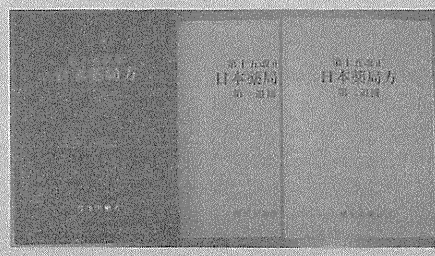
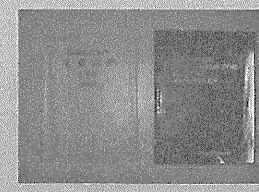
The Japanese Pharmacopoeia



The 1st Ed.: Jun 1886, The latest: 15th supplement 2 (Oct 2009), The next: JP16 (Apr 2011).
Now, JP is published every 5 years and during the 5 years, 2 supplements are prepared.

Non-JP Crude Drug Standards (Non-JPS)
(The Japanese Herbal Medicine Codex)

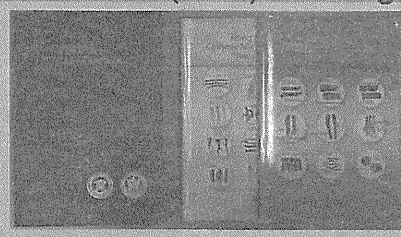


Left: Non-JPS (in Japanese)

Right:The Japanese standards for herbal medicines; it contains English version of monographs of crude drugs in non-JP crude drug standards and JP

The Non-JP crude drug standards is the notification of the director, Pharmaceuticals and Cosmetics division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare in 1989, although JP is the Ministerial Notification.

Other standards on natural medicines in (East) Asia regions



Philippine Pharmacopoeia March 2004

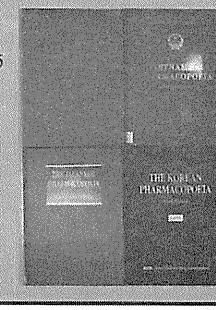
Hong Kong Chinese Materia Medica Standards Volume I (2005), Volume II (2008), Volume III

The latest ones of the English version of the four Pharmacopoeia

Each country published English version of their own pharmacopoeia. But normally the publishing date is about 1 year delay, comparing to the date of their own language version.

CP2005 E

JP 15th E



VP 4th E

KP 9th E

Number of herbal medicines in Volume I of CP 2010 and CP 2005

Categories	Items	CP 2010 edition	CP 2005 edition
Standards for Chinese Materia Medica and Prepared Slices of Chinese Crude Drugs	New admissions of Chinese Materia Medica	65	551 (including 13 individually listed standards for Prepared slices of Chinese Crude Drugs)
	New admissions of Prepared slices of Chinese Crude Drugs	438	
	Total new admissions	503	
	Total	1054	
Standards for oil, fats and Extractives	New Admissions	16	31
	Total	47	
Standards for Traditional Chinese Patent medicine	New Admissions	498	564
	Total	1063	
Total		2164	1146

Numbers of natural medicines in Korean and Vietnamese Pharmacopoeia

KP 9th Ed. 181 (176 crude drugs and 5 preparations), Dec 2007
KHP 387 (crude drugs) Jan 2005
+ 25 (processed crude drugs), Nov 207
+ 7 (crud drugs moved from KP), Dec 2007
Total: 570 crude drugs, 25 processed ones, 5 preparations

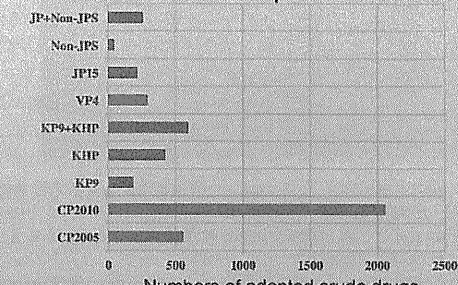
VP 3rd Ed. 314 (move into new edition: adoption 46, Omission 46)
VP 4th Ed. 314 (290 crude drugs and herbal medicines and 24 traditional pharmaceutical finished products)

Numbers of natural medicines in Japanese Pharmacopoeia

JP15: 200 crude drugs (52 powders), 6 Kampo extracts and 32 other herbal preparations
JP15 supplement I, 7 crude drugs (2 powders) and 2 Kampo extracts
JP15 supplement II, 6 crude drugs (1 powder) and 3 Kampo extracts
Total: 213 crude drugs (55 powders) and 11 Kampo extracts and 32 other herbal preparations
Non-JP crude drug standards: 42 crude drugs
Total: 258 crude drugs (including powders) and 11 Kampo extracts and 32 herbal preparations

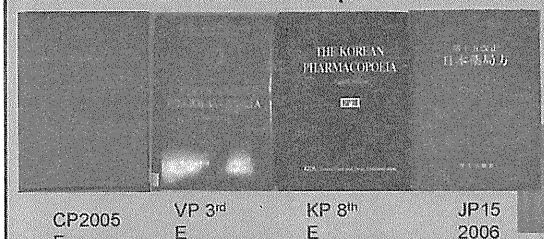
JP16: additional 4 crude drugs and 11 Kampo extracts

Comparison of numbers of crude drugs (including processed ones) adopted in the four Pharmacopoeia



Numbers of adopted crude drugs

Comparison studies among the 4 Pharmacopoeias

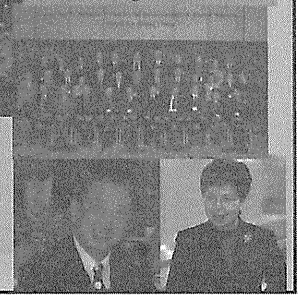


Non-JPS

CP2005 E 2005 | VP 3rd E 2005 | KP 8th E 2003 | JP15 2006

Since the publishing year of each pharmacopoeia is different and we need English version of Pharmacopoeia except for JP to understand the contents, the studies were performed by using the above Pharmacopoeias

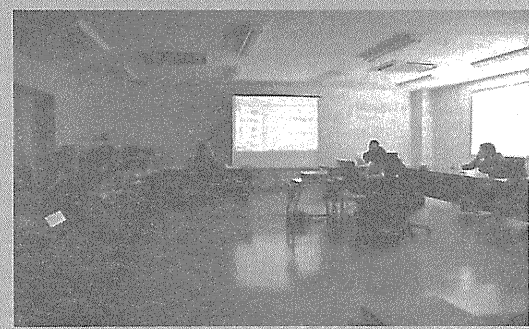
Workshop was hold on November 2001 in Seoul organized with help of Prof. Il-Moo Chang



Western Pacific Regional Forum for the Harmonization of Herbal Medicines (FHH, founded at Beijing meeting on March 2002)

FHH Sub-C 1 Meeting in Tokyo (May 21～24, 2002)

All participants recognized the importance of comparison on descriptions for HMs in member party's Pharmacopoeia as a first step for harmonization.



FHH Sub-C Meeting in Tokyo (May 21～24, 2002)

57 Common crude drugs using the same plant source among the 4 Pharmacopoeias

ACHYRANTIS RADIX, PROCESSI ACONII RADIX, ALISMATIS RHIZOMA, ALPINIAE FRUCTUS, ANEMARRHENAE RHIZOMA, ANGELICAE DAHURICAE RADIX, ASTRAGALI RADIX, ATRACTYLODIS RHIZOMA, ATRACTYLODIS LANCEAE RHIZOMA, BUPLEURI RADIX, CARTHAMI FLOS, CIMICIFUGAE RHIZOMA, CINNAMOMI CORTEX, COICIS SEMEN, CORNI FRUCTUS, CURCUMAE RHIZOMA, CYPERI RHIZOMA, EPHEDRAE HERBA, EPIMEDII HERBA, EUCOMMIAE CORTEX, LOGAN ARILLUS, EVODIAE FRUCTUS, FOENICULI FRUCTUS, FORSYTHIAE FRUCTUS, FRITILLARIAE BULBUS, GARDENIAE FRUCTUS, GLYCYRRHIZAE RADIX, IMPERATA RHIZOMA, LEONURI HERBA, LONICERAE FLOS, MAGNOLIAE CORTEX, MENTHAE HERBA, MORI CORTEX, MYRISTICAE SEMEN, NELUMBIS SEMEN, NOTPTERYGII RHIZOMA, PAEONIAE RADIX, MOUTAN CORTEX, GINSENG RADIX, PLATYCODI RADIX, POGOSTEMONI HERBA, POLYGONATHI RHIZOMA, POLYPORUS, PORIA, PRUNELLAE SPICA, ARMENIACAE SEMEN, PERSICAE SEMEN, RHEI RHIZOMA, SCHISANDRAE FRUCTUS, SCUTELARIAE RADIX, STRYCHNI SEMEN, CARYOPHYLLI FLOS, TRICHOSANTHIS RADIX, TRICHOSANTHIS SEMEN, ZINGIBERIS RHIZOMA, ZIZYPHI FRUCTUS, ZIZYPHI SEMEN. **Total 57 crude drugs**. Red: Completely same among the 4 Pharmacopoeias (27 crude drugs). Blue: Same at the level of species, but one or two Pharmacopoeia(s) regulated at the level of sub-species (3 crude drugs). Black: Each pharmacopoeia defines the same plant speices as the original plat, but one, two or three Pharmacopoeia(s) additionaliy define other plant species (26 crude drugs). Green: Existence of hybrid makes difficult to distinguish the two species (*Mentha arvensis* var.

Example of red, blue and black pattern and percentage of the common crude drug in each pharmacopoeia

Pharmacopoeia	JP15	CP2005	KP8th	VP3rd
Latin name Scientific name	PORIA *Poria cocos*	PORIA *Poria cocos*	HOELEN *Poria cocos*	PORIA *Poria cocos*
Latin name Scientific name	COICIS SEMEN *Coix lacryma-jobi* var. *ma-yuen*	SEMEN COICIS *Coix lacryma-jobi* var. *ma-yuen*	COICIS SEMEN *Coix lacryma-jobi* var. *ma-yuen*	SEMEN COICIS *Coix lacryma-jobi*
Latin name Salentific name	GLYCYRRHIZAE RADIX *Glycyrrhiza uralensis* *Glycyrrhiza glabra*	RADIX GLYCYRRHIZAE *Glycyrrhiza uralensis* *Glycyrrhiza inflata* *Glycyrrhiza glabra*	GLYCYRRHIZAE RADIX *Glycyrrhiza uralensis* *Glycyrrhiza glabra*	RADIX GLYCYRRHIZAE *Glycyrrhiza* *Glycyrrhiza inflata* *Glycyrrhiza glabra*
Number of crude drugs for comparison	***290***	***198 (+53powder)***	***551***	***121 (+41 powder)***
Percentage of	***29%***	***10%***	***47%***	***20%***

49 Common crude drugs using the same plant source among 3 Pharmacopoeias

Common in CP, KP and VP (2 crude drugs): PIPERIS NIGRI FRUCTUS, SALVIAE MILTIORRHIZAE RADIX.

Common in JP, CP and KP (16 crude drug): AKEBIAE CAULIS, ARECAE SEMEN, SENNAE FOLIUM, CRATAEGI FRUCTUS, CROCUS, DIOSCOREAE RHIZOMA, GENTIANAE SCABRAE RADIX, PHARBITIDIS SEMEN, PHELLODENDRI CORTEX, PLANTAGINIS SEMEN, POLYGALAE RADIX, PUERARIAE RADIX, SAPOSHNIKOVIAE RADIX, SCHIZONEPETAE SPICA, SOPHORAE RADIX, SOPHORAE FLOS

Common in JP, CP and VP (25 crude drugs): ALOE, ALPINIAE OFFICINARI RHIZOMA, ANGELICAE PUBESCENTIS, ARCTII FRUCTUS, ARECAE PERICARPIUM, ASTERIS RADIX, SAPPAN LIGNUM, CHRYSANTHEMI FLOS, AURANTII FRUCUTUS IMMATURUS, CLEMATIDIS RADIX, CNIDII MONNIERIS FRUCTUS, KAKI CALYS, ERIOBOTRAYAE FOLIUM, HOUTTUYNIAE HERBA, LINDERAE RADIX, LYCII CORTEX, PERILAE FRUCTUS, PEUCEDANI RADIX, MUME FRUCTUS, REHMANNIAE RADIX, SAUSSUREAE RADIX, SMILACIS RHIZOMA, CHEBULAE FRUCTUS, TRIBULI FRUCTUS, VITICIS FRUCTUS

Common in JP, KP and VP (2 crude drugs): ZEDOARIAE RHIZOMA, GERANII HERBA.

2 common plant source in 3 different Pharmacopoeias (4 crude drugs): ARISAEMATIS TUBER（天南星）, CASSIAE SEMEN（決明子）, LYCII FRYCTUS（枸杞）, SCROPHULARIAE RADIX（玄参）

Example of "2 common plant source in 3 Pharmacopoeias"

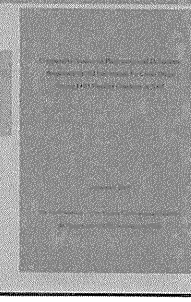
Pharmacopoeia	JP15+nonJPS	CP2005	KP8th	VP3rd
決明子 Latin name	CASSIAE SEMEN	SEMEN CASSIAE	CASSIAE SEMEN	SEMEN CASSIAE TORAE
Scientific name	*Cassia obtusifolia* *C. tora*	*Cassia obtusifolia* *Cassia tora*	*Cassia obtusifolia*	*Cassia tora*
玄参 Latin name	SCROPHULARIAE RADIX	RADIX SCROPHULARIAE	SCROPHULARIAE RADIX	RADIX SCROPHULARIAE
Scientific name	*Scrophularia buergeriana* *S. ningpoensi*	*Scrophularia ningpoensis*	*Scrophularia buergeriana*	*Scrophularia buergeriana* *S. ningpoensis*

Number of common crude drugs using the same plant source at least 3 pharmacopoeia in each pharmacopoeia

Pharmacopoeia	*JP15+nonJPS*	*CP2005*	*KP8th*	*VP3rd*
Number of crude drugs for comparison	*290*	*198 (+53powder)*	*551*	*121 (+41 powder)*
4 Pharmacopoeia	*57*	*57*	*57*	*57*
At least 3 Pharm.	*33*	*47*	*47*	*24*
Total	*104*	*104*	*81*	*90*
Percentage of common crude drugs	*53%*	*19%*	*67%*	*31%*

Comparative studies on Pharmacopoeial definitions, requirements and information for crude drugs among FHH member countries in 2007

Ed., Dr. Nobuo KAWAHARA
National Institute of Health Sciences (NIHS), Japan



The sub-committee I of the Western Pacific Regional Forum for the Harmonization of Herbal Medicine (FHH)

Contents of the booklet

1) Comparative table on names of crude drugs in CP, JP, KP and VP (for the 106 common crude drugs)
2) Comparative table on description of crude drugs in JP, CP, KP and VP
3) Comparative table on English titles and part of use of crude drugs in JP, CP, KP and VP
4) Comparative Table on Testing Methods and Specification Values for Crude Drugs in JP, CP, KP and VP (for the 106 common crude drugs)
5) Comparative Table on TLC Conditions of Identification for Crude Drugs in CP, JP, KP and VP
6) Comparative Table on Assay Conditions for Crude Drugs in CP, JP, KP and VP
7) List of CRS in Japanese Pharmacopoeia (JP)
8) List of reference sample in JP
9) List of CRS in Korean Pharmacopoeia (KP)
10)List of CRS in Vietnamese Pharmacopoeia (VP)
11)List of Reference of Medicinal Plant Materials (RMPM) in CP
12)List of Reference of Medicinal Plant Materials (RMPM) in KP
13)List of Reference of Medicinal Plant Materials (RMPM) in VP
14)Analytically validated chemical assay and purity test for herbal materials in JP15
15)Analytically validated chemical assay or purity test for herbal materials in KP
16)Comparative Table on General Testing Methods for Crude Drugs in JP, KP, CP and VP

All of the comparison data are able to be downloaded from the FHH and our institite

Comparison of formulae among TCM, Korean traditional medicines and Kampo medicines in CP2000, Korean National Insurance List and the Kampo 291 formula in Japan

Number of formula; China 458, Korea 56, Japan 291 (Ethical 148, OTC 203)

Similar component (and name) formulae between Korea and Japan: 32 (57% in Korea F), between Korea and China : 8 (14% in Korea F), between Japan and China: 30 (10% in Kampo F) and among 3 countries: 7 (2.4% in Kampo F)
* Similar component formula means that the corresponding formula uses almost the same crude drug combination. But in this case, the amounts of each crude drug (composition) used for 1-day decoction are somewhat different each other.

The 7 similar formulae among China, Korea and Japan

1) 加味逍遥散 (Kampo medicines)
当帰3、芍薬3、朮3、茯苓3、柴胡3、牡丹皮2、山梔子2、甘草1.5-2、乾生姜1、薄荷葉1

加味逍遙散(Korean Traditional Medicines : K T M)
當歸 6 g、白芍藥 6 g、白朮 6 g、柴胡 3 g、甘草 3 g、梔子 4 g、牧丹皮 4 g、白茯苓 1.2 g、薄荷 1 g、生薑 0.8 g

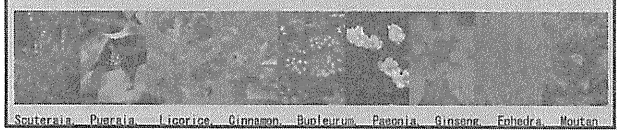
加味逍遙丸(CP2000)
柴胡 300 g、当帰 300 g、白芍 300 g、白朮（麸炒） 300 g、茯苓 300 g、甘草 240 g、牡丹皮 450 g、梔子（姜炙） 450 g、薄荷 60 g

Kampo medicine-KTM-CP2000
2)参蘇飲-夢蘇飲-参苏丸, 3)三黃瀉心湯-三黃瀉心湯-一清飘散, 4)小青竜湯-小青龍湯-小青龙合剂/小青龙颗粒, 5)五淋散-五淋散-五淋丸, 6)人参湯（理中丸）/附子理中丸-理中湯-附子理中湯, 7) 二陳湯-二陳湯-二陈丸

Renewal of the comparison tables

After the publishing of JP16 and the English version of CP2010, the work for the renewal of the comparison tables will start by the team of Dr. Kawahara by using CP2010, KP9th, VP4th and JP16th.

We have to recognize that each Pharmacopoeia in East Asia countries has their specific monographs of herbal medicines reflecting own medicinal history and culture, even though the plant sources of some crude drugs are the same.



Scuterain, Puerain, Licorice, Cinnamon, Bupleurum, Paeonia, Ginseng, Ephedra, Mouten

Thank you for your attention

統合医療
理論と実践

Revised Edition 2012
Part1.【理論篇】

責任編集　日本統合医療学会理事長
東京大学名誉教授
渥美和彦

編集・発行　一般社団法人
日本統合医療学会

第8章1項

家庭医と統合医療
(プライマリ・ケアの視点から)

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はじめに

相補代替医療（complementary and alternative medicine：CAM）が脚光を浴び，熱狂的な1990年代を経て，時代は統合医療に向かっている。筆者はこれまで家庭医の立場から，CAMをどのように理解し，対応すべきか考えてきた。その過程で家庭医療と統合医療に多くの共通項があると実感し，家庭医療の概念を拡大解釈することで，統合医療の発展に貢献できると確信するようになった。

本章では家庭医療，プライマリ・ケア，総合診療など同義語を整理するとともに，その概念を紹介する。家庭医療と統合医療の接点に注目しながら，家庭医療の実践で必要とされる臨床能力について論じる。さらにはアリゾナ大学で実践されているintegrative family medicine（IFM）の研修プログラムを紹介し，統合医療の担い手として欧米では家庭医が期待されていること紹介する。

家庭医療－総合医療－プライマリ・ケアとは

家庭医の学問的基盤は家庭医療であるが，同義語が複数存在し，その概念をわかりにくくしている。学問的な名称としては，家庭医療（family medicine, family practice）の他，プライマリ・ケア（primary care），総合医療・総合診療（general medicine, general practice），総合内科（general internal medicine），地域医療（community medicine）が挙げられる。これらを担う医師を示す用語となるとさらに増え，家庭医（family physician），プライマリ・ケア医（primary care physician），一般医・総合医（general practitioner：GP），かかりつけ医，ジェネラリスト（generalist），ホームドクター，町医者，山医者などがある。家庭医という用語は米国やカナダなど北米で，GPは英国で主に用いられ，プライマリ・ケアは万国共通である。医師の置かれた環境により用語が使い分けさている現状があるが，コアとなる概念はプライマリ・ケアである。

米国医学会ではプライマリ・ケアを「日常の健康問題の大半を責任もって取り扱うことができるような幅広い臨床能力を有する医師によって提供される，包括的な，地域の第一線で提供されるヘルスケア・サービスである。そのヘルス・ケアは，継続的で地域や家族を視野に入れたものでなければならない」，と定義している。

ACCCA

プライマリ・ケアの基本理念を示したものに，ACCCAがある。ACCCAとは，近接性（Accessibility），包括性（Comprehensiveness），協調性（Coordination），継続性（Continuity），責任性（Accountability）の5項目の頭文字を並べたものである。図1にACCCAの具体的な内容を列挙した。「全人的」「予防から治療，リハビリテーションまで」などの包括性，「ゆりかごから墓場まで」などの継続性，「専門家との密な連携」「Patient request approach」などの協調性，に注目していただきたい。これらは，統合医療の目指すものとして本学会が提示している項目，①患者中心の医療，②身体・精神のみならず人間を包括的にみる全人的医療，③治療だけでなく疾病の予防や健康増進に寄与する医学，④生まれて死ぬまでの一生をケアする包括的医療，とオーバー・ラップする。勿論，近接性や責任性も統合医療を実践するうえで基本的な要素であろう。統合医療とプライマリ・ケアはコアとなる理念がよく似ており，プライマリ・ケアの理念に介入の手段としてのCAMを考慮することで，統合医療に近づくと考えてもよいのではなかろうか。そのように考えると，統合医療の学術的な発展には，プライマリ・ケアでこれま

図1　ACCCA

Ⅰ. Accessibility 近接性	①地理的 ②経済的 ③時間的 ④精神的
Ⅱ. Comprehensiveness 包括性	①予防－治療－リハビリ ②全人的 ③common disease ④小児－老人
Ⅲ. Coordination 協調性	①専門医と連携 ②チームでの協調 ③住民との協調 ④社会資源の活用
Ⅳ. Continuity 継続性	①ゆりかごから墓場まで ②病気の時も健康な時も ③外来－病棟－外来
Ⅴ. Accountability 責任性	①監査システム ②生涯教育 ③患者への充分な説明

図2　五十嵐の10の軸

総合医療の最も重要な基盤は

①近接性	無差別性　患者や問題を選ばない 精神的　良好な医師患者関係 時間的　時間外の初期救急も含めて 経済的　費用効果思考で行動
②日常性	日常問題，日常病 単純な頻度ではなく，重症度，影響度の大きい順に

この基盤のもと以下の場で，そのニーズを反映して仕事をする

③全人	生物医学的視点と平行して 心理的 社会的 倫理的視点からも思考と行動ができる
④家庭	家庭を一単位とした思考と行動ができる
⑤地域	地域を一単位とした思考と行動ができる 保健，医療，福祉を統合した地域医療を実践する

この基盤と場を背景にして，総合医療は次のことを実現する

⑥質の保証	QOL（いきがい，自己実現）の維持向上を尺度とした医療，保健，福祉の質を保証する思考と行動ができる
⑦個別性	個別の事情に応じた思考と行動 多くの選択肢を示しつつ，患者の自己決定の支援ができる
⑧生態学的接近	多面的，学際的，有機的，総合的な思考と行動ができる

これらを実現するためには，以下の役割と責任が必要である

⑨役割	患者の道案内役，弁護士役，患者や医療関係者の調整役，聴き役，説明役，連絡役を担う思考と行動
⑩責任	継続性（当面の問題，生涯にわたる継続性） 責任制（主治医としての） 民主制（患者との対等な関係）

で築かれた知を応用していくことが効率的と思われる。ACCCAを掘り下げ，より細かく具体的に表現し，日本のプライマリ・ケアを実現するための思考と行動を明確化したものに，五十嵐の10の軸（図2）がある。家庭医の理念としてカナダのマクウィニーが９つの機能を示しており（図3），こちらも参照されたい。

図3　家庭医療の理念
"A Textbook of Family Medicine" by Ian R McWhinney

① 家庭医は人をみる
② 家庭医は「病い」の文脈を理解しようとする
③ 家庭医は予防と健康教育に取り組む
④ 家庭医は患者個人だけでなく住民全体もみる
⑤ 家庭医は地域ネットワークの一端を担う
⑥ 家庭医は患者の暮らす地域に住む
⑦ 家庭医は患者を患者の家でみる
⑧ 家庭医は自分の診療を振り返る
⑨ 家庭医は医療資源のマネージャーである

どのような臨床能力が必要か

ここでは，家庭医療の実践にどのような能力やスキルが必要か紹介する。

◎幅広い疾患への対処能力

臓器別に細分化された現代西洋医学では，「あなたの専門は何科？」と問われることが多い。家庭医は老若男女問わず，あらゆる疾患への対応を迫られるので，この問いかけへの返事は難しい。家庭医はありふれた疾患の専門家である。これをcommon diseaseといい，高血圧や糖尿病などの生活習慣病，感冒から肺炎，膀胱炎から腎盂腎炎などの感染症，脳梗塞などの脳血管障害，小外科的処置を要する外傷，骨粗鬆症や変形性関節症などの整形外科疾患，更年期障害，不安神経症やうつ病などの精神疾患，など例をあげるときりがない。専門的な治療がもはやできない神経難病，末期がんなども対象となり，在宅ケアや緩和ケアも実践できなければならない。common diseaseを明確に定義することは難しく，プライマリ・ケア領域の重要な研究対象でもあるが，幅広い疾患に対応しなければならないことを認識してほしい。したがって，頻度が多い疾患や慢性疾患への対応，初期救急，小外科的なスキル，感染症や悪性疾患のスクリーニング，在宅ケアや緩和ケア，重症度の判定，専門医紹介など，多様な臨床能力が問われる。

◎包括的に考える

「臓器でなく人をみる」と形容されることが多い。患者がこれまでどのような人生をおくり，病が患者にとって何を意味するのか，すなわち患者の物語（narrative）を把握し対応する。患者とともに暮らし，患者を支える家族も一単位と考え，相互の影響を考慮する。さらには患者が暮らす地域も視野に入れる。その地域で利用可能な社会資源を熟知し，その地域特有の文化観や健康観も把握できれば質の高いケアにつながる。

◎EBMの実践

家庭医に限らず臨床家は，最良のエビデンスを収集し，その情報を吟味し，患者に明示し，患者の価値観と照らし合わせ，相談のうえ意思決定を行わなければならない。それを明確に示したスキルがEBM(evidence-based medicine)に他ならない。EBMがうまれた1990年代初頭，エビデンスのないものがCAMと位置づけられていた。CAMのランダム化比較試験（randomized controlled trial： RCT）を行うことも探すことも不適切と考えられた。しかし1990年代後半になると，コクラン共同計画やNCCAMが中心となり，CAMもRCTで評価しようとする気運が先進各国で高まる。こうして，CAMのRCTを世界中から収集しデータベース化するプロジェクト等が次々とはじまっていく。15年ほど経過し，現在では図4のように様々な媒体からCAMのエビデンスを収集できるようになった。サプリメントから東洋医学，さらには祈祷に至るまで，有効性に関するRCTを探すことが可能となってきた。日本でも漢方薬をはじめ，鍼灸，あん摩・指圧・マッサージ，健康食品などでRCTを収集する作業が進行中で一部はホームページ等で公開されている。大事なことは，現代西洋医学とCAMを統合していくモノサシとしてEBMが重要視されていることだ。家庭医のみならず，統合医療の実践家にとってEBMは必須のスキルである。

図4　CAMの情報源

- インターネット（HP）
  - 厚生労働省HP：　保健機能食品・健康食品
  - 国立健康栄養研究所HP：健康食品の安全性有効性情報
  - 東京都福祉保健局HP：　健康食品ナビ
- データベース
  - コクラン・ライブラリーPubMed(CAM on PubMed)，医中誌，Natural Medicine Comprehensive Database（NMCD）
- 二次情報誌
  - FACT誌（Focus on Alternative and Complementary Treatment）
  - 鍼のエビデンス（FACT誌翻訳集）
- クリニカル・エビデンス集(エビデンスレポート)
  - The Desktop Guide to CAM，EBM漢方，漢方治療におけるエビデンス・リポート（日本東洋医学会），医療従事者のためのEBMサプリメント事典，健康食品のすべて（NMCD翻訳集）
- 教科書
  - Up To Date，ハリソン内科学，CMDT

◎NBMの実践

エビデンスだけでは患者の健康問題を解決できないことを，多くの臨床家が現場で実感している。またエビデンスを伝えても，医療者－患者間における価値観や健康観の相違から治療を拒否されることさえある。時は同じく1990年代後半，このようなジレンマに悩んだ英国のGP達からEBMを補完する意味でNBM（narrative-based medicine）が生まれた。NBMは患者が独自に考える病の物語（narrative）を傾聴し，その意味を理解し，対応しようとするアプローチである。多様な価値観が氾濫し，多様な医療システム，すなわちCAMが混在する現代社会では，患者のニーズを的確に把握し意思決定を手助けするNBMも必須のスキルといえよう。

◎コミュニケーション・スキル

家庭医にとってコミュニケーション・スキル（medical communication skill：

MCS）は重要である。患者との人間関係，信頼関係を構築することは医療を行う上での前提といえよう。患者へのインタビューがきちんとでき，患者から適切な情報を引き出すことができれば，多くの場合，診断や治療への道のりは近い。MCSを学んだことのない医療者は，このスキルを「口が上手な人」と形容するが，面白いことに実際の臨床で言語的コミュニケーションの占める範囲はわずか７％である。その多くは，表情やしぐさ等の非言語的コミュニケーション（55%）であったり，声のトーンや速さ等の準言語的コミュニケーション（38%）である。開放型質問や閉鎖型質問，沈黙・相槌・促し・繰り返し・要約などのスキルを駆使し，患者の解釈モデル（explanatory model）や物語を引き出されば，質の高いケアにつながる。

◎多職種協働

現代の医療は，様々な職種の医療者によって提供されている。たった一人の匠の技で，もはや現代医療を実践することはできない。多職種チームがひとつの有機体となって患者のケアにあたることが一般的である。いわゆる「チーム医療」だが，ビジネス業界などのチームとの大きな違いは，個々のメンバーが有資格者であり特殊技能を持つことだ。これを多職種協働（interprofessional work：IPE）という。地域医療の現場では，保健や福祉の専門家達とチームをつくりIPEを実践している。ここでは，他職種向けのコミュニケーション・スキルも必要となる。同じ現象をみても，それぞれの職種の教育の違いは，言葉の違いをうみ，アプローチの違いをうむ。CAMの治療者がメンバーに入れば，さらにアプローチは変わってくるであろう。患者に物語があるように，医師にも各職種にも，それぞれの物語がある。それぞれの物語が患者を中心に寄り添えば，患者中心の医療を実践可能にする。家庭医はIPEの実践において，リーダーシップを発揮できなければならない。

関連学会の動向

プライマリ・ケア領域の学会には，三大学会として，これまで日本プライマリ・ケア学会，日本家庭医療学会，日本総合診療医学会があった。2010年にこの三学会が合併して，日本プライマリ・ケア連合学会となった。専門医制度は日本プライマリ・ケア学会が実施していた制度を軸に実施されている。同学会の専門医取得には，内科・外科・小児科・精神科・救急など複数科での研修実績，症例報告50例の書類審査とともに，臨床能力評価試験（CSA：Clinical Skill Assessment）と論述試験を受けなければならない。CSAは近年医学部の学生に実施されているOSCE（Objective Structured Clinical Examination：客観的臨床能力試験）をイメージしていただくと理解の助けとなろう。受験者が医学生でなく経験豊富な臨床医なので，要求される能力は高い。例えば，生活習慣病の生活指導，禁煙指導，認知症への対応，小児へ

の対応などを実際の病院の診察室を試験会場とし模擬患者（simulated patientもしくはstandardized patient：SP）への診療をみることで評価する。ここでは勿論コミュニケーション・スキルなども評価の対象となる。また，シミュレーターを使っての心肺蘇生（ACLS：Advanced Cardiovascular Life Support）では気管内挿管や心臓マッサージ（胸骨圧迫）のスキルだけでなく，リーダーとなって適切なマネージメントができているかなども評価される。さらには豚足を使った小外科のスキルなど，そのほとんどが実践形式で評価される。今後の試験には日本家庭医療学会で積極的に行われてきたポートフォーリオも取り入れられる。私は受験する側と評価する側の両者を体験したが，ともに大変な労力を要する専門医試験である。筆記試験だけでは総合的な臨床能力を評価することは極めて難しく，統合医療の専門医制度を検討するにあたっては参考にされたい。

家庭医の仕事場

上記のようなトレーニングを受けた家庭医やプライマリ・ケア医は，どのような仕事場で活躍しているのであろうか。

診療所の医師を想像することが最も簡単である。都会，郊外，下町，山村，離島など設定は様々であるが，外来診療を中心に，在宅医療，予防接種や健康教育などの保健活動，介護・福祉関係者との協働，学校医などに従事し地域医療を支えている。家庭医やプライマリ・ケア医の他，かかりつけ医，開業医，町医者，ホームドクターなどと呼ばれる医師達である。

小規模な病院では，内科医として外来・入院・在宅の診療を行っていることが多い。大学病院のような大病院では，総合診療科や総合内科という部門で外来と入院患者の診療にあたる。総合医と呼ばれる医師達である。総合医は，common diseaseから複数の健康問題を抱える患者，心療内科的な患者の治療，原因不明の疾患の精査，救急医療，専門科への振り分け業務など行っている。

ジェネラリストとしての臨床能力を身につけ，JICA・WHO・国境なき医師団など国際医療で活躍する者もいれば，健診や人間ドックなど予防医療の道を進む者もいる。個々の患者ではなく，地域住民全体の保健・医療・福祉の向上を目指し，公衆衛生の分野に興味を持ち，保健所・厚生労働省・WHOなど行政に関わる者もいる。

専門家と異なり，家庭医の仕事場は多様である。大事なことは，家庭医・プライマリ・ケア医・総合医と呼ばれる医師達の役割を最終的に決定づけるのは，地域であり，環境であり，住民である。家庭医は，与えられた環境やニーズを的確に把握し，自らの診療スタイルを決めていくのである。

家庭医療と統合医療

“Orthodox meets Alternative”と題して，BMJ誌から刊行された統合医療特集号は大変な話題と呼んだ。この特集号が21世紀の幕開けともいえる2001年の１月に刊行されたことは，新しい時代の予感を感じさせた。２羽のフラミンゴが首を絡ませた表紙の写真は印象的で，１羽は西洋医学，もう１羽はCAMなのであろう。この特集号でLeeとWeilによって統合医療という概念が紹介されたが，英国の医学雑誌ということもあり，“integrative medicine”でなく，“integrated medicine”と書かれていた。“integrated medicine”という言葉は，日本のプライマリ・ケア関係者の間では別の意味でよく知られている。医学書院から刊行されているプライマリ・ケア向け医学雑誌『JIM』のことである。『JIM』誌はJournal of Integrated Medicineを略で，雑誌の表紙には「プライマリ・ケア／総合診療のための『ジム』」と紹介されている。本学会が設立された時，略称がJIMであったので，これは用語をめぐって混乱を来たすのではないかと少し心配になった。余談ではあるが，これもまたプライマリ・ケアと統合医療に共通項が多いからであろう。

米国のアリゾナ大学にはProgram in Integrative Medicine（PIM）という部門がある。PIMは先のWeilが設立したことで有名で，統合医療のメッカである。私は2006年に訪問したが，アリゾナ大学の位置するTucsonは砂漠のオアシスといった印象で，CAM治療者のクリニックやオフィスが目立つ独特の町並みだ。PIMの臨床部門は“PIM Clinic”と称し，大学病院の中に一診療科として存在していた。カイロプラクティック，アロマセラピー，鍼，ホメオパシー，オステオパシー，ハーブ療法，ヨガなど複数のCAM治療者とネットワークを構築しながら診療が行なわれていた。このクリニックで，すなわち統合医療の現場で，学生教育も研修医教育もなされ，統合医療を学びたい医療従事者が世界中から集まってくるという。注目すべきは，PIM ClinicのMedical Directorが総合内科医であり，PIMの診療・教育・研究を統括するExecutive Directorが家庭医であったことだ。PIMを運営する二人がジェネラリストであることは大きな意味があると思われる。さらに驚かされたのが研修プログラムの名前が，Integrative family medicine（IFM）と呼ばれていること。IFMとはその名の通り統合医療を実践する家庭医を意味するが，これは統合医療を担う西洋医学側の医師として家庭医，総合医，プライマリ・ケア医などのジェネラリストが適していることを反映している。IFMプログラムはNCCAMがサポートしており，この当時すでにアリゾナ大学を始め米国の６大学ですでに始められていた。

プライマリ・ケアの視点からみると，欧米と日本ではCAMに接する態度が大きく異なる。欧米では家庭医が臨床の現場でCAMに興味を持ち，研究し，教育を担っていることが多い。たとえば米国の医学部では，CAMの授業を担当する教員はFamily medicine（家庭医療）もしくはGeneral medicine（総合医療）の所属者が最も多い。一方，日本では全80大学医学部のうちCAM関連の授業は69大学で実施さ

れているが，プライマリ・ケア関係者が実施しているのはわずか4校しかない。実際この結果を，同じTucsonで開催された第34回北米プライマリ・ケア研究会定例総会で発表すると，会場から驚きの声があがった。その意味は，「日本は米国よりもCAM利用者が多いのに，なぜ家庭医が興味を持たないのか？米国でCAMはすでにコモンなトピックとして扱われている」であった。

おわりに

統合医療の担い手として，欧米では家庭医やプライマリ・ケア医に期待が寄せられている。家庭医療と統合医療の概念はよく似ており，家庭医療の臨床技能を少し広げ，CAMを考慮することで統合医療の実践につながる。統合医療の関係者には，家庭医療やプライマリ・ケアに興味を持っていただき，これまで蓄積された学問体系を知ってほしい。地域医療を支える家庭医・プライマリ・ケア医・総合医等の理解を促すことが統合医療推進の近道であることは言うまでもない。一方，家庭医にはCAMを利用する患者を受け入れ，向かい合ってほしい。欧米の家庭医達と同じようにCAMをコモンなトピックとして扱い，統合医療に関心をもっていただきたい。本稿が統合医療の発展に貢献し，日本の統合医療と家庭医療に橋をかける役割をしてくれればと願っている。

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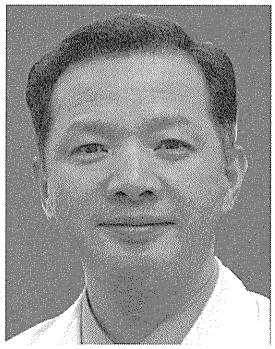
FEATURE ARTICLE

Traditional Japanese Medicine, Kampo: Its History and Current Status

Yoshiharu Motoo[1,2], Takashi Seki[1,3] and Kiichiro Tsutani[1,4]

ABSTRACT Traditional Japanese medicine, Kampo, is used by over 80% of medical doctors in Japan. Owing to its high quality and safety, Kampo has been integrated into modern medicine, and there are 345 randomized controlled trials using Kampo in Japan as of 2010. Although there are a number of articles in top journals about basic science research, we can find only small numbers of high-quality clinical evidence. Since undergraduate education on Kampo has been established, integrative approach with the balanced combination of modern medicine and Kampo is expected to generate good clinical evidence in the near future.

KEYWORDS Kampo, traditional medicine, evidence, randomized controlled trial, integrative medicine



Prof. Yoshiharu Motoo

The consumption per capita of herbal medicine in Japan may be the highest in the world[(1)]. Traditional Japanese medicine is one of the traditional East Asian medicines (TEAM) as shown in Figure 1. According to the Web survey[(2)] by the Japan Kampo Medicines Manufacturers Association (JKMA) during the period from August 5, 2008 to September 12, 2008, 83.5% of 684 medical doctors answered that they were using Kampo[(2)]. However, many countries have difficulties in handling traditional medicine in their medical system partly due to the lack of evidence in clinical settings and partly due to the problems in safety and quality control. Why is Kampo so popular and well integrated into modern medicine in Japan? The authors would like to show how Kampo developed in Japan.

History

Before Meiji Restoration

Kampo was introduced to Japan from ancient China via Korea, or directly in the 5th century, together with Buddhism and other cultures. Kampo was first used in higher social classes, but since the 15th century it has provided general people natural material-based medicine. During Edo era, Japanese government kept an isolationism policy, and only the Dutch could trade with Japan only through the Dejima island, Nagasaki. "Abdominal diagnosis" was invented by Japanese Kampo practitioners, and the way of diagnosis and treatment was greatly developed. Tremendous cases of Kampo treatment were reported in the Japanese literatures.

After Meiji Restoration

The Meiji legislation decided that only those who mastered Western medicine were certified as medical doctors. Therefore, Kampo practitioners became uncertified professionals, and Kampo was eliminated from official medical education. Although there was resistance to this governmental decision, it was in vain. However, Kampo practice survived, and the Japan Society for Oriental Medicine (JSOM) was established in 1950. Since the coverage of Kampo by national health insurance started in 1967, Kampo has been recognized as an important medical approach in modern medicine (Figure 2).

Current Status

Clinical Practice

Kampo is used by approximately 85% of clinical practitioners in Japan, as mentioned above. National health insurance started to cover the clinical practice of Kampo in 1967, and the number of Kampo formulas greatly increased since 1976. At present, 148 formulas are covered by national health insurance. Although the

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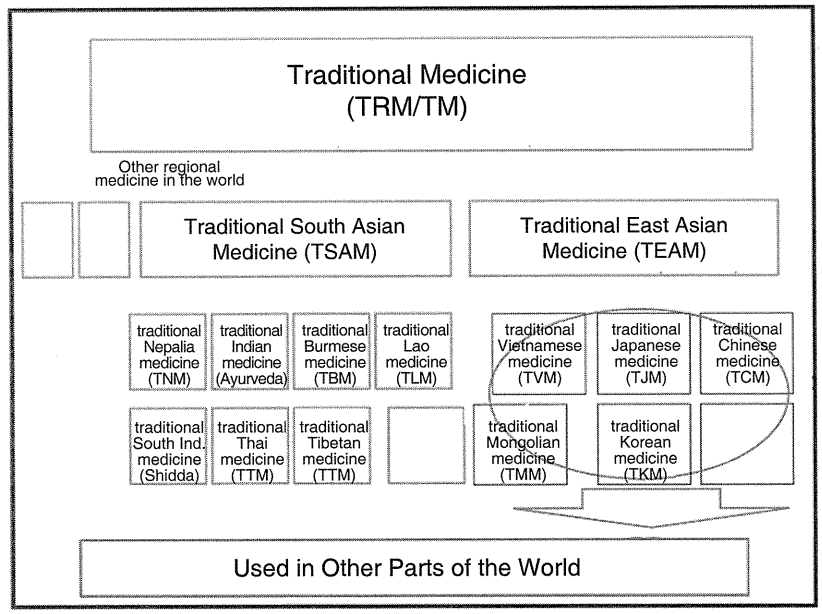

Figure 1. Positioning of Traditional East Asian Medicine

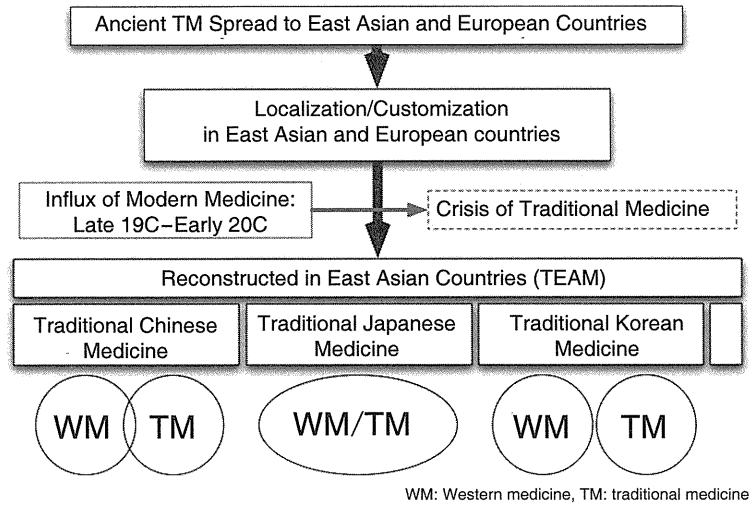

Figure 2. The History of Traditional East Asian Medicine

government sometimes tried to eliminate Kampo from the health insurance, such as in autumn 2009, the action was protested by approximately 920 000 Japanese citizens through volunteer signatures. Approximately 10% of Japanese clinical practice guidelines contain descriptions on Kampo. However, evidence-based descriptions with evidence levels and recommendation grades are seen only in 15.9% of the 44 clinical practice guidelines[3]. In addition, clinical practice guidelines in the People's Republic of China contain evidence-based descriptions in 7.1% of the 14 clinical practice guidelines[4]. Developers of clinical practice guidelines should recognize and search the evidence of Kampo and traditional medicine more accurately[5].

Education

The Japanese government decided to introduce Kampo into medical education in 2001. Kampo education has been conducted at all of the 80 medical schools in Japan since 2005. Textbooks in both Japanese and English were published. The problem is the lack of university teachers who know Kampo well both basically and clinically.

Research

Recently basic research has greatly developed in Japan, and the accomplishments have been published in top journals. For example, rikkunshito prevents the decrease in plasma acyl-ghrelin levels[6], and also

recovers the decreased expression of ghrelin receptor mRNA in the hypothalamus of cisplatin-treated rats[7].

Perspectives

Although it is hard to say that Kampo is used worldwide, Kampo is greatly integrated in modern medicine in Japan owing to its quality and safety, and to the national health insurance system. Especially extracted granules for ethical use are very suitable for clinical trials because of their quality, and many randomized controlled trials are expected to generate evidence as published in Evidence Reports of Kampo Treatment 2010 (EKAT 2010: 345 randomized controlled trials) by the Special Committee for Evidence-Based Medicine, the Japan Society for Oriental Medicine[8]. It would not be necessary to mention that those clinical trials should follow the CONSORT (CONsolidated Standards of Reporting Trials) statement, which was revised in 2010[9].

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Statement

The article titled "Anticancer Effects of HESA-A: An Herbal Marine Compound" was published in Chin J Integr Med 2010;16(4):366-367. The authors' affiliation address was changed during the period of proof reading and publication of manuscript, the affiliation should be corrected to "Tehran University of Medical Sciences" instead of "Medical Sciences/University of Tehran".

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REVIEW

A systematic review of nonrandomized controlled trials on the curative effects of aquatic exercise

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Background: The objectives of this review were to integrate the evidence of curative effects through aquatic exercise and assess the quality of studies based on a review of nonrandomized controlled trials (nRCTs).

Methods: Study design was a systematic review of nonrandomized controlled trials. Trials were eligible if they were nonrandomized clinical trials. Studies included one treatment group in which aquatic exercise was applied. We searched the following databases from 2000 up to July 20, 2009: MEDLINE via PubMed, CINAHL, and Ichushi-Web.

Results: Twenty-one trials met all inclusion criteria. Languages included were English (N = 9), Japanese (N = 11), and Korean (N = 1). Target diseases were knee and/or hip osteoarthritis, poliomyelitis, chronic kidney disease, discomforts of pregnancy, cardiovascular diseases, and rotator cuff tears. Many studies on nonspecific disease (healthy participants) were included. All studies reported significant effectiveness in at least one or more outcomes. However results of evaluations with the TREND and CLEAR-NPT checklists generally showed a remarkable lack of description in the studies. Furthermore, there was the problem of heterogeneity, and we were therefore not able to perform a meta-analysis.

Conclusion: Because there was insufficient evidence on aquatic exercise due to poor methodological and reporting quality and heterogeneity of nRCTs, we were unable to offer any conclusions about the effects of this intervention. However, we were able to identify problems with current nRCTs of aquatic exercise, and propose a strategy of strengthening study quality, stressing the importance of study feasibility as a future research agenda objective.

Keywords: aquatic exercise, systematic review, nonrandomized controlled trials

Introduction

Over the years, aquatic exercise has been known as pool therapy, hydrotherapy, and sometimes in earlier literature, as balneotherapy.[1] Exercise in warm water, usually termed hydrotherapy or aquatic therapy, is a popular treatment with a pain relief effect for many patients with painful neurologic or musculoskeletal conditions.[2] The warmth and buoyancy of water may block nociception by acting on thermal receptors and mechanoreceptors, thus influencing spinal segmental mechanisms.[3,4] In addition, the warmth may enhance blood flow, which is thought to help in dissipating algogenic chemicals, and it may facilitate muscle relaxation. The hydrostatic effect may also relieve pain by reducing peripheral edema[5] and by dampening sympathetic nervous system activity.[6]

Recent reports have demonstrated the effectiveness of comprehensive health education, including lifestyle education and exercise in combination with spa bathing,

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for male white-collar workers,[7] and middle-aged and elderly people.[8,9]

It is well known in research design that evidence grading is highest for a systematic review (SR) with meta-analysis of randomized controlled trials (RCTs). In "the recent review (summary)[10] of the SRs of RCTs", it was reported that there were three SRs[1,2,11] that included meta-analyses of RCTs on aquatic exercise. Bartels et al[1] reported that aquatic exercise had some beneficial short-term effects for patients with hip and/or knee osteoarthritis. Hall et al[2] reported that aquatic exercise had a small post-treatment effect in relieving pain compared with no treatment for patients with neurologic and musculoskeletal diseases, but there were no differences in pain relieving effects between aquatic and land exercise. Pittler et al[11] suggested that spa exercise may be effective for treating patients with chronic low back pain. However, we did not find any SRs of RCTs in which physical (eg, cardiovascular fitness) or psychological (eg, depression) effects were the primary outcome measurements.

An RCT is initially very difficult to execute and contains etiological issues, while the design of a non-RCT (nRCT) is easy to implement compared with an RCT. Although many studies have reported the curative effects of locomotrium diseases through aquatic exercise, there have been no systematic reviews of the evidence based on nRCTs. The objective of this study was to integrate the evidence from nRCTs on the curative effects through aquatic exercise for various diseases, and to assess the quality of those trials.

Methods

Criteria for considering studies included in this study

Studies were eligible if they were nRCTs and included one treatment group in which curative aquatic exercise was applied. Any type of aquatic exercise for cure and not for sports (eg, swimming) was permitted. The use of medication, alternative therapies, or lifestyle changes was described, and had to have been comparable in the group studies. There was no restriction on language.

Search methods for identification of studies

We searched the following databases from 2000 up to July 20, 2009: MEDLINE via PubMed, CINAHL, Web of Science, and Ichushi-Web (in Japanese). The International Committee of Medical Journal Editors (ICMJE) recommended uniform requirements for manuscripts submitted to biomedical journals in 1993. We selected articles published on and after 2000 because it appeared that the ICMJE recommendation had been adopted by the relevant researchers and had strengthened the quality of reports.

All searches were performed by two specific searchers (hospital librarians) who were qualified in medical information handling, and who were sophisticated in clinical trial research.

Search strategies

The search strategies contained the following elements and terms for all databases:

I: Search "aquatic exercise" or "water exercise"
II: Search "water gymnastic" or "water aerobics" or "pool exercise" or "pool therapy" or "aerobic aquatics" or aquatics
III: Search "exercise therapy"[MeSH] and "water"[MeSH]
IV: Search "water-based exercise"[All Fields] or "water-based training"[All Fields] or "aquatic therapy"[All Fields] or "aquatic physical therapy"[All Fields] or "water training"[All Fields] or "water-gymnastics"[All Fields]
V: Search I or II or III or IV Limits: Publication Date from January 1, 2000 to 2009
VI: Search I or II or III or IV Limits: Publication Date from January 1, 2000 to 2009, Randomized Controlled Trial
VII: Search V not VI.

Only keywords about intervention were used for the searches. First, titles and abstracts of identified published articles were reviewed to determine the relevance of the articles. Next, references in relevant studies and identified nRCTs were screened.

2000 is the year the CONSORT Statement became available on the Internet. The CONSORT Statement was created in the mid-1990s for improving the quality of RCTs. Because of the impact of the Internet, the quality of RCTs has improved since 2000.

Reference checking, hand-searching and others

We did not check the references of included studies, perform any hand-searching, or contact any institutions, societies, or specialists known to have expertise in aquatic exercise, or authors of included studies to identify any additional published or unpublished data.

Selection of trials

To make the final selection of studies for the review, all criteria were applied independently by two authors (JK and NS) to

the full text of articles that had passed the first eligibility screening (Figure 1). Disagreements and uncertainties were resolved by discussion between the review authors.

Studies were selected when 1) the design was an nRCT and 2) one of the interventions was a form of aquatic exercise. Curative effects were used as a primary outcome measure. Trials that were excluded are presented with reasons for exclusion (Appendix 1).

Quality assessment and summary of studies

To ensure that variation was not caused by systematic errors in the study design or execution, two review authors (MK and HK) independently assessed the quality of articles. A full quality appraisal of these papers was made using the TREND statement checklist[12] and CLEAR-NPT checklist,[13] developed to assess the methodological quality of nRCTs

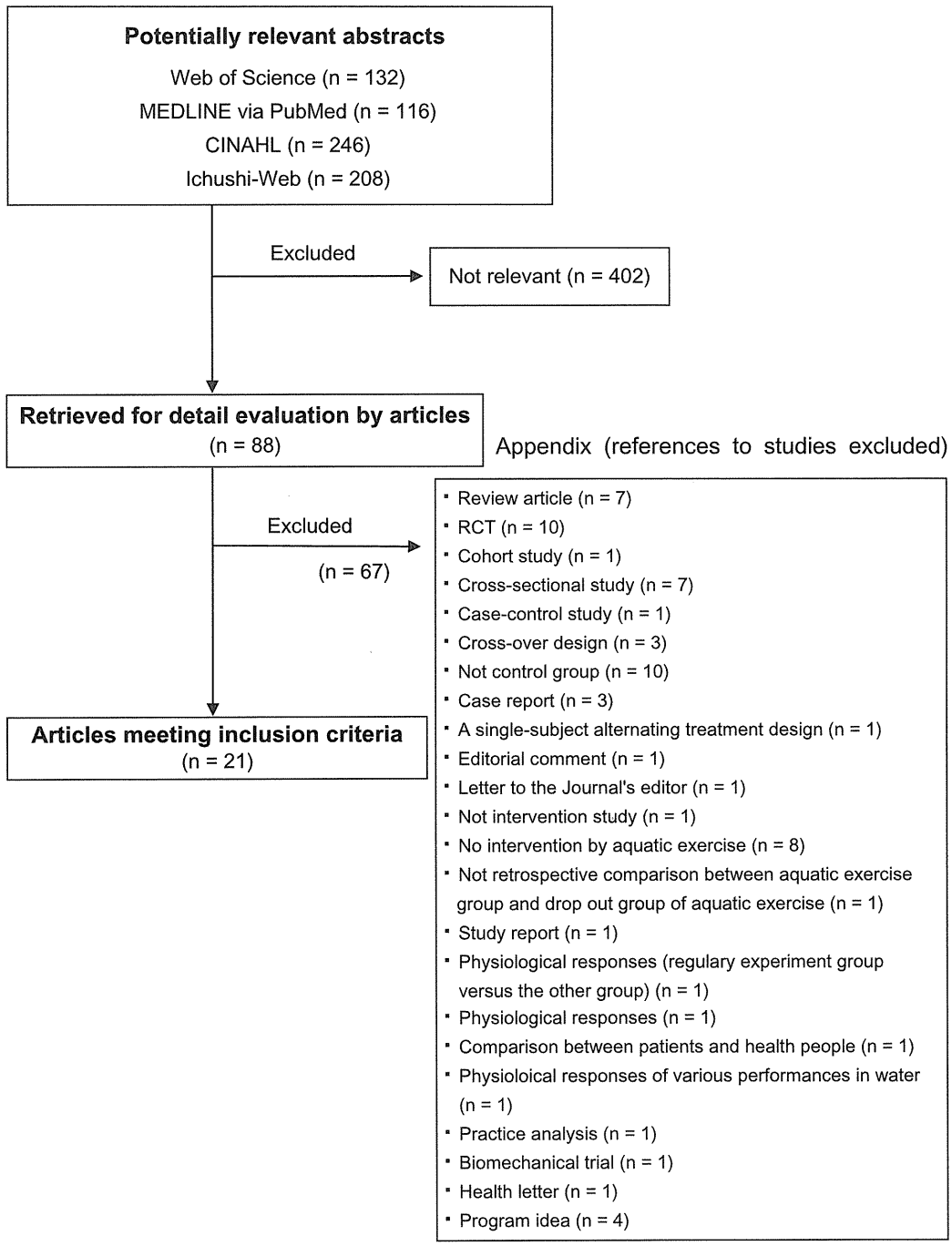

Figure 1 Flowchart of trial process.
Abbreviation: RCT, randomized controlled trial.

and nonpharmacological trials, respectively. Disagreements and uncertainties were resolved by discussion between the review authors.

For meta-analysis preparation, the target objects and main outcomes in each study were examined. We found that there were various kinds of target diseases in the studies reviewed: healthy young students, middle-aged or elderly people, or people with a certain disease. In addition, the studies were heterogeneous, and the main outcomes varied. Moreover, the quality of most studies was low according to the checklist results, and such low-quality studies were excluded from the analysis based on the Cochrane Review.[1] We could not perform a meta-analysis since no variable was eligible.

One review author (HK) selected the summary from each of the structured abstracts.

Benefit, harm, and withdrawals

The GRADE Working Group[14] reported that the balance between benefit and harm, quality of evidence, applicability, and the certainty of the baseline risk were all considered in judgments about the strength of recommendations. Adverse events, withdrawals, and the cost for intervention were especially important information for researchers and users of clinical practice guidelines, and we presented this information with the description of each article.

Results

Study characteristics

The literature searches included 402 potentially relevant articles (Figure 1). Abstracts from those articles were assessed and 88 papers were retrieved for further evaluation (checks for relevant literature). Sixty-seven publications were excluded because they did not meet the eligibility criteria (see Appendix 1). Twenty-one trials[15–35] met all inclusion criteria (Table 1). The languages of the eligible publications were English (N = 9), Japanese (N = 11), and Korean (N = 1). Target diseases were knee and/or hip osteoarthritis,[19,24,28] poliomyelitis,[15] chronic kidney disease,[21] discomforts of pregnancy,[30] cardiovascular diseases,[33] and rotator cuff tears.[35] Many studies[16–18,20–23,25–27,29,31,32,34] on nonspecific disease (healthy participants) were included (Table 2). All studies reported significant effectiveness in one or more outcomes. In particular, many studies reported that aquatic exercise had a significant effect on pain relief and outcome measurements for locomotor diseases.[15,19,24,28,35] These intervention periods ranged from 2 weeks to 12 months. These reflected the difficulty of maintaining long-term participation in each intervention trial. Whatever the case, the long-term effects are not clear.

Withdrawals and adverse events

Withdrawals (dropouts) were reported in five studies,[24,28,29,32,34] and adverse events were reported in four studies (Table 2). There were three studies[15,19,35] that reported 'nothing' on adverse events, and one study[28] reported a slipping accident on the poolside (details of the injury were unclear). Other studies did not provide information on withdrawals or adverse events.

Intervention costs

A description of intervention costs was included in only one trial,[30] but the summary of that trial did not describe the costs (Table 2).

Quality assessment

We evaluated 21 items from the TREND checklist in more detail (Table 3). This assessment evaluated the quality of how the main findings of the study were summarized in the written report. A lack of description was noteworthy for the studies in general. The items for which the description rate was less than 30% were as follows: "information on how units were allocated to interventions (23.8%)"; "how sample size was determined and, when applicable, explanation of any interim analyses and stopping rules (23.8%)"; "method used to assign units to study conditions, including details of any restriction (19.0%)"; "inclusion of aspects employed to help minimize potential bias induced due to non-randomization (4.8%)"; "whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed (14.3%)"; "if the unit of analysis differs from the unit of assignment, the analytical method used to account for this (9.5%)"; "statistical methods used for additional analyses, such as subgroup analyses and adjusted analysis (9.5%)"; "methods for imputing missing data, if used (14.3%)"; "flow of participants through each stage of the study: enrollment, assignment, allocation and intervention exposure, follow-up, analysis (19.0%)"; "dates defining the periods of recruitment and follow-up (14.3%)"; "baseline comparisons of those lost to follow-up and those retained, overall and by study condition (9.5%)"; "comparison between study population at baseline and target population of interest (4.8%)"; "indication of whether the analysis strategy was 'intention to treat' or, if not, description of how noncompliers were treated in the