN, USA).

4. Participants

Participants were menopausal American women between 45 and 58 years with a hot flash score of at least 28 points/week (n=178).

5. Intervention

Arm 1: oral administration of TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules (12.5 g/day) for 12 weeks (n=57).

Arm 2: oral administration of TSUMURA Keishibukuryogan (桂枝茯苓丸) Extract Granules (7.5 g/day) for 12 weeks (n=62).

Arm 3: oral administration of placebo for 12 weeks (n=59).

6. Main outcome measures

The Greene Climacteric Index (GCI), Pittsburgh Sleep Quality Index (PSQI), and a hot flash scale score.

7. Main results

The hot flash scale score decreased significantly ($P<0.001$) in all groups 12 weeks after commencement of the study, however no significant difference was observed among the three groups. Similarly, no significant among-group difference was observed in the Greene Climacteric Index (GCI) or the Pittsburgh Sleep Quality Index (PSQI).

8. Conclusions

There is no difference between the effects of keishibukuryogan and placebo on overall climacteric disorder symptoms and sleep quality in American menopausal women.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

The incidence of diarrhea was 1.7% in the placebo group, but approximately 20% in the keishibukuryogan groups.

11. Abstractor's comments

This study tested the effects of keishibukuryogan on climacteric disorder, a traditional therapy used in Japan, with the researchers asking menopausal American women to score their symptoms, chiefly hot flashes. keishibukuryogan has been one of the main therapeutic Kampo medicines used for climacteric disorder; it is the subject of many academic articles, and its clinical effects have been reported from a variety of perspectives. The present study found that keishibukuryogan extract preparation, compared to placebo, did not improve outcome in American women. However, keishibukuryogan is not necessarily the first choice for symptoms such as hot flashes, which frequently occur in estrogen-deficiency and climacteric disorder. This study might have demonstrated the superiority of estrogen preparations, which are chiefly Western drugs. However, the study did compare keishibukuryogan's effects on menopausal women whose hot flash score exceeded a certain number and its results do not appear to negate the use of keishibukuryogan in therapy for menopausal women, who suffer a variety of unspecified complaints (especially *oketsu* [瘀血, blood stasis] conditions). The authors say they hang their hopes on the emergence of more effective trial methods to test the effectiveness of traditional therapies such as Kampo. One hopes that the development of such research will revolve around RCTs that compare groups according to objective data based on *sho* (証, pattern).

12. Abstractor and date

Ushiroyama T, 31 December 2012.

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Yasui T, Matsui S, Yamamoto S, et al. Effects of Japanese traditional medicines on circulating cytokine levels in women with hot flashes. *Menopause* 2011; 18: 85–92. CENTRAL ID: CN-00787935, Pubmed ID: 20647958

1. Objectives

To evaluate the effects of keishibukuryogan (桂枝茯苓丸) and kamishoyosan (加味逍遙散) on levels of circulating cytokines in patients with hot flashes.

2. Design

Quasi-randomized controlled trial (Quasi-RCT).

3. Setting

Outpatients Clinic, Department of Obstetrics and Gynecology, Tokushima University Hospital, Japan.

4. Participants

One hundred twenty women with vasomotor symptoms (hot flashes, night sweats, etc.) but no use of drugs affecting the immune system within the previous year, including 17 women who received bilateral ovariectomy within the previous year and 103 perimenopausal women who were menstruating regularly (n=7), menstruating irregularly within the previous 12 months (n=51), and no longer menstruating (last menses within the previous year; n=45).

5. Intervention

Participants who wanted to receive treatment were allocated to arm 2 (odd-number days) or arm 3 (even-number days). Participants who did not want treatment were allocated to arm 1.

Arm 1: follow up only, no treatment (n=40).

Arm 2: TSUMURA Keishibukuryogan Extract Granules (2.5 g t.i.d) for 6 months (n=40).

Arm 3: TSUMURA Kamishoyosan Extract Granules (2.5 g t.i.d) for 6 months (n=40).

6. Main outcome measures

Hot flash symptoms (severe, moderate, or mild according to FDA hot flash assessment criteria); circulating levels of IL-1 β , IL-5, IL-6, IL-7, IL-8, IL-10, TNF- α , MCP-1, and MIP-1 β before and 6 months after administration.

7. Main results

Improvement rates in hot flashes were significantly higher in arm 2 and arm 3 compared to arm 1 ($P<0.01$). Comparisons before and after treatment in the hot flash improvement group showed that MCP-1, IL-8, and MIP-1 β decreased significantly in arm 2 ($P<0.05$ for both), while IL-6, IL-8, and MIP-1 β decreased significantly in arm 3 ($P<0.05$ for both).

8. Conclusions

Keishibukuryogan and Kamishoyosan improve hot flashes by lowering circulating levels of IL-8 and MCP-1, which are indicators of blood vessel inflammation.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This article describes the therapeutic value and mechanism of action of keishibukuryogan and kamishoyosan in menopausal hot flashes. Animal research has shown that keishibukuryogan is effective for peripheral hot flashes mediated by calcitonin gene-related peptide, and kamishoyosan is effective for central hot flashes mediated by luteinizing hormone-releasing hormone; therefore, it may be possible to clarify the differences between keishibukuryogan and kamishoyosan by allocating participants according to their *sho* (証, pattern), using a medical questionnaire or the like. The outcomes of further research are anticipated.

12. Abstractor and date

Nakata H, 31 December 2012.

15. Ante/Post-partum Diseases**Reference**

Takushima Y, Michigami F. Clinical study of Saireito on gestational edema and upper gastrointestinal symptoms. *Igaku to Yakugaku (Japanese Journal of Medicine and Pharmaceutical Science)* 2010; 64: 709–15 (in Japanese). Ichushi Web ID: 2011072703 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the effectiveness of saireito (柴苓湯) combined with either sojutsu (蒼朮, *Atractylodes Lancea* Rhizome) or byakujutsu (白朮, *Atractylodes* Rhizome) as constituent crude drugs for lower limb edema and functional dyspepsia-like gastrointestinal symptoms.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One hospital, Japan.

4. Participants

Fifty women in the latter stage of pregnancy with lower limb edema not associated with hypertension requiring drug therapy, and gastrointestinal symptoms such as appetite loss.

5. Intervention

Arm 1: saireito (柴苓湯) extract granules (manufacturer not identified) 3.0 g t.i.d. combined with sojutsu (蒼朮, *Atractylodes Lancea* Rhizome) for 4 weeks (n=25).

Arm 2: saireito (柴苓湯) extract granules (manufacturer not identified) 4.05 g b.i.d. combined with byakujutsu (白朮, *Atractylodes* Rhizome) for 4 weeks (n=25).

6. Main outcome measures

Ankle edema (ankle circumference), plantar edema (plantar circumference), gastrointestinal symptoms (questionnaire).

7. Main results

Ankle circumference began to improve significantly 2 weeks after saireito administration in both arms 1 and 2 ($P<0.05$). Improvement of plantar circumference after 4 weeks was significant in Arm 2 but not in Arm 1. Epigastralgia and bloating after meals at the end of the 4-week period of administration ($P<0.05$), epigastric heat sensation after treatment for 3 weeks ($P<0.01$), heaviness in the stomach after treatment for 3 weeks ($P<0.05$), and upper gastrointestinal symptoms overall (including gastrointestinal symptoms) after treatment for 3 weeks ($P<0.05$) were significantly improved in Arm 2 only.

8. Conclusions

Saireito combined with sojutsu and saireito combined with byakujutsu are both effective for lower limb edema in pregnancy. Of these combinations, only saireito + byakujutsu improve epigastric symptoms significantly.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse effects were observed.

11. Abstractor's comments

This is a quasi-randomized controlled trial in which medications were allocated in order of patient presentation. It is a significant clinical trial that compared the effects of byakujutsu or sojutsu with saireito for lower limb edema and epigastric symptoms in pregnancy. Before-after comparison demonstrated that only saireito combined with byakujutsu is effective for epigastric symptoms. This was probably a reflection of byakujutsu's capacity to promote gastrointestinal function. Therefore, the two different saireito formulae appear to be indicated for different patterns. A further study is recommended for comparison of groups in a randomized trial that includes a placebo group.

12. Abstractor and date

Okabe T, 31 December 2012.

18. Symptoms and Signs**Reference**

Irifune K, Hamada H, Ito R, et al. Antitussive effect of bakumondoto a fixed kampo medicine (six herbal components) for treatment of post-infectious prolonged cough: controlled clinical pilot study with 19 patients. *Phytomedicine* 2011; 18: 630–3. CENTRAL ID: CN-00790677, Pubmed ID: 21514123

1. Objectives

To evaluate the combined effects of bakumondoto (麦門冬湯) and a bronchodilator for prolonged cough following common cold.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT - envelope).

3. Setting

Six hospitals including Ehime University Hospital, Japan.

4. Participants

Twenty-seven adult patients who presented between February 2007 and March 2009 with prolonged cough for more than 3 weeks following a common cold. Patients whose prolonged cough was not attributable to common cold, and patients currently taking β 2 stimulants or anti-cholinergic drugs were excluded.

5. Intervention

Ultimately, 20 patients were registered after exclusions for adverse events and allocation errors.

Arm 1: TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. before or between meals, and 50 μ g Meptin[®] (n=9).

Arm 2: Meptin[®] 50 μ g b.i.d. after breakfast and before bed (n=10).

Patients with severe cough received Medicon[®], if requested.

6. Main outcome measures

Cough intensity on a 5-point scale and timing recorded in a cough diary, VAS (visual analogue scale) score for cough intensity and frequency, and sleep quality questionnaire.

7. Main results

A significant antitussive effect (based on cough diary data: arm 1, 11 subjects; arm 2, 8 subjects) was observed in arm 1 four and five days after administration ($P<0.05$). There was no significant difference between groups for sleep quality (questionnaire) or cough improvement (VAS).

8. Conclusions

Additional treatment with bakumondoto achieves earlier antitussive results in cases of prolonged cough that do not respond to centrally acting antitussives.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Meptin[®] (50 μ g) caused palpitations or tremors in 6 participants and bakumondoto extract granules caused rash in 1.

11. Abstractor's comments

Irifune et al. cite the assertion by Fujimori et al. (1997) that bakumondoto is effective for prolonged cough after common cold, whereas standard antitussive drugs are not. They also conducted a trial to compare the antitussive effects of Medicon[®] and bakumondoto, finding that bakumondoto has more rapid effects. The present study is the first randomized controlled trial (RCT) to clarify bakumondoto's antitussive effects. The use of central antitussives containing codeine for long periods is not recommended because of their adverse effects. Thus, using bakumondoto, which has few adverse effects, is apparently advantageous. Meptin[®] (50 μ g) results in frequent adverse effects when taken in combination, so further investigation into dosage, etc. is required.

12. Abstractor and date

Fujisawa M, 31 December 2012.

18. Symptoms and Signs**Reference**

Shimizu Y, Yoshimura K, Soda T, et al. The effects of Gosha-Jinki-Gan, a blended herbal medicine, and furosemide for nocturnal polyuria with elevated B-type natriuretic peptide: a crossover trial. *Neurourology and Urodynamics* 2010; 29: 833–4. CENTRAL ID: CN-00766683

1. Objectives

To evaluate the effectiveness of goshajinkigan (牛車腎気丸) for nocturnal polyuria with elevated B-type natriuretic peptide.

2. Design

Crossover randomized controlled trial (RCT – cross over).

3. Setting

No information about location of the trial (the first author belongs to the Department of Urology, Kyoto University), Japan.

4. Participants

Twenty-four patients over 50 years with a nocturia frequency of more than three times/night, a nocturnal polyuria index of more than 35%, and serum B-type natriuretic peptide (BNP) level of over 20 pg/mL.

5. Intervention

Arm 1: goshajinkigan (牛車腎気丸) (manufacturer not identified) 2.5 g t.i.d. for 4 weeks, then furosemide 20 mg q.d. (p.m.) for 4 weeks (n=14).

Arm 2: furosemide 20 mg once/day (p.m.) for 4 weeks, then goshajinkigan (牛車腎気丸) (manufacturer not identified) 2.5 g t.i.d. for 4 weeks (n=10).

6. Main outcome measures

International Prostate Symptom Score (IPSS), Pittsburgh Sleep Quality Index (PSQI), frequency volume chart (FVC), blood pressure, serum brain natriuretic peptide (BNP), and total body water assessed before and after each administration.

7. Main results

Mean age of participants was 73.8 years (54–85 years). Nocturia frequency and volume decreased significantly with furosemide administration compared to goshajinkigan administration (both $P<0.05$). However, IPSS-7, IPSS-QOL, and nocturia frequency improved significantly with both goshajinkigan and furosemide in before/after comparisons ($P<0.05$, $P<0.01$, $P<0.05$ for the three measures respectively with goshajinkigan, and $P<0.01$ for all three measures with furosemide). IPSS-total and nocturia volume improved significantly only with furosemide (both $P<0.01$). Nocturia volume decreased markedly with furosemide administration but only slightly with goshajinkigan administration. PSQI scores and subjective sleep scores improved significantly only with furosemide (both $P<0.05$).

8. Conclusions

Furosemide is more effective for nocturnal polyuria associated with elevated BNP, but goshajinkigan may be almost as effective.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This clinical study investigated the effectiveness of goshajinkigan for nocturnal polyuria associated with elevated B-type natriuretic peptide. By classifying the causes of subjects' condition (nocturnal polyuria), effective condition for using goshajinkigan can be identified. Furthermore, furosemide's effectiveness for this condition is clear, so choosing it as the control for comparing effects adds to the study's merits. On the other hand, the methods and results of the study remain unclear because the paper is in abstract form. There are no details on the washout period and when scores were assessed. These details should have been included to improve the validity of the results. Yet, Goshajinkigan may be effective for patients with slight nocturnal polyuria symptoms or patients who cannot take furosemide due to its adverse effects, which include electrolyte disturbance. It is, therefore, a highly significant clinical study.

12. Abstractor and date

Goto H, 31 December 2012.

18. Symptoms and Signs**Reference**

Jeong JS, Ryu BH, Kim JS, et al. Bojungikki-tang for cancer-related fatigue: A pilot randomized clinical trial. *Integrative Cancer Therapies* 2010; 9: 331–8. CENTRAL ID: CN-00770648, Pubmed ID: 21059621

1. Objectives

To evaluate the effectiveness of hochuekkito (補中益氣湯) for cancer-related fatigue.

2. Design

Randomized controlled trial (RCT).

3. Setting

East-West Neo Medical Center, Kyung Hee University, Republic of Korea.

4. Participants

Forty patients with cancer-related fatigue (May to October 2009).

5. Intervention

Arm 1: TSUMURA Hochuekkito (補中益氣湯) Extract Granules 7.5 g/day for 2 weeks (n=20).

Arm 2: no treatment, course monitored for 2 weeks (n=20).

6. Main outcome measures

Primary outcome measure: Visual Analogue Scale of Global Fatigue (VAS-F)

Secondary outcome measures: Functional Assessment of Cancer Therapy-General (FACT-G), Functional Assessment of Cancer Therapy-Fatigue (FACT-F), Trial Outcome Index-Fatigue (TOI-F).

7. Main results

Eighteen patients were included in each group for evaluation. Significant improvements were observed in arm 1 compared to arm 2 for before/after changes in all measures, VAS-F ($P=0.040$), FACT-G ($P=0.047$), FACT-F ($P=0.025$), and TOI-F ($P=0.049$).

8. Conclusions

Hochuekkito improves cancer-related fatigue.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Blood tests (aspartate amino transferase [AST], alanine aminotransferase [ALT], creatinine, blood urea nitrogen [BUN]) were performed before and after administration, and participants were asked about subjective symptoms using a questionnaire based on version 2.0 of the NCI-CTC-AE questionnaire. Although these results showed no significant change in liver or kidney function, two participants complained of grade 1 stomach discomfort.

11. Abstractor's comments

While fatigue is the most commonly known indication for hochuekkito, this study is valuable for having verified its effectiveness and safety for cancer patients through an RCT. Yet, the inclusion criteria included a two-month gap since chemo- or radiotherapy, which raises questions about whether their influence could really be ruled out. Furthermore, a placebo effect cannot be completely ruled out because no treatment was administered in arm 2, and the administration period was only two weeks. In future, such a study would hopefully give the control group a placebo, or increase the number of subjects, for treatment over a longer period.

12. Abstractor and date

Motoo Y, 31 December 2012.

21. Others**References**

Fujinami H. Assessment of diminished peristalsis using shakuyakukanzoto (TJ-68) as premedication for endoscopic retrograde cholangiopancreatography (ERCP): randomized placebo-controlled trial. *Nikkei Medical (Supplement)* 2010; 8: 34 (in Japanese).

Fujinami H, Kudo T, Nakayama Y, et al. Assessment of diminished peristalsis using shakuyakukanzoto (TJ-68) as premedication for endoscopic retrograde cholangiopancreatography (ERCP): a randomized, placebo-controlled trial. *Gastrointestinal Endoscopy* 2010; 71: AB227.

1. Objectives

To evaluate the effectiveness of shakuyakukanzoto (芍薬甘草湯) as premedication for endoscopic retrograde cholangiopancreatography (ERCP) in suppressing duodenal peristalsis.

2. Design

Randomized controlled trial (RCT).

3. Setting

No. 3 Department of Internal Medicine, Toyama University Hospital, Japan.

4. Participants

Thirty patients undergoing ERCP (20 males, 10 females; mean age 66.5 years).

5. Intervention

Arm 1: shakuyakukanzoto group: TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 5.0 g dissolved in 50 mL warm water (n=10).

Arm 2: anticholinergic group: scopolamine butylbromide solution 20 mg/mL intravenous injection (n=10).

Arm 3: placebo group: warm (37°C) water 50 mL (n=10).

The liquids in arm 1 and arm 3 were sprayed directly into the duodenum through an endoscope.

6. Main outcome measures

Assessment by DVD image analysis of the time required to stop peristalsis (RT: seconds) and period of cessation of peristalsis (DT: minutes).

7. Main results

Peristalsis stopped in 8/10 patients in arm 1, 10/10 in arm 2, and 0/10 in arm 3. RT was 76.0 ± 23.9 in arm 1 and 42.4 ± 6.1 in arm 2. DT was 11.3 ± 4.2 in arm 1 and 14.9 ± 5.3 in arm 2. There was no significant difference in RT and DT between these groups.

8. Conclusions

Shakuyakukanzoto is effective as premedication for ERCP in suppressing duodenal peristalsis. Its effects are similar to scopolamine butylbromide solution 20 mg/mL intravenous injection.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

In clinical terms, this is a highly significant clinical trial because it assessed peristalsis in three groups during actual ERCP. Anticholinergics are generally used to reduce peristaltic action for upper gastrointestinal endoscopy and ERCP, but they are contraindicated for patients with ischemic heart disease, prostatic hypertrophy, glaucoma, etc. Such patients cannot take anticholinergics. Shakuyakukanzoto appears to be a very safe premedication that will reliably suppress peristalsis in such patients.

12. Abstractor and date

Kogure T, 31 December 2012.

21. Others**Reference**

Kita T, Sumino M. The effect of dosage frequency of ethical Kampo extract formulations on drug compliance – a comparison of twice a day and three times a day prescriptions. *Igaku to Yakugaku (Japanese Journal of Medicine and Pharmaceutical Science)* 2011; 66: 117–22 (in Japanese). Ichushi Web ID: 2011300492 [MOL](#), [MOL-Lib](#)

1. Objectives

To assess whether differences in ethical Kampo extract formulation dosage and dosing frequency have an effect on compliance and patient satisfaction.

2. Design

Crossover randomized controlled trial (RCT – cross over).

3. Setting

Not specified (the authors are from the Center for Environment, Health and Field Sciences, Chiba University.), Japan.

4. Participants

One hundred and nine outpatients who had been taking ethical Kampo extract formulation for chronic disease or symptoms for more than one month, whose condition had stabilized, and who gave their consent.

5. Intervention

Kracie KB - stick packages (twice a day) and Kracie EK - stick packages (three times a day) containing the same ethical Kampo extract formulation as currently being taken. Administered for one week each.

Arm 1: three times a day for the first week, then twice a day for the second week (n=54).

Arm 2: twice a day for the first week, then three times a day for the second week (n=55).

6. Main outcome measures

Questionnaire on dosing circumstances (timing, whether dosing was missed, and how often dosing was missed), patients' satisfaction with frequency and dosage (5-step scale: satisfied, slightly satisfied, no change, slightly dissatisfied, dissatisfied), and lifestyle (which suits lifestyle better, twice a day or three times a day) during each period.

7. Main results

In arm 1, dosing was missed in 36 of 54 participants during the first week (three times a day) and 15 of 54 participants in the second week (twice a day), which meant a significant difference ($P<0.0001$). Similarly, there was a significant difference in missed dosing in arm 2 ($P<0.001$). The mean amount and proportion of left-over medication was 2.0 ± 2.2 packages and $9.4\pm 10.4\%$, respectively, during the three-times-a-day period and 0.4 ± 0.8 and $2.8\pm 6.0\%$ respectively during the twice-a-day period. There was a significant difference in the proportion of left-over medication between the periods ($P<0.0001$). Participants missed their medication most often around midday (63 participants, 87.5%) during the three-times-a-day period. Thirty-nine participants (72.2%) were satisfied or slightly satisfied in arm 1, where dosage frequency decreased in the second week, while 36 participants (65.5%) were satisfied or slightly satisfied in arm 2, where dosage frequency increased in the second week. Ninety-four participants (86.2%) chose the twice-a-day medication for consistency with lifestyle, while 6 participants chose the three-times-a-day medication (5.5%) and 9 (8.3%) were indifferent.

8. Conclusions

Reducing the frequency of Kampo extract preparation dosing from three to two times a day decreases missed dosing, and therefore is an effective means of improving compliance.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This RCT employed different dosing frequencies in the intervention and measured outcomes in terms of dosing compliance and satisfaction. This trial is, therefore, very instructive in that it demonstrates that such an approach can be used in an RCT. It also has great clinical significance in the sense that doctors' prescribing behavior can change patients' dosing compliance. Researchers should be encouraged to develop further research along these lines, perhaps by including symptoms among the outcomes.

12. Abstractor and date

Tsuruoka K, 31 December 2012.

10. Respiratory Diseases (including Influenza and Rhinitis)**References**

Iwasaki K, Kato S, Monma Y, et al. A pilot study of banxia houpu tang, a traditional Chinese medicine, for reducing pneumonia risk in older adults with dementia. *Journal of the American Geriatrics Society* 2007; 55: 2035-40. CENTRAL ID: CN-00699802, Pubmed ID: 17944889

Iwasaki K, Kato S, Monma Y, et al. A pilot study of banxia houpu tang, a traditional Chinese medicine, for reducing pneumonia risk in brain-damaged elderly. *International Journal of Stroke* 2010; 5 suppl 2: 38-9. CENTRAL ID: CN-00782273

1. Objectives

To evaluate whether hangekobokuto (半夏厚朴湯) prevents aspiration pneumonia and pneumonia-related mortality in elderly people with dementia.

2. Design

Randomized controlled trial (RCT).

3. Setting

Two hospitals (the authors belong to Tohoku University, Dokkyo University, and two hospitals), Japan.

4. Participants

One hundred and four elderly people with cerebrovascular disease, Alzheimer's disease, or Parkinson's disease (31 males, 73 females, mean age 83.5±7.8 years).

5. Intervention

Ninety-five participants were randomly allocated to two groups for treatment.

Arm 1: Tsumura Hangekobokuto (半夏厚朴湯) Extract Granules 2.5 g t.i.d. (body weight ≥50 kg) or 2.5 g b.i.d. (body weight <50 kg) for 12 months, n=47.

Arm 2: placebo (lactose) 1.0 g t.i.d. (body weight ≥50 kg) or 1.0 g b.i.d. (body weight <50 kg) for 12 months, n=48.

6. Main outcome measures

The occurrence of pneumonia, mortality due to pneumonia, and amount of oral food intake.

7. Main results

Data from 92 of the 95 subjects were analyzed. One of four patients who developed pneumonia in arm 1 died as a result, whereas 6 of 14 patients who developed pneumonia in arm 2 died as a result. There was a significant decrease in pneumonia onset in arm 1 compared to arm 2 ($P=0.008$). Mortality related to pneumonia tended to be less in arm 1 than in arm 2 ($P=0.05$). Hangekobokuto (半夏厚朴湯) reduced the relative risk of pneumonia to 0.51 (95% CI: 0.27–0.84) and death by pneumonia to 0.41 (95% CI: 0.10–1.03). Amount of oral food intake was significantly greater in arm 1 than arm 2 ($P=0.06$).

8. Conclusions

Treatment with hangekobokuto (半夏厚朴湯) reduces the risk of pneumonia in elderly people with cerebral disorder. The results also suggest that hangekobokuto (半夏厚朴湯) administration is effective in sustaining food intake.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse effects were observed.

11. Abstractor's comments

The findings of this well-designed randomized controlled study suggest the efficacy of hangekobokuto in preventing aspiration pneumonia in elderly people with dementia. In addition, hangekobokuto administration tended to improve activities of daily living such as self-feeding and to reduce the number of febrile days. Further studies to assess these points are expected. In Kampo medicine, hangekobokuto is a therapeutic prescription indicated for nonfebrile patients with *tan'in* (痰飲, fluid retention) pattern. However, many elderly people present with *sosho* (燥証, dryness pattern). Hopefully, the researchers will analyze the data from this study from the perspective of patterns, once the patterns of the 95 elderly participants in this study become available.

12. Abstractor and date

Okabe T, 25 November 2008, 1 June 2010, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**References**

Arai M. Rikkunshito significantly enhances the secretion of ghrelin in patients with functional dyspepsia*. *Kampo Igaku (Kampo Medicine)* 2009; 33: 405–6.

Matsumura T, Arai M, Suzuki T, et al. The traditional Japanese medicine rikkunshito improves upper gastrointestinal symptoms in patients with functional dyspepsia. *Gastroenterology* 2010; 138: S471. CENTRAL ID: CN-00796662

Arai M, Matsumura T, Yoshikawa M, et al. Analysis of the Rikkunshito efficacy on patients with functional dyspepsia*. *Nihon Yakurigaku Zasshi (Folia Pharmacologica Japonica)* 2011; 137: 18–21. (in Japanese). [J-STAGE](#)

1. Objectives

To clarify the effect of rikkunshito (六君子湯) on ghrelin secretion and symptoms and to clarify its mechanism of action in patients with functional dyspepsia (FD).

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned (the author belongs to the Department of Gastroenterology, Graduate School of Medicine, Chiba University), Japan.

4. Participants

Twenty-seven patients with FD fulfilling the Rome III criteria.

5. Intervention

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 4 weeks (number of participants not mentioned).

Arm 2: domperidone 30 mg/day for 4 weeks (number of participants not mentioned).

6. Main outcome measures

Blood acylated ghrelin levels, gastrointestinal symptoms (assessed by Gastrointestinal Symptom Rating Scale [GSRS] score), and depressive symptoms (assessed by Self-rating Depression Scale [SDS] score) before administration and 2 and 4 weeks after administration began.

7. Main results

Blood acylated ghrelin level tended to increase during the 4-week treatment period in arm 1; no change was observed in arm 2. Four weeks after administration, gastrointestinal symptoms including reflux, abdominal pain, and indigestion improved in arm 1, but only indigestion improved in arm 2. Depression scores did not change significantly in either group.

8. Conclusions

Rikkunshito increases blood acylated ghrelin levels and improves gastrointestinal symptoms in FD patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This valuable RCT suggests that rikkunshito increases blood acylated ghrelin levels and relieves symptoms in FD patients. The 2009 article only mentions postprandial distress syndrome, however, the 2011 article objectively analyzes effects on improvement in gastrointestinal symptoms (using the Gastrointestinal Symptom Rating Scale [GSRS] score) and depressive symptoms (using the Self-rating Depression Scale [SDS] score). However, while it appears that Kampo medical parameters might not have been taken into consideration intentionally, an analysis of the relation between the effect of rikkunshito (increased blood level of acylated ghrelin), the type of *sho* (証, pattern; e.g., *kyosho* [虚証, deficiency pattern] or *jitsusho* [実証, excess pattern]), and the presence or absence of coldness/fatigue might have provided clearer outcomes. This study includes a larger number of participants and measures than the one published in the Evidence Reports of Kampo Treatment 2010 (Arai, 2009) and makes general remarks with reference to the study data. The number of participants mentioned in the abstract is five fewer than stated in the present paper (Matsumura, et al. 2010). The abstract mentions that there were no safety issues.

12. Abstractor and date

Motoo Y, 1 June 2010, 31 December 2012.

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**References**

Imazato S, Kai S, Koizumi K, et al. A Clinical Study of Shakuyaku-Kanzo-to (Kampo) as a Preparation for Double Contrast Barium Enema. *Therapeutic Research* 1997; 18: S505-10 (in Japanese). [MOL](#), [MOL-Lib](#)

Imazato S, Kai S, Koizumi K, et al. A Clinical Study of Shakuyaku-Kanzo-to (Kampo) as a Preparation for Double Contrast Barium Enema. *Kampo Igaku (Science of Kampo Medicine)* 1998; 22: 87-92 (in Japanese).

1. Objectives

To evaluate the effectiveness of Shakuyakukanzoto (芍薬甘草湯) for complaints and distress related to pre-enema treatment.

2. Design

Randomized controlled trial (RCT).

3. Setting

One general hospital, Japan.

4. Participants

Sixty patients who visited the hospital to undergo an enema X-ray examination..

5. Intervention

Arm 1: modified Brown method + TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 2.5 g before evening meal and sleep on the day before examination, and in the morning before examination (n=30).

Arm 2: modified Brown method (n=30).

6. Main outcome measures

Subjective symptoms (questionnaire).

7. Main results

Subjective symptom scores in arm 1 and arm 2 were 96.7% and 46.7% (respectively) for “not so much” abdominal pain the night before; 86.7% and 6.7% for “usual” sleep the night before; 90% and 66.7% for “no problems” referring to distress associated with enema examination pretreatment when visiting the hospital; and 66.7% and 0% for “easier than last time” referring to a previous occasion. Daily stool frequency was reduced in arm 1 (time range: 0~6 AM).

8. Conclusions

Shakuyakukanzoto reduces distress associated with enema examination pretreatment.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned. The examination itself was reported to have no ill effects and barium adhesion was reported to be satisfactory in arm 1.

11. Abstractor’s comments

This RCT is worthy of praise for having evaluated the effects of shakuyakukanzoto on pain and distress associated with pretreatment for the barium enema X-ray examination using a large number of participants. The evidence could have been made easier to understand by giving subjective symptoms numerical values and by comparing the two groups in greater detail.

12. Abstractor and date

Kogure T, 8 August 2008, 1 June 2010, 31 December 2012.

List of Excluded References

(Appendix 2011-2012)

Note: Original English titles assigned by authors were used in this list and the structured abstracts. When references had no English titles, the Task Force translated the original Japanese titles into English ones (〃).

Abbreviations: C, The Cochrane Library (CENTRAL); I, *Igaku Chuo Zasshi (Japana Centra Revuo Medicana, Ichushi)*; N, Database Offered by Nikkankyo (the Japan Kampo Medicines Manufacturers Association)

Reasons for exclusion were classified as follows:

- (1) Clinical studies that were not RCTs or meta-analyses.
- (2) Studies using medicines that were not approved as Kampo preparations in Japan (Kampo tozai [decoctions], Chinese preparations, and others).
- (3) Studies using Kampo preparations manufactured before 1985 (their quality being different from that currently available).
- (4) Studies citing existing RCT papers.
- (5) Studies with unclear content.
- (6) Others (reasons are described in the list).

ICD-10	Research Question	Kampo Formula	References	Reason for Exclusion	Source
C22.0	Protective effect of juzentaihoto on hepatocarcinogenesis	juzentaihoto (十全大補湯)	Tsuchiya M, Kono H, Matsuda M, et al. Protective effect of Juzen-taiho-to on hepatocarcinogenesis is mediated through the inhibition of Kupffer cell-induced oxidative stress. <i>International Journal of Cancer</i> 2008; 123: 2503-11.	(6) This was a basic study.	C
D64.9	Influence of juzentaihoto on hemoglobin recovery during preoperative autologous blood donation and after hip surgery	Juzentaihoto (十全大補湯)	Kishida Y, Nishii T, Inoue T, et al. Juzentaihoto (TJ-48), a traditional Japanese herbal medicine, influences hemoglobin recovery during preoperative autologous blood donation and after hip surgery. <i>International Journal of Clinical Pharmacology and Therapeutics</i> 2009; 47: 716-21.	(1)	C
D64.9	Evaluation of the relation between clinical effects of tokishakuyakusan and Peony Root (<i>Paeoniae Radix</i>) materials	tokishakuyakusan (当帰芍薬散)	Shimada K, Kawase M, Shibahara N, et al. The relation between clinical effects of Tokishakuyakusan and the identity of <i>Paeonia lactiflora</i> materials. <i>Journal of Ethnopharmacology</i> 2010; 132: 438-42.	(2)	C
F34.9	Effects of Kampo therapy on mood disorder and depression	saikokaryukotsuboreito, etc. (柴胡加竜骨牡蛎湯 ほか)	Chijiwa T, Itoh T. Japanese Association of Oriental Psychosomatic Medicine, EBM Team Report: Kampo therapy evidence for psychosomatic disease and stress-related disease - 3) Mood disorder*. <i>Nihon Toyo Shinshin Igaku Kenkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)</i> 2009; 24: 80-4 (in Japanese).	(4)	I
G62.9	Preventive effect of goshajinkigan on peripheral neurotoxicity of FOLFOX therapy	goshajinkigan (牛車腎気丸)	Kono Toru, Mishima H, Shimada M, et al. Preventive Effect of Goshajinkigan on Peripheral Neurotoxicity of FOLFOX Therapy: A Placebo-controlled Double-blind Randomized Phase II Study (the GONE Study). <i>Japanese Journal of Clinical Oncology</i> 2009; 39: 847-9.	(5)	C&I
I67.9	Efficacy and safety of hachimijiogan in patients with hypertension or cerebrovascular disease and their concomitant symptoms.	hachimijiogan (八味地黄丸)	Ito K, Yamamoto H, Saibara T, et al. The usefulness of Kanebo Hachimijiogan in patients with hypertension or cerebrovascular disease (excluding acute phase symptoms) and their concomitant symptoms: a multicenter, double-blind, crossover study*. <i>Shindan to Chiryō (Diagnosis and Treatment)</i> 1988; 76: 1096-114 (in Japanese).	Although previously published in EKAT2010, this study was excluded based on the criterion (3)	I

ICD-10	Research Question	Kampo Formula	References	Reason for Exclusion	Source
K30.0	Evaluation of a Kampo formula on functional dyspepsia	rikkunshito (六君子湯)	Okumi H, Sekiya N, Terasawa K. Japanese Association of Oriental Psychosomatic Medicine, EBM Team Report: Kampo therapy evidence for psychosomatic disease and stress-related disease 1) EBM evaluation of a Kampo formula on functional dyspepsia*. <i>Nihon Toyo Shinshin Igaku Kenkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)</i> 2009; 24: 70-5 (in Japanese).	(4)	I
K59.0	Evaluation of the bowel-habit improving effect and safety of young barley leaf powder	young barley leaf powder (大麦若葉粉末)	Matsui N, Yamamoto S, Nagao M, et al. Bowel Habit-improving Effect and Safety of a Young Barley Leaf Powder-containing Diet in Male and Female Adult Volunteers with Low Fecal Frequency : A Dose-finding Study and an Efficacy Confirmation Study*. <i>Nihon Rinsho Eiyo Gakkai Zasshi (Journal of Japanese Society of Clinical Nutrition)</i> 2011; 32: 243-51.	(2)	I
L20.9	Evaluation of Kampo therapy for atopic dermatitis	shosaikoto, etc. (小柴胡湯ほか)	Toyoda M. Kampo Therapy for Atopic Dermatitis: From the Evaluation of Evidenced-Based Medical Point of View. <i>Hifu no Kagaku (Skin Research)</i> 2010; 9: suppl. 15: 22-6	(4)	I
M06.9	Effects of Kampo medicines on rheumatoid arthritis patients receiving methotrexate	keishinieppiryojutsubu (桂枝二越婢苓朮附)	Kogure T, Tatsumi T, Sato H, et al. Traditional herbal medicines (Kampo) for patients with rheumatoid arthritis receiving concomitant methotrexate: a preliminary study. <i>Alternative Therapies in Health and Medicine</i> 2009; 16: 46-51.	(1), (2)	C
M35.9	Effects of Kampo medicines in treating connective tissue disease	saireito, etc. (柴芩湯ほか)	Ohno S. Roles of Kampo medicine in treating rheumatic diseases. <i>Journal of Traditional Medicines</i> 2007; 24: 73-80.	4)	C
N18.9	Creatinine level improvement in chronic renal failure with yojinkodakuto (養腎降濁湯)	yojinkodakuto (養腎降濁湯)	Nagasaka K, Fukuda H, Hashimoto M, et al. Yozinkodakuto, a traditional Chinese (Japanese Kampo) medicine, improves the creatinine level in chronic renal failure. <i>Journal of Traditional Medicines</i> 2007; 24: 87-9.	(1), (2)	C
R51.0	Effects of Kampo therapy on primary headache (non-migraine)	chotosan, etc (釣藤散ほか)	Chiba N, Oka T, Tsuji S. Japanese Association of Oriental Psychosomatic Medicine, EBM Team Report: Kampo therapy evidence for psychosomatic disease and stress-related disease - Primary headache (non-migraine)*. <i>Nihon Toyo Shinshin Igaku Kenkyu (Journal of Japanese Association of Oriental Psychosomatic Medicine)</i> 2009; 24: 85-8 (in Japanese).	(4)	I
T75.2	Combined effects of balneotherapy with other therapies	Tokishigyakuka-goshuyuto (当帰四逆加呉茱萸湯), goshajinkigan (牛車腎気丸), bushimatsu (ブシ末)	Wang H, Eboshida A, Kagamimori S. Balneotherapy in Combination with Other Therapies. <i>Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2010; 73: 143-58.	(4)	I
Z01.8	Effect of bushimatsu (ブシ末) on plasma serotonin and interleukin 18 levels	bushimatsu (ブシ末)	Nakae H. Plasma serotonin and interleukin 18 levels after taking powdered processed aconiti tuber. <i>Journal of Complementary and Integrative Medicine</i> 2010; 7: 1-9.	(2) A single crude drug was used.	N
Z01.8	Effect of bushimatsu (ブシ末) on degree of oxidation and antioxidative activity	shuchibushimatsu (修治ブシ末), bushimatsu (ブシ末)	Nakae H. Clinical evaluation of oxidative stress after taking powdered processed aconiti tuber. <i>Nihon Toyo Igaku Zasshi (Kampo Medicine)</i> 2010; 61: 15-8.	(2) A single crude drug was used.	N
Z01.8	Comparison of differences in human gene expression induced by tokishakuyakusan (当帰芍薬散) containing different quality grades of crude drug	tokishakuyakusan (当帰芍薬散)	Hayasaki T, Katoh A, Shoji M, et al. Differences in human gene expression induced by tokishakuyakusan containing different grades of Angelica radix. <i>Journal of Traditional Medicines</i> 2010; 27: 166-78.	(1)	I
-	Effects of abdominal examination practice with simulated patients on acupuncture and moxibustion students	None	Okuno Y, Taniguchi M. Effects of abdominal examination practice with simulated patients on acupuncture and moxibustion students (No. 1) Communication ability among sighted students*. <i>Shinkyu Syugi Ryoho Kyoiku (Education of Acupuncture and Manual Therapy)</i> 2010; 6: 10-5.	(6) This was a study of acupuncture and moxibustion	I