和漢薬製剤開発部門　Department of Kampo-pharmaceutics

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◇研究目的

和漢薬製剤開発部門は、富山県と県内の薬業界からの寄付部門として2004年7月に開設された。本部門は富山県の薬業（とくに配置薬業）を支援する実用研究（Kampo-pharmaceutics）を行う。また漢方医療情報研究（Kampo-informatics）を踏まえて医療人（とくに配置薬販売員）の研修や県民の生涯学習にも貢献することを目指している。

なおKampo-pharmaceutics研究の一部は21世紀COEプログラム「東洋の知に立脚した個の医療の創生」の基盤研究と連携して遂行される。

◇研究概要

Ⅰ）　新和漢薬製剤（とくに配置薬）の開発支援研究（Kampo-pharmaceutics）

1）漢方薬材研究：

a) 和漢薬製剤原料生薬の資源科学研究【原著論文：2), 9), 10)；総説：1)】

【原著論文2）と総説1）はCOEプログラムの分担課題成果である】

2）漢方薬剤研究：

a) 和漢薬製剤原料生薬の評価研究【原著論文：3)】

b) 新和漢薬製剤の開発と評価研究【原著論文：4)；総説：2), 3)；その他：13)】

c) 新和漢薬処方を考案する医薬史学的根拠を考証する基礎研究【原著論文：1)】

Ⅱ）　既存の漢方製剤や生薬製剤の評価研究

1）薬効薬理研究：【原著論文：6), 7), 8), 11)】

2）生物薬剤学研究：【原著論文：5)；その他：6)】

Ⅲ）　漢方医療情報研究（Kampo-informatics）

1）配置販売員や薬剤師の研修活動【その他：1), 3), 14)】

2）県民の生涯学習支援活動【その他：4)】

◇著書

1) （分担執筆）谿　忠人：薬食同源－過去・現在・未来－．「食品薬学ハンドブック」、北川勲、吉川雅之（編著），講談社，東京，pp. 7-21,2005.

2) （分担執筆）谿 忠人：薬用植物の渡来と御薬園（補追：人参と六君子湯の薬能と薬理）．「漢方薬・生薬薬剤師講座テキストV」第２版、（財）日本薬剤師研修センター（編），（財）日本薬剤師研修センター，東京，pp. 51-61,2005.

◇原著論文

1) **府和隆子，小曽戸 洋，谿　忠人：『脾胃論』における生薬の用法と『内外傷弁惑論』との関係．薬史学雑誌, 40 (1): 13-21, 2005.**

Abstract: PiWeiLun (Hi-i-ron in Japanese) is a traditional Chinese medical formulary written in the 13th century discussing on endogenous disease (Naisho). For curing endogenous diseases caused by functional deficiency of *pi-* and *wei qi* (Hi-I-Ki-Kyo), PiWeiLun was recommended QingShuYiQi-Tang (Seish-ekki-to), BanXiaBaiZhuTianMa^Tang (Hange-byakujutsu-tenma-to) as well as BuZhongYiQi-Tang (Hochu-ekki-to), which is described in Nei-Wai-Shang-Bian-Huo-Lun (Naigaisho-benwaku-ron). It is characteristic that PiWeiLun discusses the combining uses of Phellodendri Cortex woth sweet Q-tonics (Hoki0yaku) as Ginseng and Atractylodis macrocephalae Rhizome for improving false heart syndrome (Kyo-netsu-sho) due to yin-deficiency (In-kyo sho), In PiWeiLun, Cimicifugae Rhizome, Angericae Radix and Atractylodes Rhizome are more frequently used than in Nei-Wai-Shang-Bian-Huo-Lun. These uses of drugs presented in PiWeiLun may be useful to devise new crude drug formulation good for modern deficiency syndrome attendant on person of postoperative complications.

2) **Rauchensteiner F., Matsumura Y., Yamamoto Y., Yamaji S., and Tani T.: Analysis and comparison of Radix Glycyrrhizae (licorice) from Europe and China by capillary-zone electrophoresis (CZE). *J. Pharm. Biomed. Analysis,* 38(4): 594-600, 2005.**

Abstract: A simple and fast capillary-zone electrophoresis (CZE) method for the analysis of plant specimens, *Glycyrrhiza glabra* L., *G. uralensis* FISCH (cultivated) and *G. inflata* BAT. (Leguminosae) as well as commercial licorices from Europe and China was developed. Contents of glycyrrhizin (GL), glycyrrhetic acid (GA), glabridin (GLAB), liquiritin (LQ) and licochalcone A (LC_A) in 50% aqueous ethanolic extracts were investigated. Optimum separation was achieved with sodium tetraborate buffer (pH 9.22; 70 mM); fused silica capillary, 57(50: effective length) cm × 50 μm I.D.; voltage, 25 kV. Recovery rate for GL was found to be 101.90 ± 2.54 %. The adequate correlation was observed between GL contents measured by CZE and HPLC (r= 0.977). Advantages to conventional HPLC analysis of *Glycyrrhiza* species are short analysis time (<15 min), simple running buffer preparation and the none-use of organic solvents. GL contents were in average higher in Chinese commercial licorices. Relatively high LC_A contents were detected especially in a Chinese commercial licorice (Xinjiang-Gancao, origin estimated as *G. inflata*). Liquiritin apioside was found in all samples. By the present CZE method, it was proved that 1) *G. glabra* was distinguished from *G. uralensis* especially by phenolic compounds GLAB (only in *G. glabra*, 0.19 ± 0.11 %; n=53) and LQ (major contents in *G. uralensis*, 1.34 ± 0.34 %, n=10); 2) The same *Glycyrrhiza* species were also distinguished by applying PCA on the basis of CZE peak area data of GL, GLAB, GA, LQ and LC_A; and 3) The roots cultivated in eastern Nei-Menggu of China are comparable to medicinal Radix Glycyrrhizae originating from *G. uralensis* used in Japan.

3) **Mizuno M., Chung H.J., Maruyama I., and Tani T.: Inhibitory effects of Bezoar Bovis on intimal formation and vascular smooth muscle cell proliferation in rat. *Am. J. Chin. Med.*, 33 (3): 439-447, 2005.**

Abstract: Intimal formation of animal carotid arteries induced by balloon endothelial denudation has been considered to be an "accelerated atherosclerosis" model and used in primary screening methods to evaluate natural drugs and chemical candidates. The aim of the present study was to examine whether intimal formation is prevented by Bezoar Bovis (dried cattle gallbladder stones: Niuhuang in Chinese and Go-o in Japanese), which has been used to prevent heart palpitation in patients with hypertension. The intimal-to-medial area ratio in rat carotid arteries 7 days after balloon endothelial denudation was significantly reduced by oral administration of Bezoar Bovis. Bezoar Bovis also suppressed vascular smooth muscle cells (VSMCs) proliferation, which is thought to play important roles in the intimal formation after endothelial damage and also atherosclerosis resulting from long-term inappropriate life-style. The present findings suggest that Bezoar Bovis may be useful for preventing atherosclerosis and for protection against restenosis after percutaneous coronary intervention, for which effective reduction method is not currently available.

4) **Tega E., Kiga C., Chino A., Sakurai H., Koizumi K., Tani T., and Saiki I.: A newly devised formulation for self-medication enhances interferon-γ production and proliferation of splenic lymphocytes. *Biol. Pharm. Bull.*, 28 (10): 1869-1872, 2005.**

Abstract: A newly devised formulation for self-medication in Toyama, PanaWang, is a new herbal medicine (so called Toyama original brand formulation) developed based on traditional philosophy and scientific evidence. We here tried to examine the effect of oral administration of PanaWang on the balance of type I helper T cells (Th1) and Th2 cells. Splenic lymphocytes from normal mice were stimulated with concanavalin A (Con A) in vitro and the secretion of Th1- and Th2-type cytokines, interferon-γ (IFN-γ) and interleukin-4 (IL-4) respectively, was investigated. Con A-induced production of IFN-γ from spleen cells, but not IL-4, was enhanced by the administration of PanaWang. Increase production of IFN-γ was also detected in splenic lymphocytes from Th2- predominant BALB/c mice after DNP-immunization, without a change in antigen-specific IgE levels in vivo. Antigen-specific proliferative responses were also increased in lymphocytes from PanaWang-treated mice. These findings raise the possibility that PanaWang has Th1-stimulating activity and induces Th1-predominatnt immunity.

5) **Goto, E., He, J.X., Akao T., and Tani T.: Bioavailability of glycyrrhizin from Shaoyao-Gancao-Tang in laxative treated rats. *J. Pharm. Pharmacol.*, 57 (10): 1359-1363, 2005.**

Abstract: Shaoyao-Gancao-Tang (SGT), a traditional Chinese formulation composed of Shaoyao (Paeoniae Radix) and Gancao (Glycyrrhizae Radix), is frequently used in conjunction with laxatives such as sodium picosulfate (Pico) in colonoscopy to relieve abdominal pains. The present study aimed to investigate the alterations of the bioavailability of glycyrrhizin when SGT was co-administered with Pico and to identify a regimen that may minimize the alterations. Glycyrrhizin is one of the active glycosides in Gancao and SGT and is hydrolyzed into the bioactive metabolite, 18β-glycyrrhetic acid (GA) by intestinal bacteria following oral administration.

We found that the maximum plasma concentration (C_{max}) and the area under the mean concentration vs time curve from zero to 24 h ($AUC_{0\text{-}24\,h}$) of GA from a single dose of SGT administered 5 h after a single Pico pre-treatment were significantly reduced to 15% and 20% of the control level in rats, respectively. These reductions were still significant 4 days after Pico pre-treatment, but were restored by repetitive administration of SGT following Pico pre-treatment. Similar reductions and recovery were also observed for the glycyrrhizin-metabolizing activity of intestinal bacteria in rat faeces. The present findings warrant clinical studies for co-administration of laxatives such as Pico and SGT.

6) **Chung H.J., Liu Y., Maruyama I., and Tani T.: Orengedokuto inhibits neointimal formation, proliferation and migration of rat vascular smooth muscle cells in vivo and in vitro. *J. Trad. Med.*, 23 (5):278-283, 2005.**

Abstract: Orengedokuto (OGT), a traditional Chinese formulation containing four crude drugs (Scutellariae Radix, Coptidis Rhizoma, Phellodendri Cortex and Gardeniae Fructus), has been used for various conditions accompanied with atherosclerotic-related disorders. Oral administration of OGT for 3 days before and 7 days after balloon injury resulted in a dose-dependent attenuation of neointimal formation and vascular smooth muscle cell (VSMC) proliferation in balloon-injured carotid arteries in cholesterol-fed rats. Furthermore, the serum collected from cholesterol-fed rats orally treated with OGT significantly reduced the migration of cultured VSMC. Thus, OGT may attenuate carotid artery neointimal formation following balloon endothelial denudation via inhibition of VSMC proliferation and migration. The inhibitory effects of OGT on neointimal formation were mediated primarily by Scutellariae Radix and Coptidis Rhizoma composed of OGT. The present results suggest that OGT may be promising candidates as preventive agents for atherosclerosis in humans.

7) **Baba T., Nishino T., and Tani T.: Anti-diarrheal effects of wood creosote pill preparation compounded with four crude drugs on castor oil-induced diarrhea in rats and the role of crude drugs in the expression of the efficacy. *J. Trad. Med.*, 23 (5): 284-289, 2005.**

Abstract: Wood creosote pill preparation, in which 4 crude drug powders, Gambir, Phellodendri Cortex, Glycyrrhizae Radix, and Citri Unshiu Pericarpium are compounded, has been used as a therapeutic drug for diarrhea. In the present study, the significance of compounding of these crude drug powders was examined in castor oil-induced diarrhea model in rats.

Oral administration of small wood creosote pill (P4Rx5) exerted anti-diarrheal action for up to 3 hours and intestinal peristaltic motility-suppressive action, which was assessed by charcoal meal test. These suppressive actions were not noted in the groups of the rats receiving wood creosote alone at a dose level (11 mg/kg) that is contained in P4Rx5. From these findings, it was revealed that crude drugs compounded were responsible for the anti-diarrheal and intestinal peristaltic motility-suppressive actions of P4Rx5.

Pharmacological actions were examined for variant pills (without one of the crude drug powders), revealing that Citri Unshiu Pericarpium was responsible for retention of the anti-diarrheal effects and the suppression of castor oil-induced intestinal peristaltic motility by P4Rx5. Furthermore, it was found that the crude drug powders compounded increased absorption of guaiacol (a major anti-diarrheal component of wood creosote), being involved in the intestinal peristaltic motility-suppressive action of P4Rx5. The results obtained in the present study may provide evidence supporting the usefulness of compounding of the crude drugs in traditional wood creosote pills such as "Seiro-gan", and give a rationale for development of new preparations compounding wood creosote with crude drug powders.

8) **Ohno K., Chung H.J., Maruyama I., and Tani T.: Bofutsushosan, a traditional Chinese formulation, prevents intimal thickening and vascular smooth muscle cell proliferation induced by balloon endothelial denudation in rats. *Biol. Pharm. Bull.*, 28 (11): 2162-2165, 2005.**

Abstract: Bofutsushosan (BOF), a traditional Chinese formulation (Kampo-formulation in Japanese), is used widely for patients with obesity and hyperlipidemia resulting from long-term inappropriate life-styles. Since atherosclerosis, a life-style related disease, is accompanied by an abnormal accumulation of vascular smooth muscle cell (VSMC) in intimal area of the artery, we investigated the preventive effect of BOF on intimal thickening.

Oral administrations of BOF extract 3 days before and 7 days after balloon endothelial denudation dose-dependently suppressed the intimal thickening and proliferation of vascular smooth muscle cell (VSMC) in the intimal area in rat carotid arteries. This model has a similar pathological process to atherosclerosis and is considered to be an "accelerated atherosclerosis" model. BOF extract also

dose-dependently inhibited the migration of cultured VSMC. BOF extract suppressed the serum lipids, which is the major risk factor of atherosclerosis. These findings clarified the usefulness of BOF in cardiovascular risk reduction therapy.

9) **Xie H., Wang T., Matsuda H., Morikawa T., Yoshikawa M., and Tani T.: Bioactive constituents from Chinese natural medicines. XV. Inhibitory effects on aldose reductase and structures of saussureosides A and B from *Saussurea medusa*. *Chem. Pharm. Bull.*, 53 (11): 1416-1422, 2005.**

Abstract: The 80% aqueous acetone extract from the whole plant of *Saussurea medusa* Maxim. Was found to inhibit rat lens aldose reductase (IC_{50} = 1.4 μg/ml). From the aqueous acetone extract, flavonoids, lignans, and quinic acid derivatives were isolated together with two new ionone glycosides, sauusureosides A and B. Their absolute sterostructure were elucidated on the basis of chemical and physicochemical evidence including the application of modified Mosher's method. In addition, some isolated were found to show inhibitory effect on aldose reductase.

10) **楊冬野、蔡少青、王　璇、楊文蓮、谿忠人、山路誠一、難波恒雄：不同生長年限野生与栽培黄芩的薬材鑑定研究. 中国中薬雑誌, 30 (22): 1728-1735, 2005.**

Abstract: Objective: To identify Radix Scutellariae (Huangqin) of different growth years, to distinguish whether it is wild or cultivated and to provide useful information for the quality control of Huangqin crude drug. Method: By using morphological and histological methods, we studied 87 individuals of 45 specimens from 12 habitats of 5 provinces of China, which grew wild or were cultivated in different growing years. Moreover, 22 commercial samples of Huangqin from 7 provinces were also investigated. Results: The identification was performed base on morphological and histological characteristics, such as the shape, color, cork, remaining stems, decayed central xylem, and vessels arrangement, xylem cork ring, growing rings, etc. Conclusion: We established an identification method for distinguishing Huangqin wild or cultivated in different growing years. Furthermore, the structure of annual rings in the transaction of Radix Scutellariae has been discovered for the first time.

11) **Saito, M., Hamazaki, T., Tani, T., and Watanabe, S.: Bofutsusyosan, a traditional Chinese formulation, inhibits pancreatic lipase activity in vitro and suppresses the elevation of plasma triglycerols after oral administration of lipid emulsion. *J. Trad. Med.*, 23 (6): 308-313, 2005.**

Abstract: pancreatic lipase activity measured as fatty acid liberation from lipid emulsion was shown to be inhibited by the addition of Bofutsusyosan (BOF) or Daijoukito (DJT) extracts at > 30 mg/ml/ The extracts of Orengedokuto (OGT), Chotosan (CTS), Boiogito (BOT) or Shinbuto (SBT) was ineffective in inhibiting pancreatic lipase activity up to 60 mg/ml. Mice were orally administered with lipid emulsion in the presence of BOF extracts at 750 and 2250 mg/kg and subsequent elevation of plasma triacylglycerols (TAG) was significantly suppressed as compared that in the mice received lipid emulsion alone. However, the addition of DJT extracts did not suppress the elevation of plasma TAG after oral administration of lipid emulsion. Our results suggest that BOF suppresses the absorption of ingested fats and this effect could account for the reported anti-obese effects of BOF.

◇総　説

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2) 谿　忠人：富山県内の産官学連携で開発された新配置家庭薬：和漢薬研究所の寄付部門和漢薬製剤開発部門の地域連携活動の成果. MEDCHEM. NWES, **15**(4): 15-19, 2005.

3) 谿　忠人：富山県の産官学連携研究で考案された新しい配置薬．漢方の臨床, **52**(11): 1783-1791, 2005.

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1) 斉藤正隆、浜崎智仁、谿　忠人、渡辺志朗：防風通聖散の血中中性脂肪濃度上昇抑制およびリパーゼ活性阻害作用．日本薬学会第 125 回年会，2005.3.29-31，東京.

2) Yang D. Y., Cai S. Q., Wang X., Yang W. L., Tani T., Yamaji S., Namba T.: Growth ring and abnormal structure in Radix Scutellariae and identification of its habitat, growth years and different producing areas. 2005' Internal Symposium in Beijing on Pharmacognosy. 2005, 5. 13-14, Beijing, China.

* 3) 何　菊秀、谿　忠人：（シンポジウム）漢方製剤（芍薬甘草湯）と西洋薬剤との相互作用の検証と対策ー腸内細菌の代謝活性と活性代謝物の血漿動態の変動を指標にしてー．第 26 回和漢薬研究所特別セミナー．2005, 7.13，富山.

* 4) 谿　忠人、丸山征郎：（シンポジウム）擦過傷害後の動脈内膜肥厚を抑制する漢方方剤～柴胡加竜骨牡蛎湯と血管平滑筋細胞を中心にして～．第 22 回和漢医薬学会大会，2005, 8.22，東京.

5) 永井秀昌、何　菊秀、山本　豊、赤尾光昭、谿　忠人：新疆甘草の腸管収縮抑制作用と成分．第 22 回和漢医薬学会大会，2005, 8.21-22，東京.

6) 片貝真寿美、真々田和矢、谿　忠人：『傷寒論』の加減の指示における用薬法．第 22 回和漢医薬学会大会，2005, 8.21-22，東京.

7) 大野賢二、何　菊秀、赤尾光昭、谿　忠人：漢方製剤と nifedipine の小腸における相互作用．第 22 回和漢医薬学会大会，2005, 8.21-22，東京.

◇その他

1) 谿　忠人：富山オリジナルブランド配置薬（パナワン）開発と配置薬業界の今後（新春インタビュー）．家庭薬新聞．2005, 1.1.

2) 谿　忠人：漢方製剤の服薬指導に必要な漢方医療の知識と応用．北陸大学薬学部卒後研修会（主催：北陸大学薬学部）．2005, 1.16．富山.

3) 谿　忠人：オリジナルブランド医薬品「パナワン」の開発経緯と販売指針．富山県薬業配置北海道部会研修会（主催：富山県薬業連合会），2005, 1.19．富山.

4) 谿　忠人：飽食時代のエコノミークラス症候群を予防する漢方医療の知恵．第 6 回国際伝統医学センター公開研究報告会（主催：富山県国際伝統医学センター）．2005, 3.13. 富山.

5) 谿　忠人：飽食時代のエコノミークラス症候群を予防する漢方医療の知恵．富山県国際伝統医学センター公開研究報告会における講演内容（記事）．薬日新聞, 2005, 4.6

6) 谿　忠人：甘草～腸内細菌代謝の関与する薬物相互作用～．漢方調剤研究, **13**(2): 15-18, 2005.

7) 谿　忠人：漢方医薬基礎講義（gender specific medicine を中心に）．和漢薬研究所夏期セミナー（主催：和漢薬研究所），2005, 8.24．富山.

8) 谿 忠人：富山オリジナルブランド配置薬（パナワン）の開発経緯．富山 TV．2005, 8.31.

9) 谿　忠人：富山の産学官：独自ブランド薬、来年１月に発売（製造承認取得の知事記者会見記事）．日本經濟新聞．2005, 9.1

10) 谿 忠人：富山ブランド薬販売へ（製造承認取得の知事記者会見記事）．富山新聞．2005, 9.1

11) 谿 忠人：富山オリジナルブランド配置薬（パナワン）の開発経緯．NHK-TV．2005, 9.6

12) 谿 忠人：パナワンに製造承認（製造承認取得の知事記者会見記事）．薬日新聞．2005, 9.7.
13) 谿　忠人：漢方医療薬学からみた「いわゆる健康食品」の功過と今後．技術交流サロン（主催：富山大学地域共同研究センター），2005, 10.7．富山.
14) 谿　忠人：オリジナルブランド医薬品「パナワン」の開発経緯と特徴．富山県薬事講習会（主催：富山県薬事研修センター），2005, 10.14，富山.

◇共同研究

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2) 丸山征郎：鹿児島大学医学部・臨床検査医学、「動脈硬化を予防する漢方方剤の研究」1999，4～
3) 赤尾光昭：富山大学薬学部・薬品生理学、「漢方方剤と西洋薬剤の併用療法の生物薬剤学的解析」、1999，4～
4) 小曽戸洋：北里研究所東洋医学総合研究所・医史学研究部、「漢方用薬の医薬史学的研究」2000，4～
5) 済木育夫：富山大学和漢医薬学総合研究所･病態生化学分野、「富山オリジナルブランド配置薬開発研究」、2001，4～
6) 島田　豊：富山大学医学部・和漢診療学、「富山オリジナルブランド配置薬開発研究」、2001.4～
7) 北島　勲：富山大学医学部・臨床検査医学、「冷えと痛みを軽減する漢方方剤の評価研究」2002，4～
8) 鈴木英世：富山県薬事研究所、「動物生薬の規格評価研究」、2002，4～
9) 吉川雅之：京都薬科大学・生薬学、「中国産薬用資源の研究」、2004，4～

海外

1) 蔡 少青、王 璇：北京大学葯学院・生葯学 （中国）、「栽培生薬と野生生薬の判別と同質性」、1999，6～
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◇研究費取得状況

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◇学位（修士、博士）取得者

薬学士：

岡崎瑞希：Capillary electrophoresis 法を用いた日本産防已と中国産青風藤の比較.

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大野賢二：高血圧随伴症状に用いる漢方製剤と Ca 拮抗剤との相互作用の検証：ラット小腸における薬物代謝を中心にして.

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◇人事移動

何　菊秀：助手（2005, 03.31 退職）