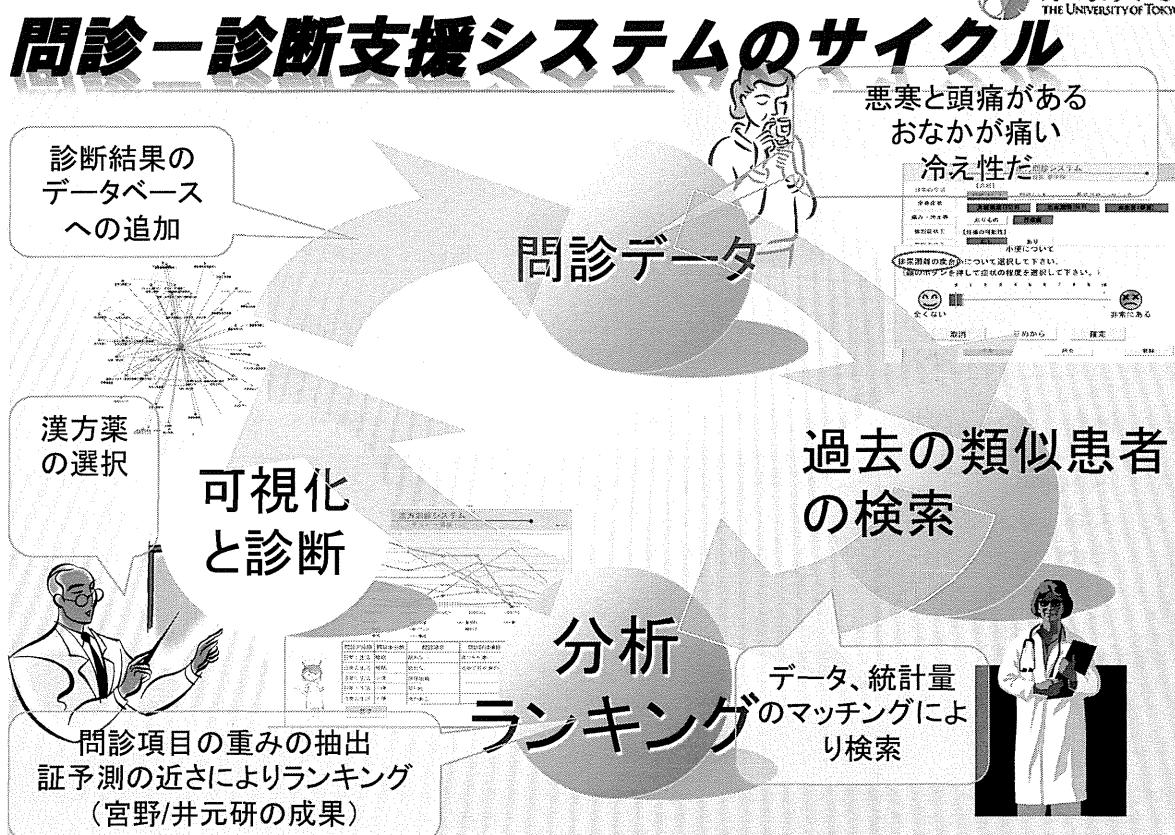


## 診断支援

- ※ 医師の90%が日常診療で漢方を用いているが漢方専門医以外は使用処方は限定されている。
- ※ 漢方医学的診断「証」は経験知であり、科学的・統計学的な解明が為されていないため、どう使っていいか分からない。
- ※ 臨床的エビデンス（診断・治療）が得られるようになれば一般総合医もある一定のレベルで効果的な漢方治療ができると期待される。

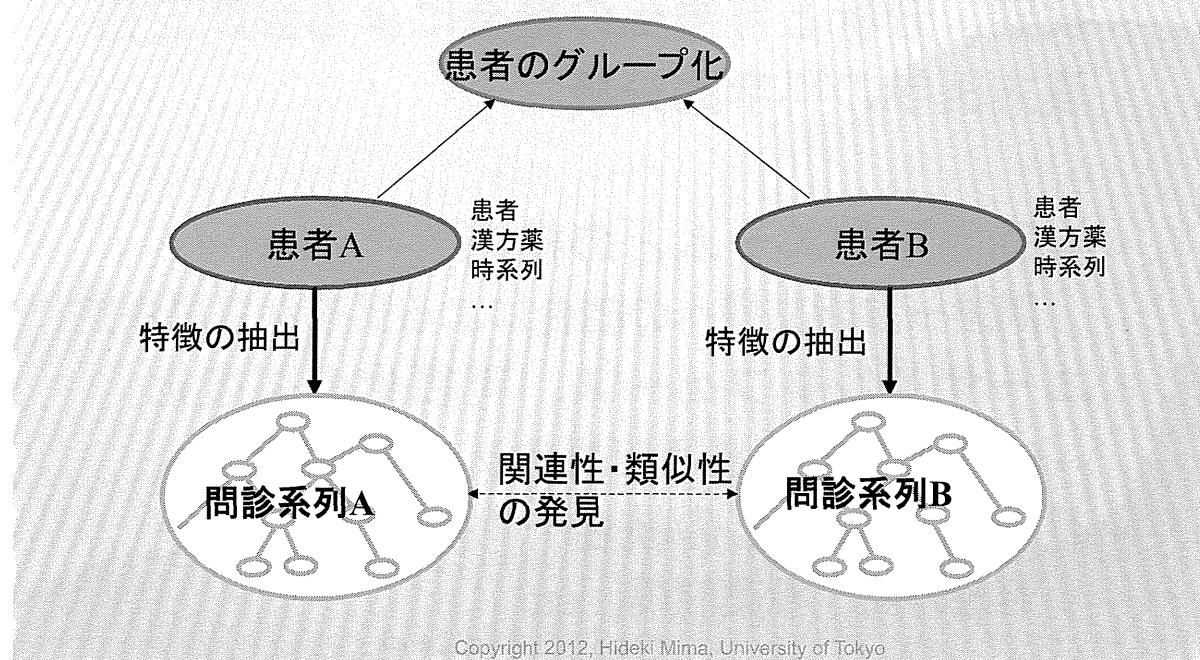
  

- ※ **ITによる効率的な診断支援**
  - + 過去の臨床的エビデンスの効率的な検索
  - + 類似性、関連性の効果的な分析
  - + 可視化による経験知の「見える化」
  - + 漢方薬の「見える化」による迅速な意思決定





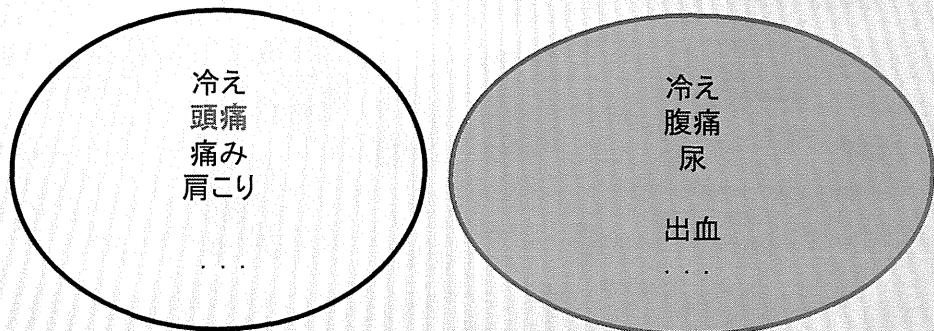
## 基本理論



# 関連の分析

## × 関連性の計算

- + 特徴の抽出-問診、投薬、時系列
- + 特徴の統計的な重なり



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# まとめと今後

- × 検索、分析と可視化の融合による診断支援
- × 漢方医学の科学的分析
- × 自動問診システムとの接続
  - + 問診→診断支援への統合による迅速な意思決定
- × ユーザインターフェース、可視化の高度化
  - + MIMAサーチ+各種可視化ライブラリ
- × 時系列抽象化との統合
  - + 治療時間、投薬間隔、etc.

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# 漢方診断改良の 科学的な取り組み

並木 隆雄  
千葉大学大学院医学研究院  
和漢診療学

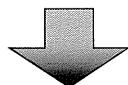
厚生労働科学研究費「漢方の特性を利用したエビデンス創出と適正使用支援システムの構築」発表会 於：慶應義塾大学 2012.11.29

## 本日の内容

1. 問診システムによる漢方概念の検討～気血水スコアの再検討～
2. 問診システムと舌撮影装置の併用による漢方診断の改良

## 中医学の国際標準化が及ぼす影響

中国は用語、治療法、免許、製造方法なども含めた中医学全体の国際標準化をめざしている。

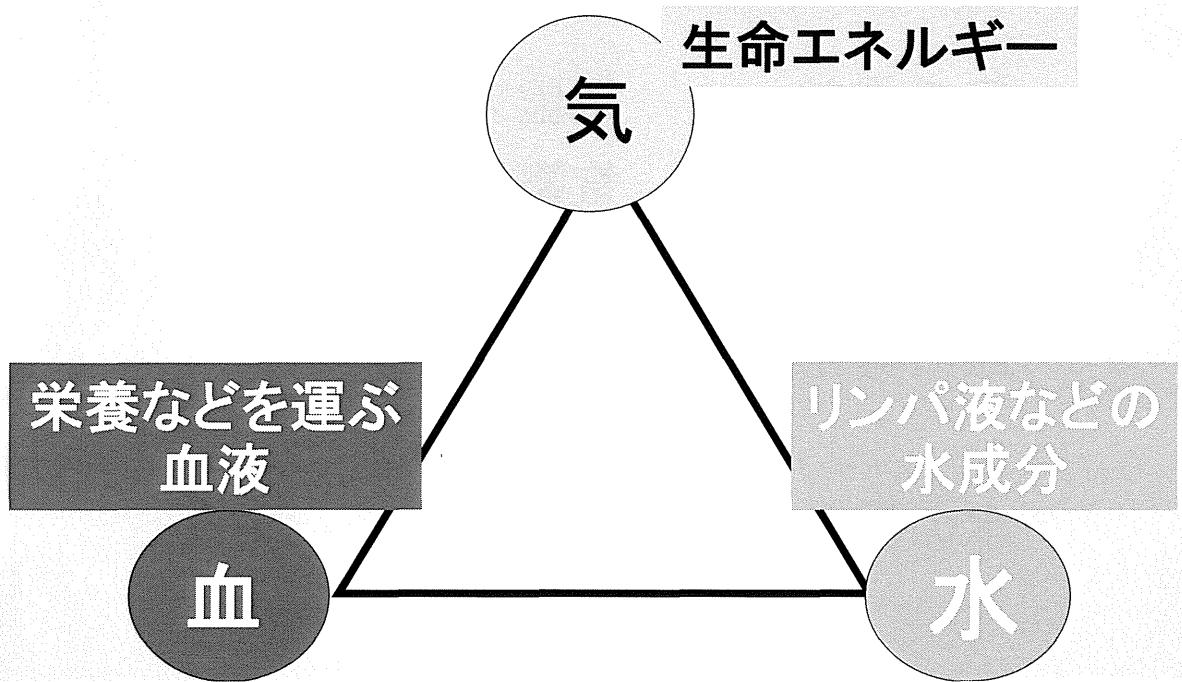


中国は東アジア伝統医学に関して、医療、経済、教育などのあらゆる面でのイニシアチブを獲得することになる。

## 漢方の生理・病理概念

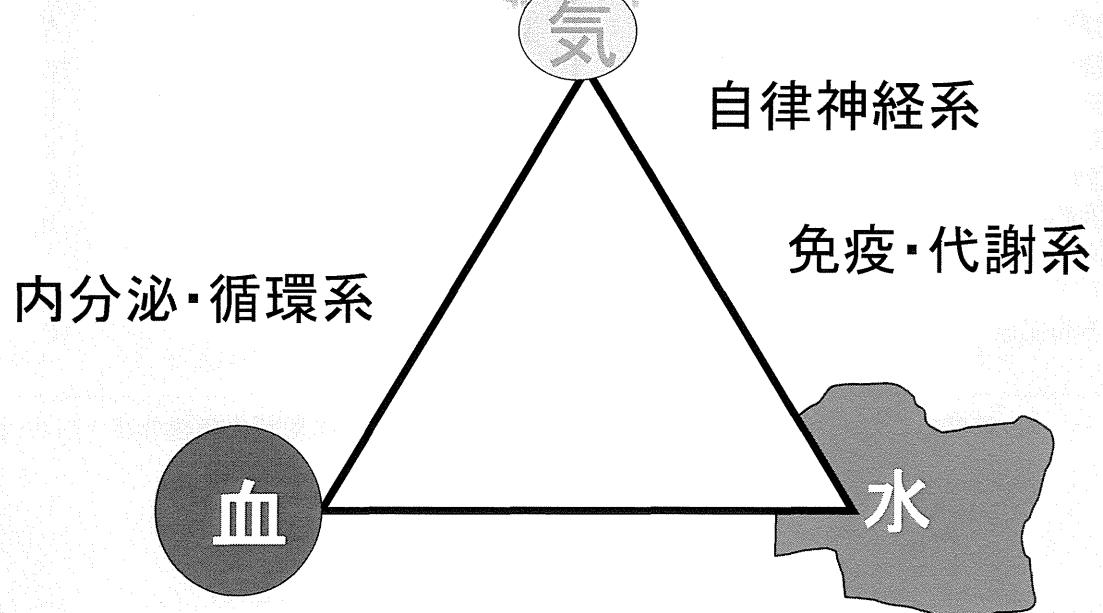
### 気・血・水とは

# 氣・血・水



## 氣・血・水の乱れ

### II 病氣



# 氣血水の診断 ～スヨマニ化の利用～

気の異常	気虚スコア
	気鬱スコア
	気逆スコア
血の異常	血虚スコア
	瘀血スコア
水の異常	水滯スコア

寺澤 捷年ら

## 瘀血の診断基準

(科学技術庁・研究班  
1983)

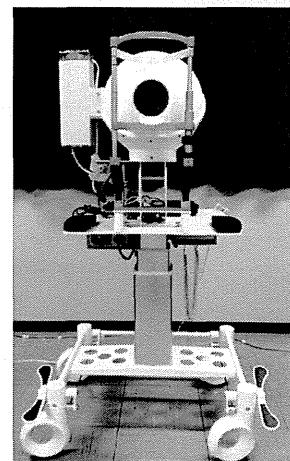
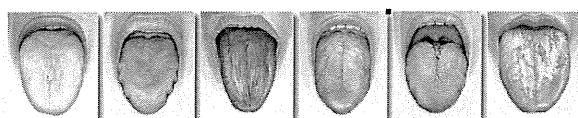
### 瘀血スコア

男	女	男	女
眼瞼部の色素沈着	10	10	5
顔面の色素沈着	2	2	10
皮膚の甲錯 <sup>1)</sup>	2	5	5
口唇の暗赤化	2	2	2
歯肉の暗赤化	10	5	5
舌の暗赤紫化	10	10	5
細絡 <sup>2)</sup>	5	5	5
皮下溢血	2	10	10
手掌紅斑	2	5	5
		臍傍圧痛抵抗 左	5
		臍傍圧痛抵抗 右	10
		臍傍圧痛抵抗 正中	5
		回盲部圧痛抵抗	5
		S状部圧痛抵抗	5
		季肋部圧痛抵抗	5
		痔疾	5
		月経障害	10

1) 皮膚の荒れ、ザラツキ、駁裂 2) 毛細血管の拡張、くも状血管腫など

判定 非瘀血病態 : 20点以下,  
軽度瘀血病態 : 21点以上, 40点未満  
重度瘀血病態 : 40点以上

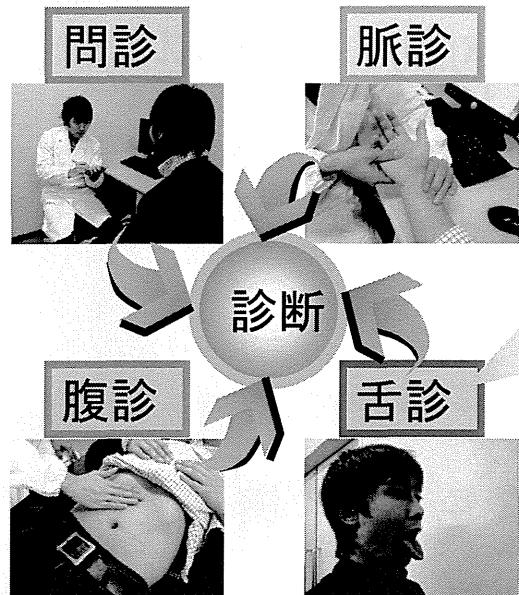
# 問診システムと舌撮影装置の併用による漢方診断の改良



## ～舌撮影解析システム (TIAS)について～

### 問題点

#### 東洋医学



#### 利点

- ✓ 非侵襲的な診断法
- ✓ 病気の原因、病名が分からなくて治療方針が立つ。

→ 身体の異常を判断  
欠点 診断が定性的・習得困難

→ 定量化

コンピュータ支援診断

## 瘀血の診断基準

(科学技術庁・研究班  
1983)

## 瘀血スコア

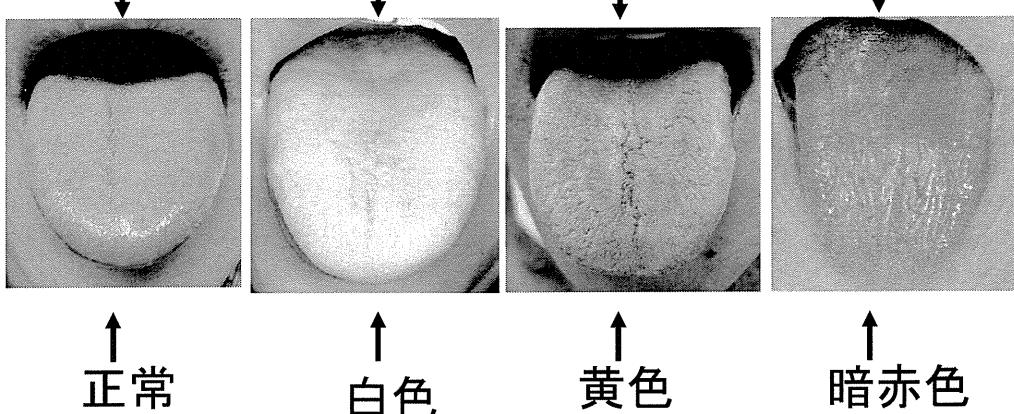
	男	女		男	女
眼瞼部の色素沈着	10	10	臍傍圧痛抵抗	左	5
顔面の色素沈着	2	2	臍傍圧痛抵抗	右	10
皮膚の甲錯 <sup>1)</sup>	2	5	臍傍圧痛抵抗	正中	5
口唇の暗赤化	2	2	回盲部圧痛抵抗		2
歯肉の暗赤化	10	5	S状部圧痛抵抗		5
舌の暗赤紫化	10	10	季肋部圧痛抵抗		5
細絡 <sup>2)</sup>	5	5			
皮下溢血	2	10	痔疾		10
手掌紅斑	2	5	月経障害		10

1) 皮膚の荒れ、ザラツキ、破裂 2) 毛細血管の拡張、くも状血管腫など

判定 非瘀血病態 : 20点以下,  
軽度瘀血病態 : 21点以上, 40点未満  
重度瘀血病態 : 40点以上

舌を診断しているのが、何を診断しているのか

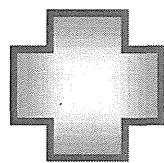
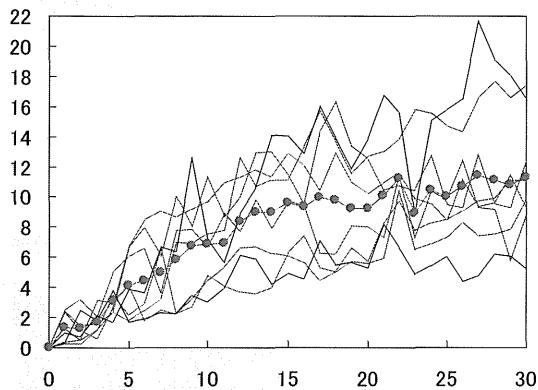
苔が薄い 苔がやや厚い 苔が厚い 苔がない



# \*千葉大学での技術と伝統の蓄積

千葉大学フロンティア・ディア  
カル工学研究開発センター

千葉大学医学研究院  
和漢診療学講座



粘膜色の定量的測定・解析

13

2009/3/26

## 【背景】

- 東洋医学では舌色や舌の形態などを観察すること（舌診）で患者の体質や病状を知ることができると考えている。しかし、舌診の観察においては光源・室温・乾燥度などの外部環境要因、医師の知識・経験に依存する主観的要因など様々な要因が複雑に絡むため、診療や教育において、舌による診断やその技術の習得に時間がかかるなど困難が多い。
- 舌診を科学的に解析する場合、客観的・定量的な指標が必要である。

# 舌診の問題点

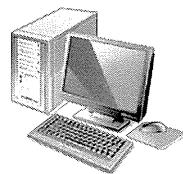
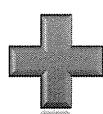
問題点

所見が医師の主観や経験に大きく依存しやすい

解決法



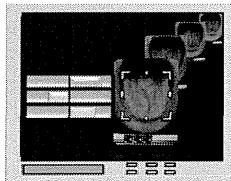
経験的な判断



統計的な判断

## 舌撮影解析システム (TIAS) の構築

カメラ撮影



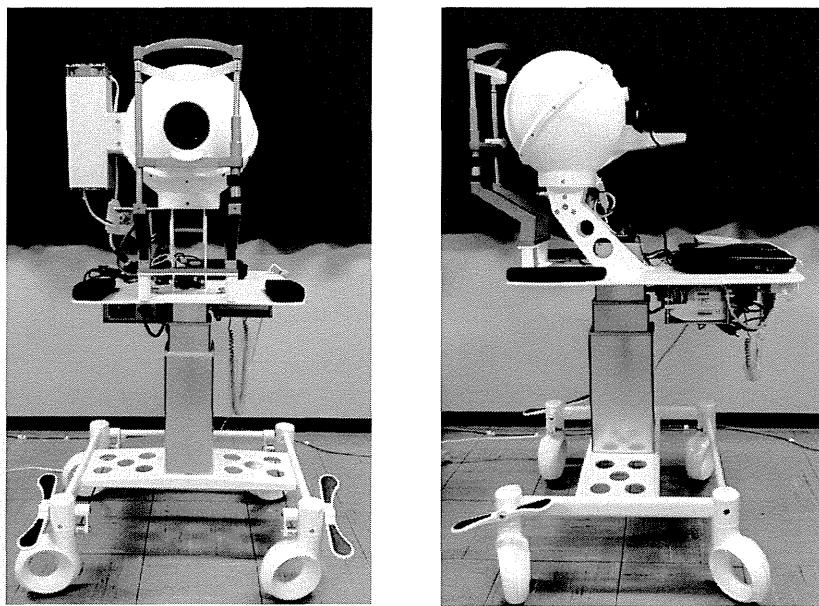
- 舌特徴の基礎的研究
- 舌色診断支援システム

## 【背景】

■ そこで我々は、文部科学省委託事業・都市エリア  
产学連携促進事業の一環で、一定の条件下で撮影  
でき、色調から漢方医学的診断をコンピュータで  
行う舌色診断支援システム構築を目的として  
撮影診断装置を開発した。

■ 今回、その舌撮影解析システム  
(Tongue Image Analyzing System: TIAS) の  
概要とこのシステム活用の可能性について  
紹介する。

# 舌撮影解析システム (TIAS)



## 今後の予定

- 舌診の客観化のための舌撮影解析システム (Tongue Image Analyzing System: TIAS) の概要説明とこのシステム活用の可能性の一つとして、渡辺班の問診システムとの併用での研究をする予定。
- 平成24-25年度厚労科研並木班に、日本漢方の中核となる多くの大学研究機関に参加していただき、このシステムを普及するために貸与した。今後、舌診の科学化のため多くのデーターの集積とこのTIASの応用法が確立できることを目標としたい。

## 国際化に対応した科学的視点に立った日本漢方診断法・ 処方分類および用語の標準化の確立（舌診研究班）

並木 隆雄	千葉大学大学院医学研究院和漢診療学
新井 信	東海大学医学部・東洋医学
貝沼 茂三郎	九州大学大学院医学研究院臨床医学部門・ 内科学講座感染環境医学分野
柴原 直利	富山大学和漢医薬学総合研究所・漢方医学
中口 俊哉	千葉大学・医療支援システム
藤井 泰志	東京女子医科大学東洋医学研究所
三瀬 忠道	福島県立医科大学会津医療センター準備室東洋医学
渡辺 賢治	慶應義塾大学医学部漢方医学センター・漢方医学
伊藤 隆	鹿島労災病院東洋医学センター
小川 恵子	金沢大学附属病院耳鼻咽喉科・頭頸部外科 和漢診療外来
小田口 浩	北里大学 東洋医学総合研究所 EBMセンター
喜多 敏明	千葉大学環境健康フィールド科学センター
小暮 敏明	社会保険群馬中央総合病院和漢診療学
田原 英一	飯塚病院東洋医学センター漢方診療科
萩原 圭祐	大阪大学大学院医学研究科漢方医学センター
花輪 壽彦	北里大学 東洋医学総合研究所
南澤 潔	亀田メディカルセンター 東洋医学診療科
村松 慎一	自治医科大学地域医療学センター東洋医学部門
矢久保 修嗣	日本大学医学部漢方医学

## 研究協力者

\*植田圭吾<sup>1)</sup>

\*王子 剛<sup>2)</sup>・島田 博文<sup>2)</sup>

\*山本 智史・笠原裕司

\*竹田 佳那子<sup>3)</sup> 津村 徳道<sup>3)</sup>・中口 俊哉<sup>3)</sup>

\*1) 千葉大学大学院医学研究院和漢診療学

\*2) 千葉大学医学部附属病院和漢診療科

\*3) 千葉大学大学院融合科学研究所

\*その他 厚生労働科学研究費並木班班員

#### IV. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Watanabe K, Matsuura K, Gao P, Hottenbacher L, Tokunaga H, Nishimura K, Imazu Y, Reissenweber H, Witt CM.	Traditional Japanese Kampo Medicine: Clinical Research between Modernity and Traditional Medicine	eCAM	Advance Access published online on June 16, 2010 eCAM, doi:10.1093/ecam/nea067	17-28	2010
Plotnikoff GA, Watanabe K, Torkelson C, La Valleur J, Radosevich DM	The TU-025 keishibukuryogan clinical trial for hot flash management in postmenopausal women: results and lessons for future research.	Menopause	18	886-892	2012
Watanabe K, Zhang X, Choi S-H	Asian medicine: a way to compare data.	Nature	482	162	2012
Cameron S, Reissenweber H, Watanabe K;	Asian medicine: Japan's paradigm.	Nature	482	35	2012
Gao PF, Watanabe K	Introduction of the World Health Organization project of the International Classification of Traditional Medicine.	中西医結合学報	9	1161-64	2011
渡辺賢治	漢方の証を考える	漢方の臨床	59	2181-2189	2012
渡辺賢治	グローバル化時代の漢方	漢方医学の進歩と最新エビデンス別冊・医学のあゆみ		31-33 69-70 105-107	2012
K. Katayama, R. Yamaguchi, S. Imoto, H. Tokunaga, Y. Imazu, K. Matuura, K. Watanabe S. Miyano	Symbolic hierarchical clustering for visual analogue scale data	<i>KES-Springer Smart Innovations, Systems and Technologies series</i>	10	799-805	2011

K. Katayama, R. Yamaguchi, S. Imoto, K. Matsuura, K. Watanabe, S. Miyano	Transform of visual analogue scale data and their clustering	<i>International Journal of Knowledge Engineering and Soft Data Paradigms</i>	3(2)	143-151	2012
K. Katayama, R. Yamaguchi, S. Imoto, K. Matsuura, K. Watanabe, S. Miyano	Clustering for visual analogue scale data in symbolic data analysis	<i>Procedia Computer Science</i>	6	370-374.	2011
K. Katayama, R. Yamaguchi, S. Imoto, K. Matsuura, K. Watanabe, S. Miyano	Symbolic hierarchical clustering for pain vector	<i>Intelligent Decision Technologies Smart Innovation, Systems and Technologies,</i>	16	117-124	2012
K. Katayama, R. Yamaguchi, S. Imoto, K. Matsuura, K. Watanabe, S. Miyano	Connection between traditional medicine and disease	<i>ACM SIGHIT Record</i>	2	Issue 1	2012
K. Katayama, R. Yamaguchi, S. Imoto, K. Matsuura, K. Watanabe, S. Miyano	Analysis of questionnaire for traditional medical and develop decision support system		<i>Catalog Number: CFP1226D-US</i>	762-763 (ISBN: 978-1-4673-2744-2)	2012
Hideki Mima, Katsuya Masuda, Susumu Ota, Shunya	Revealing Modern History of Japanese Philosophy Using Natural Language Processing and	Proceedings of Osaka Symposium on Digital Humanities		47-50	2011

Yoshimi,	Visualization	(OSDH)			
美馬秀樹	生命科学における知の構造化	Biophilia	7(3)	47-53	2011
Hideki Mima	An Issue-oriented Syllabus Retrieval System based on Terminology-based Syllabus Structuring and Visualization, In Proceedings of The First Workshop on Speech and Language Processing Tools in Education*(SLP-TED)	COLING-2012			2012
竹田俊明, 村松慎一	ニュートラルネットワークと自己組織化マップを応用した川芎茶調散証の解析	漢方と最新治療	19(1)	71-77	2010
Muramatsu S, Aihara M, Shimizu I, Arai M, Kajii E	Current status of Kampo medicine in community health care	General Medicine	13(1)	37-45	2012
上野眞二, 村松慎一	Alzheimer病と漢方薬	神経内科	76(2)	147-154	2012
Arai M, Katai S, Muramatsu S, Namiki T, Hanawa T, Izumi S	Current status of Kampo medicine curricula in all Japanese medical schools.	BMC CAM	12	207	2012
上野眞二, 村松慎一	頭痛の漢方治療：最新のエビデンス	医学のあゆみ	242(10)	821-826	2012

## V. 研究成果の刊行物・別冊

**Review**

## **Traditional Japanese Kampo Medicine: Clinical Research between Modernity and Traditional Medicine—the State of Research and Methodological Suggestions for the Future**

**Kenji Watanabe<sup>1</sup>, Keiko Matsuura<sup>1</sup>, Pengfei Gao<sup>1</sup>, Lydia Hottenbacher<sup>2</sup>,  
Hideaki Tokunaga<sup>1</sup>, Ko Nishimura<sup>1</sup>, Yoshihiro Imazu<sup>1</sup>, Heidrun Reissenweber<sup>3</sup> and  
Claudia M. Witt<sup>2,\*</sup>**

<sup>1</sup>Center for Kampo Medicine, Keio University School of Medicine, Shinjuku-ku, Tokyo, Japan, <sup>2</sup>Institute for Social Medicine, Epidemiology and Health Economics, Charité University Medical Center, Berlin and <sup>3</sup>Research Unit for Japanese Phytotherapy (Kampo), Department of Internal Medicine, University of Munich, Munich, Germany

\*Corresponding author: Claudia M. Witt, Institute for Social Medicine, Epidemiology and Health Economics, Charité University Medical Center, 10098 Berlin, Germany. Tel: +49-30-450529132; Fax: +49-30-450529917; E-mail: claudia.witt@charite.de

The Japanese traditional herbal medicine, Kampo, has gradually reemerged and 148 different formulations (mainly herbal extracts) can be prescribed within the national health insurance system. The objective of this article is to introduce Kampo and to present information from previous clinical studies that tested Kampo formulae. In addition, suggestions on the design of future research will be stated. The literature search was based on a summary, up until January 2009, by the Japanese Society of Oriental Medicine and included only those trials which were also available in either Pubmed or ICHUSHI (Japan Medical Abstracts Society). We included 135 studies, half of these studies ( $n = 68$ ) used a standard control and 28 a placebo control. Thirty-seven trials were published in English [all randomized controlled trials (RCTs)] and the remaining articles were in Japanese only. The sample size for most studies was small (two-third of the studies included less than 100 patients) and the overall methodological quality appeared to be low. None of the studies used Kampo diagnosis as the basis for the treatment. In order to evaluate Kampo as a whole treatment system, certain aspects should be taken into account while designing studies. RCTs are the appropriate study design to test efficacy or effectiveness; however, within the trial the treatment could be individualized according to the Kampo diagnosis. Kampo is a complex and individualized treatment with a long tradition, and it would be appropriate for further research on Kampo medicine to take this into account.

**Keywords:** clinical trials – Kampo – review – study design

## **Background**

### **Historical Background**

Japanese traditional herbal medicine (Kampo medicine) obtained the unique features observed today during its phase of long historical development in Japan. In

Japan, the administration of crude herbal drug formulations dates back by more than 1500 years. Recent decades have seen a revival of Kampo medicine in medical practice, accompanied by a scientific reevaluation and critical examination of its relevance in modern health care (1).

The term 'Kampo', which literally means 'method from the Han period (206 BC to 220 AD) of ancient China', refers to its origin from ancient China. The basic therapeutic handbook for the application of herbal prescriptions was the *Shang han lun*. During the Edo-period from 1600 onwards, the specific Japanese characteristics of Kampo took shape. The seclusion of Japan from the outside world led to ever increasing differences from the predominantly Chinese concepts. The huge variety of the thousands of Chinese crude drugs was reduced to ~300, those being the most efficacious drugs which were subsequently combined into ~300 prescriptions. From a pragmatic point of view, Japanese physicians criticized the highly theoretical and speculative nature of Chinese medicine as being inadequate to meet the problems of every-day practice. The strongest critique came from Yoshimasu Todo in the 18th century who wrote: 'In clinical medicine, we should only rely on what we actually have observed by examination of the patient'. For Yoshimasu Todo, one way to gain data on the condition of the body was to examine the abdomen, for which he developed a refined palpation technique (*fukushin*) (2). The results of the abdominal palpation should give additional clinical information in order to select the most appropriate herbal prescription for the patient. Yoshimasu Todo's pragmatic attitude and his abdominal palpation as a diagnostic procedure has had a strong influence on Kampo therapy right up until the present day (3).

It is not surprising that many Japanese physicians were drawn towards medical techniques from the West to improve their therapeutic options in surgery, but most of them continued to use traditional Kampo prescriptions for treating problems of internal medicine until the 19th century. At the end of the 19th century, it became obvious that for the urgent medical problems of that time, infectious diseases and acute surgical problems, Western medicine had better tools. The German system of medical education was adopted. In 1876, the government passed a regulation that all physicians were required to study Western medicine. The practice of Kampo was not forbidden but greatly inhibited and gradually declined (4). However, after the Second World War, the first modern Kampo specialists carried on the traditions from the Edo-period. This revival of Kampo took place within a context dominated by modern Western medicine. The pragmatic and reductive approach of restricting Kampo therapy to clinically meaningful components helped to facilitate its gradual integration into modern medicine. Modern industrial society, in combination with longer life expectancy, has caused a shift in the predominant disease patterns, bringing to the therapeutic forefront chronic and degenerative diseases, functional and psychosomatic disorders and the multimorbidity of the elderly. These provide the main indications for the use of herbal

drugs, not only with respect to treatment, but also for prevention (5).

Although rooted in Chinese tradition, Kampo medicine is not the same as modern traditional Chinese medicine (TCM). TCM emphasizes the traditional concepts of East Asian natural philosophy, such as Yin and Yang and the theory of the five elements. Japanese Kampo favors diagnostic methods that directly relate the symptoms to the therapy, bypassing speculative concepts. The vast array of crude drugs has been reduced in Kampo and also the quantity of each drug in the formulation is much lower. While Kampo still uses traditional prescriptions, TCM also tends to create new drug combinations (6).

### Usage and Integration into Modern Medicine

Kampo traditional prescriptions have been included in the Japanese National Health Insurance drug list since 1971. A total of 148 Kampo herbal prescriptions are able to be funded to date. The application of Kampo has steadily increased and according to a survey by the Journal Nikkei Medical, more than 70% of physicians prescribe Kampo drugs today (7). The Japan Society for Oriental Medicine is the biggest society for Kampo medicine and has 8600 members and 2600 certified board members. In 2001, Kampo education for medical students was incorporated into 'the model core curriculum' by the Japanese Ministry of Education, Culture, Sports, Science and Technology (6).

The development of modern ready-to-use forms was directly related to the enormous increase in Kampo usage, mainly as spray-dried granular extracts of the original formulae. They have increasingly replaced the traditional decoction of the crude drugs, even though they are also covered by the national insurance system. Besides being simple to administer, industrial production has enabled several other advantages. The quality control of the purity as well as toxicity is standardized in Japan, following the Japanese pharmacopoeia and internationally established regulations for Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP). The standardization of the main components has become possible and this is a precondition of clinical research. Today, extract preparations make up to 95% of the Japanese Kampo market.

In Western countries, herbal therapies originating in other cultural areas, mainly Chinese herbal medicine as part of TCM, are receiving increasing interest. In the USA, TCM is still far more visible than Kampo. The practitioners practice herbal therapy often in combination with acupuncture, which is often a mixture of Chinese, Japanese and Korean acupuncture styles. Kampo drugs are only available over the counter, meeting Japanese GMP criteria. Since Japanese pharmaceutical companies have started clinical trials in the USA, several drugs have already been registered as investigational new drugs