



傳統中藥複方治療常見慢性疾病的系統評價

Systematic Review of Traditional Herbal Formulae
for the Treatment of Common Chronic Diseases

背景 Background



RESEARCH PROJECT REPORT (HOC172-06)

Principal Investigators

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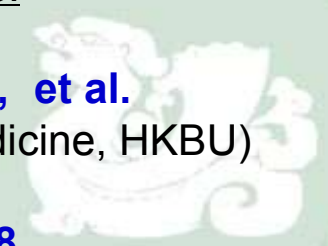
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2007-- 2008



背景 Background

慢性疾病是導致人類死亡的主要原因；可占總死亡人數的**60%**以上。

The main causes of human death were common chronic diseases, and the mortality caused by chronic diseases occupied over 60% of all mortality in Chinese.

中醫藥治療各種慢性疾病已有數千年的歷史，積累了豐富的臨床經驗。

Chinese medicines have been used to treat chronic diseases for thousands of years and there are plenty of practical experiences in clinics.

近年來中醫藥的臨床試驗研究，為評價中醫藥治療各種慢性疾病的實用價值提供了寶貴數據。

During last decades clinical trials have provided valuable evidence for evaluating efficacy and safety of Chinese medicines in the treatment of chronic diseases.

背景 Background

中藥複方是中醫臨床用藥的主要形式和特色，能充分體現中醫理論指導下臨床辯證論治的規律和經驗。

Herbal formula is the main style and feature of Chinese medicines in clinical application; and it might reflect essence of basic theory and clinical experience of traditional Chinese medicine.

傳統中藥複方歷經長期臨床應用，其組方與功效間的聯繫已被廣泛確認。

The relationship between ingredients and functions had been recognized widely as TF had been clinically applied for a long history.

許多經典複方已製成中成藥收載於現代藥典，其組成藥物、用量、劑型等固定，並已有規範的生產工藝和質量控制標準。

Traditional herbal formula (TF) --- their ingredients, dosages and forms were fixed basically; and some patent TF were recorded in the Chinese Pharmacopoeia, in which there were clear standards for their productions and quality controls.

研究目的 **Project objective**

對傳統中藥複方治療**10種**常見慢性疾病包括高血壓、冠心病、中風、慢性阻塞性肺病、肝癌、肝纖維化、糖尿病、類風濕關節炎、抑鬱症、濕疹等的有效性和安全性進行系統評價和薈萃分析。

We performed systematic reviews and meta-analyses on traditional herbal formulae (TF) in the treatment of ten chronic diseases including hypertension, coronary artery disease, stroke, chronic obstructive pulmonary disease, liver cancer, liver fibrosis, diabetes mellitus, rheumatoid arthritis, depression and eczema.



研究目的 **Project objective**

主要研究包括:

- (1) 調查治療常見慢性疾病的傳統中藥複方;
- (2) 統計在臨床試驗中最常用的中藥複方及組成中藥;
- (3) 分析和對比傳統中藥複方的有效性和安全性;
- (4) 評價臨床試驗的質量;
- (5) 綜合常見慢性疾病辨證分型的現代診斷標準及臨床調查結果等。

The project included:

- (1) investigating TF in the treatment of chronic diseases;
- (2) Identifying the most commonly used TF and their herbs in clinical trials;
- (3) evaluating the efficacy and safety of commonly used TF;
- (4) assessing the quality of design and data of clinical trials;
- (5) reviewing current diagnostic standards and survey results for types of syndrome-differentiation in the chronic diseases.

研究方法 Procedure & method

1. 研究設計 **Research strategy**
2. 資料收集 **Data search** (RCTs)
3. 資料整理 **Data extraction**
4. 品質評價 **Data quality assessment**
5. 資料分析 **Data analysis** (Meta-analysis, etc.)

循證医学

EBM

荟萃分析
Meta-analysis

目前最佳證據

Current best evidence



RCTs

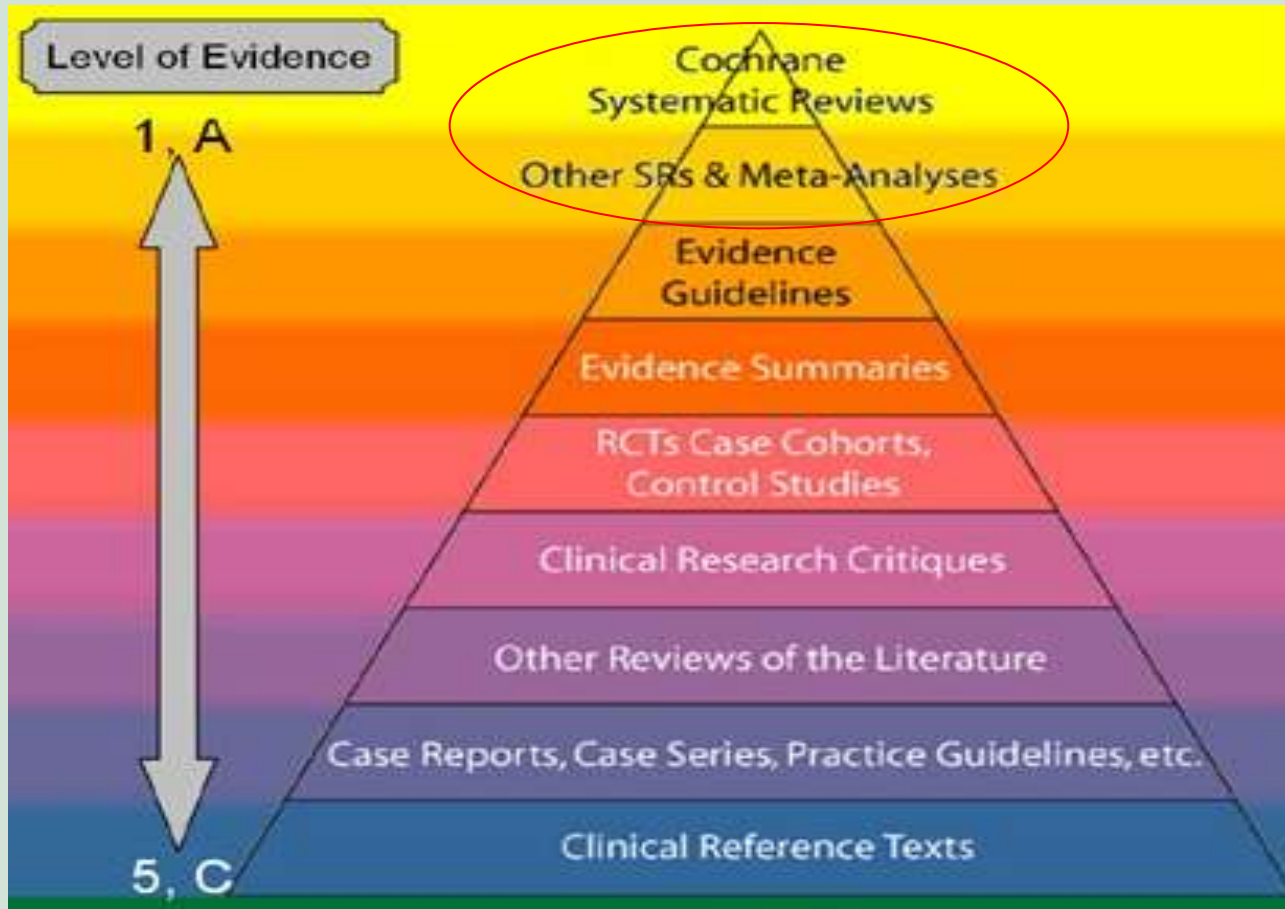
Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001)

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with <u>homogeneity</u>) of RCTs	SR (with <u>homogeneity</u>) of inception cohort studies; CDR ⁺ validated in different populations	SR (with homogeneity) of Level 1 diagnostic studies; CDR ⁺ with 1b studies from different clinical centres	SR (with homogeneity) of prospective cohort studies	SR (with homogeneity) of Level 1 economic studies
1b	Individual RCT (with narrow <u>Confidence Interval</u>)	Individual inception cohort study with ≥ 80% follow-up; CDR ⁺ validated in a single population	Validating ^{††} cohort study with good ^{†††} reference standards; or CDR ⁺ tested within one clinical centre	Prospective cohort study with good follow-up ^{****}	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	<u>All or none</u>	All or none case-series	Absolute SpPns and SnNouts ^{††}	All or none case-series	Absolute better-value or worse-value analyses ^{††††}
2a	SR (with <u>homogeneity</u>) of cohort studies	SR (with <u>homogeneity</u>) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity) of Level >2 diagnostic studies	SR (with homogeneity) of 2b and better studies	SR (with homogeneity) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR ⁺ or validated on split-samples ^{§§} only	Exploratory ^{††} cohort study with good ^{†††} reference standards; CDR ⁺ after derivation, or validated only on split-sample ^{§§§} or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" Research; Ecological studies	"Outcomes" Research		Ecological studies	Audit or outcomes research
3a	SR (with <u>homogeneity</u>) of case-control studies		SR (with homogeneity) of 3b and better studies	SR (with homogeneity) of 3b and better studies	SR (with homogeneity) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and <u>poor quality cohort and case-control studies</u>)	Case-series (and <u>poor quality prognostic cohort studies</u>)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1996.

Evidence levels (Oxford Centre of EBM)
med.fsu.edu/informatics/EBMTutorial.asp

Systematic review and meta-analysis



Evidence levels (Oxford Centre of EBM)
med.fsu.edu/informatics/EBMTutorial.asp

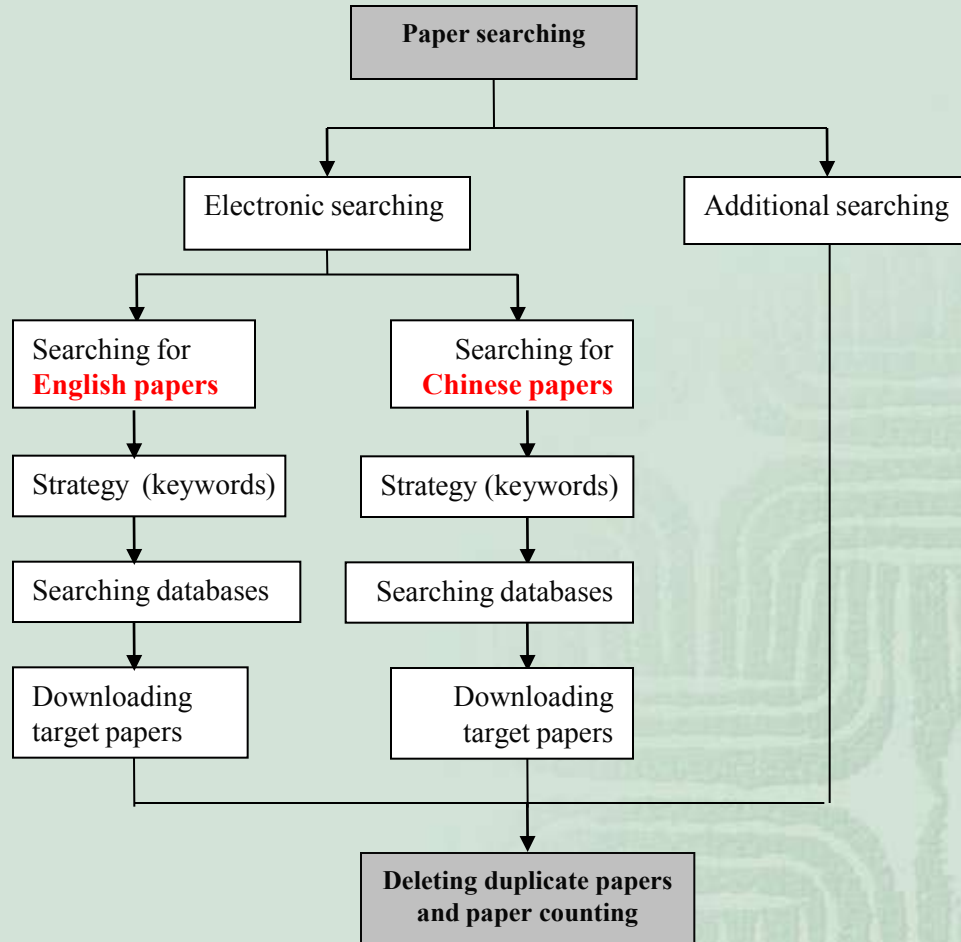
研究方法 Procedure & method

系統評價和薈萃分析 --- 包括設立文獻檢索策略，全面搜集相關的隨機對照臨床試驗(RCTs)；應用RevMan分析軟件對納入的RCTs進行綜合統計，對計數資料和計量資料分別以OR值和WMD值以及95%可信區間(95%CI)表達；並根據Jadad計分法評估納入RCTs的質量。

For systematic reviews, a comprehensive searching was performed to retrieve relative randomized controlled trials (RCTs); RevMan software was used to integrate and analyze the data in meta-analyses; Jadad's scale was used to assess the quality of included RCTs.



Paper search



Paper search

Assessment of searching quality (paper-loss rate, %)

	Retrieved RCTs			Included RCTs		
	I	II	III	I	II	III
Review 1 (Zhang M et al., 2007)	35	11	68.6%	14	7	50.0%
Review 2 (Wu TX et al., 2005)	13	7	46.2%	4	4	0.0%
Review 3 (Wei X et al., 2007)	94	52	44.7%	43	2	95.4%

Note: I = Selected RCTs by our system (according to criteria of published Cochrane meta-analyses, i.e. published year, diagnosis, intervention duration);

II = Selected RCTs by published Cochrane meta-analyses [Review1-3];

III = Paper-loss rate (%) = $(II - III) / II \times 100\%$.

Quality assessment

Jadad scale

(recommended by the Cochrane Collaboration)

1. Randomization and its description
2. Blinding and its description
3. Reporting dropout rate

Low-quality (1-2 marks)

High-quality (3-5 marks)



研究结果 Result

本研究搜集整理和系统分析了大量临床 RCTs

1. 提示傳統中藥複方已廣泛應用於防治多种慢性疾病的現代臨床試驗，並被證實是有效而安全的。

TF have been widely used in RCTs to treat chronic diseases, and has proven to be effective and safe in clinics.

2. 但現有高質量的臨床試驗尚少仍需開展更多大樣本及長期追蹤觀察等臨床研究加以驗證。

More high-quality RCTs with large sample size and long-term observations should be performed to further assess the TF.

研究结果 Result

TF analysis

高血压 Hypertension (37 TF):

天麻鉤藤飲 45_{RCTs} 六味地黃丸 26_{RCTs} 半夏白朮天麻湯 10_{RCTs}

冠心病 Coronary artery disease (74 TF):

血府逐瘀湯 79_{RCTs} 補陽還五湯 52_{RCTs} 生脈散 44_{RCTs}

中风 Stroke (41 TF):

補陽還五湯 72_{RCTs} 溫膽湯 10_{RCTs} 安宮牛黃丸 9_{RCTs}

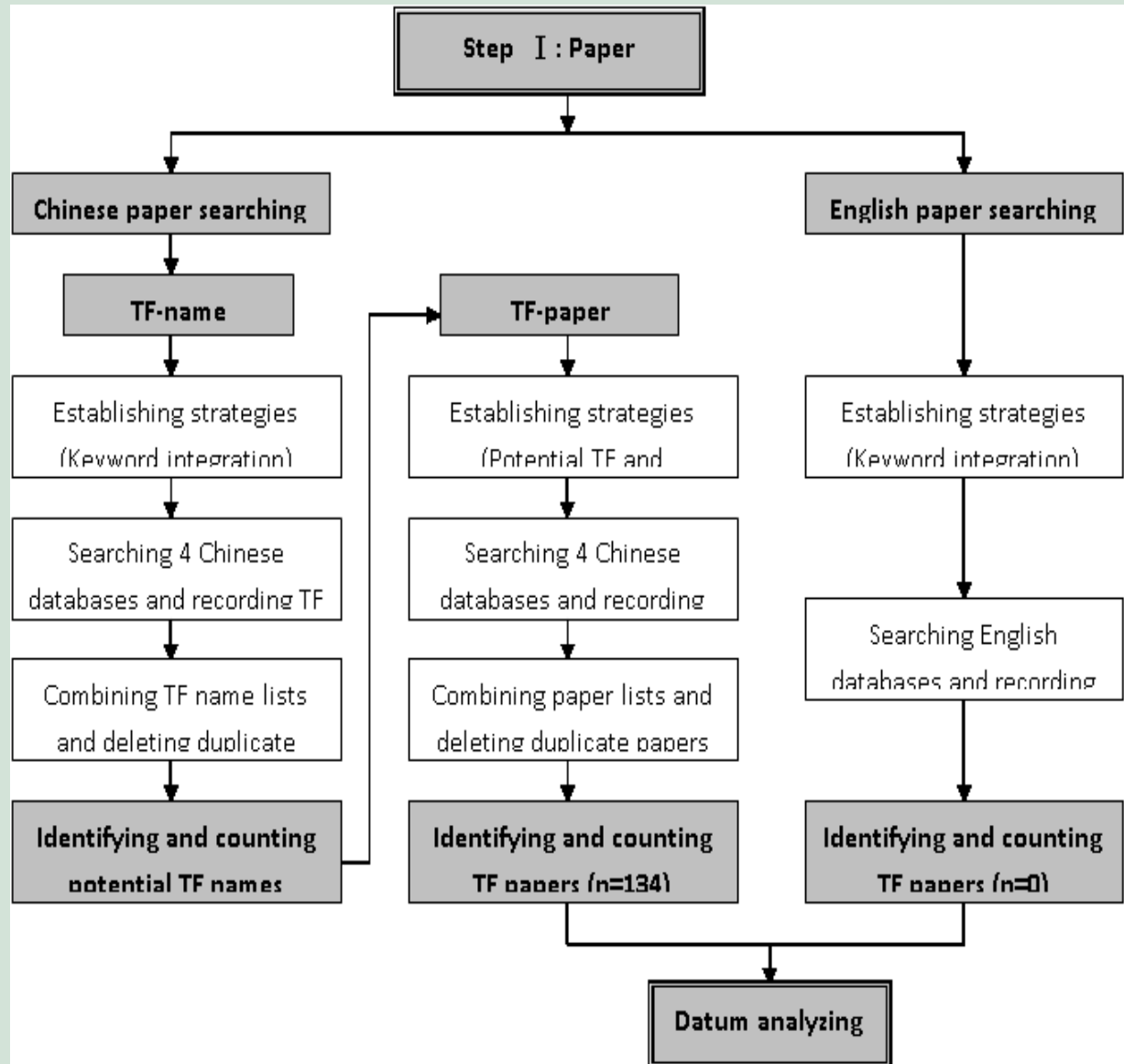
忧郁症 Depression (26 TF):

逍遙散 50_{RCTs} 柴胡疏肝散 28_{RCTs} 血府逐瘀湯 11_{RCTs}

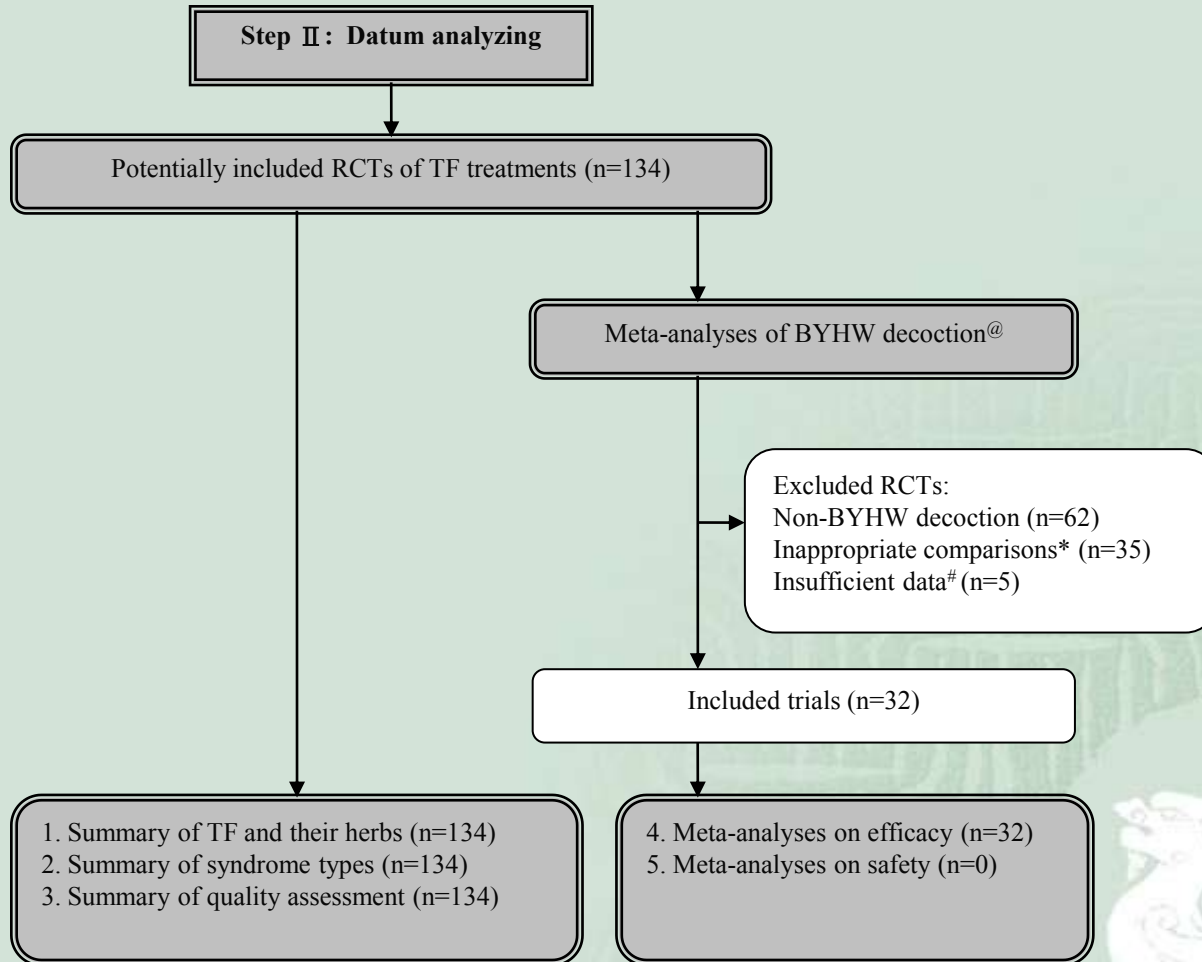
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中风 Stroke



中风 Stroke



中风 Stroke

Table 1 TF for stroke treatments

傳統藥方	藥方組成	出處	RCTs	Evidence levels	High	Low
補陽還五湯 (BYHW decoction)	黃芪,當歸,川芎,桃仁,赤芍,紅花,地龍	《醫林改錯》	72	I a+ I b	10	62
溫膽湯 (WD decoction)	半夏,枳實,陳皮,炙甘草,茯苓,竹茹	《三因極一病症方論》	10	I b	0	10
安宮牛黃丸 (AGNH pill)	牛黃,麝香,梔子,黃芩,黃連,冰片,郁金,水牛角,雄黃,朱砂,珍珠	《溫病條辨》	9	I b	2	7
大承氣湯 (DCQ decoction)	大黃,芒硝,枳實,厚樸	《傷寒論》	7	I b	1	6
癱瘓湯 (DT decoction)	南星,半夏,枳實,茯苓,橘紅,石菖蒲,人參,竹茹,甘草	《奇效良方》	6	I b	0	6
抵當湯 (DD decoction)	水蛭,虻虫,桃仁,大黃	《傷寒論》	6	I b	1	5
天麻鉤藤飲 (TMGT decoction)	天麻,鉤藤,石決明,川牛膝,梔子,黃芩,益母草,杜仲,桑寄生,夜交藤,茯神	《雜病証治新義》	6	I b	0	6
鎮肝熄風湯 (ZGXF decoction)	牛膝,龍骨,牡蠣,龜甲,白芍,代赭石,玄參,天冬,茵陳,藜蘆,川楝子,甘草	《醫學衷中參西錄》	5	I b	0	5
半夏白術天麻湯 (BXBSTM decoction)	半夏,白術,天麻	《古今醫鑿》	4	I b	1	3
導痰湯 (DT decoction)	半夏,南星,枳實,赤苓,橘紅,炙甘草,竹茹,姜汁	《海崖尊生》	3	I b	0	3
羚羊鉤藤湯 (LJGT decoction)	羚羊角,鉤藤,桑葉,菊花,鮮地黃,白芍,甘草,川貝母,竹茹,茯神	《通俗傷寒論》	3	I b	1	2
六味地黃湯 (LWDH decoction)	熟地黃,山藥,山茱萸,澤瀉,丹皮,茯苓	《小兒藥証直訣》	3	I b	1	2
龍膽瀉肝湯 (LDXG decoction)	龍膽,黃芩,梔子,木通,澤瀉,車前子,生地黃,當歸,柴胡,甘草	《醫方集解》	3	I b	0	3
四物湯 (SW decoction)	熟地黃,當歸,白芍,川芎	《仙授理傷續斷秘方》	3	I b	1	2
大黃蘗蟲丸 (DHZC pill)	熟大黃,土蠶虫,水蛭,虻虫,蛭蟻,干漆,桃仁,苦杏仁,黃芩,地黃,白芍,甘草	《金匱要略》	2	I b	0	2
大活絡丹 (DHL pill)	白花蛇,烏梢蛇,威靈仙,两头尖,草烏,天麻,全蝎,首烏,龜板,麻黃,貫仲,炙甘草,羌活,官桂,藿香,烏药,黃連,熟地,大黃,木香,沉香,細辛,赤芍,沒药,丁香,乳香,僵蚕,天南星,骨皮,骨碎补,白蔻,安息香,黑附子,黃芩,茯苓,香附,玄參,白朮,防风,葛根,虎骨,當歸,地龍,犀角,麝香,松脂,牛黃,片腦,人參	《蘭台軌范》	2	I b	1	1
黃連解毒湯 (HLJD decoction)	黃連,黃柏,黃芩,梔子	《肘后方》	2	I b	0	2
桃核承氣湯 (THCQ decoction)	大黃,芒硝,桃仁,桂枝,甘草	《傷寒論》	2	I b	0	2
通竅活血湯 (TQHX decoction)	赤芍,川芎,桃仁,紅花,老葱,鮮姜,紅枣,麝香	《醫林改錯》	2	I b	1	1
小承氣湯 (XCQ decoction)	大黃,厚樸,枳實	《傷寒論》	2	I b	0	2
小續命湯 (XXM decoction)	麻黃,桂心,甘草,防風,芍药,白朮,人參,川芎,附子,附己	《普濟方》	2	I b	0	2
血府逐瘀湯 (XFZY decoction)	桃仁,紅花,當歸,川芎,赤芍,柴胡,生地黃,枳殼,桔梗,牛膝,甘草	《醫林改錯》	2	I b	0	2
增液承氣湯 (ZYCQ decoction)	大黃,芒硝,元參,麥冬,細生地	《溫病條辨》	2	I b	0	2
白虎承氣湯 (BHCQ decoction)	生石膏,生錦紋,生甘草,白知母,元明粉,陳倉米	《重訂通俗傷寒論》	1	I b	1	0
參附湯 (CF decoction)	人參,附子	《醫方類聚》	1	I b	0	1
大秦朮湯 (DQJ decoction)	秦朮,獨活,羌活,防風,細辛,白芷,石膏,生地黃,黃芩,川芎,甘草,當歸,白芍,熟地黃,茯苓,白朮	《素問病機氣宜保命集》	1		0	1
當歸四逆湯 (DGSN decoction)	桂枝,當歸,細辛,白芍,通草,大棗,甘草	《傷寒論》	1	I b	1	0
地黃飲子 (DH decoction)	熟干地黃,巴戟天,山茱萸,石斛,肉苁蓉,茯苓,五味子,桂枝,白茯苓,麥門冬,菖蒲,遠志	《宣明論方》	1	I b	0	1
定風湯 (DF decoction)	牙皂角,白石膏,朴消,滑芥,葱白	《醫方考》	1	I b	0	1
複元活血湯 (FYHX decoction)	柴胡,瓜蒌根,當歸,紅花,甘草,川山甲,大黃,桃仁	《醫學發明》	1	I b	0	1
核桃承氣湯 (HTCQ decoction)	核桃,大黃,桂枝,甘草,芒硝	《傷寒論》	1	I b	0	1
黃芪桂枝五物湯 (HQGZWW decoction)	黃芪,芍藥,桂枝,生姜,大棗	《金匱要略》	1	I b	0	1
涼膈散 (LG powder)	大黃,朴硝,甘草,山梔子仁,薄荷,黃芩,連翹	《太平惠民和劑局方》	1	I b	1	0
羚羊角湯 (LYJ decoction)	羚羊角,菊花,龜板,石決明,生地黃,白芍,柴胡,薄荷,蟬蛻,夏枯草,牡丹皮,大棗	《醫醇駁義》	1		0	1
桂枝茯苓丸 (GZFL pill)	桂枝,茯苓,牡丹,桃仁,芍药	《金匱要略》	1	I b	0	1
牛黃承氣湯 (NHCC decoction)	大黃,牛黃,郁金,犀角,黃連,朱砂,梅片,麝香,真珠,山梔,雄黃,金箔衣,黃芩	《溫病條辨》	1	I b	0	1
生脈散 (SM powder)	人參,麥冬,五味子	《醫學啓源》	1	I b	0	1
四妙勇安湯 (SMYA decoction)	金銀花,玄參,當歸,甘草	《驗方新編》	1	I b	0	1
四逆湯 (SN decoction)	附子,干姜,甘草	《傷寒論》	1	I b	0	1
桃紅四物湯 (THSW decoction)	熟地黃,當歸,白芍,川芎,桃仁,紅花	《醫宗金鑑》	1	I b	0	1
犀角地黃湯 (XJDH decoction)	犀角,生地黃,芍药,牡丹皮	《外台秘要》	1	I b	0	1



中风 Stroke

Table 2 Top 10 frequently used herbs in TF for stroke treatments

中藥	出現率 (%)
<i>Semen Persicae</i> (桃仁)	51.70%
<i>Radix Angelicae Sinensis</i> (當歸)	50.57%
<i>Rhizoma Chuanxiong</i> (川芎)	48.30%
<i>Radix Paeoniae Rubra</i> (赤芍)	45.45%
<i>Flos Carthami</i> (紅花)	45.45%
<i>Pheretima</i> (地龍)	43.18%
<i>Radix Astragali</i> (黃芪)	42.61%
<i>Radix Glycythizae</i> (甘草)	18.18%
<i>Fructus Aurantii Immaturus</i> (枳實)	15.91%
<i>Radix Scutellariae</i> (黃芩)	15.34%

Table 4 Syndrome types in 108 patients with stroke

證名	頻數 (n)	出現率 (%)
風證	60	55.56%
痰證	59	54.63%
火熱證	52	48.15%
血瘀證	51	47.22%
氣虛證	30	27.78%
陰虛陽亢	18	16.67%



中风 Stroke

Table 5 The quality assessment of included RCTs

	n	Low (%) (1~2 scores)	High (%) (3~5 scores)
Total	134	113 (84.3%)	21 (15.7%)
BYHW decoctic	72	62 (86.1%)	10 (13.9%)

Table 7 Comparisons and outcomes of included RCTs (meta-analysis)

Comparisons	RCTs	Efficacy outcomes		
		NIP	NII	CIF
TF vs. WM	11	10	1	1
TF plus WM vs. WM	22	21	4	2

Table 8 Summary of meta-analyses for BYHW decoction

Comparisons	RCTs	Efficacy outcomes		
		NIP	NII	CIF
TF vs. WM	11	>*	>*	>*
TF plus WM vs. WM	22	>*	>*	>



中风 Stroke

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<i>Radix Angelicae Sinensis</i> (當歸)	50.57%
<i>Rhizoma Chuanxiong</i> (川芎)	48.30%
<i>Radix Paeoniae Rubra</i> (赤芍)	45.45%
<i>Flos Carthami</i> (紅花)	45.45%
<i>Pheretima</i> (地龍)	43.18%
<i>Radix Astragali</i> (黃芪)	42.61%
<i>Radix Glycythizae</i> (甘草)	18.18%
<i>Fructus Aurantii Immaturus</i> (枳實)	15.91%
<i>Radix Scutellariae</i> (黃芩)	15.34%

Table 4 Syndrome types in 108 patients with stroke* [135]

證名	頻數 (n)	出現率 (%)
風證	60	55.56%
痰證	59	54.63%
火熱證	52	48.15%
血瘀證	51	47.22%
氣虛證	30	27.78%
陰虛陽亢	18	16.67%



THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 15, Number 12, 2009, pp. 1347-1353
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DOI: 10.1089/acm.2009.0202

Adjuvant Phytotherapy in the Treatment of Cervical Cancer: A Systematic Review and Meta-Analysis

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Abstract

Objective: Clinical trials have investigated phytotherapy (PT) in the treatment of cervical cancer. This study aimed to assess the quality and data of current available trials, to compare the efficacy and safety of conventional therapies (CT) including surgical therapy, radiotherapy, and chemotherapy with that of CT plus PT (CT-PT), and to identify herbs used commonly in clinical trials.

Methods: Forty-three (43) electronic databases were searched. The quality of eligible trials was assessed by Jadad's scale, and Revman 5.0 software was used for data syntheses and analyses.

Result: (1) Of the 48 potential trials retrieved, 18 trials involving 1657 patients met the inclusion criteria, and two trials were graded as high-quality trials; (2) CT-PT achieved a higher 1-year survival rate (SR, $p=0.0002$) and tumor remission rate (TRR, $p<0.0001$) than CT alone; (3) PT showed therapeutic effects comparable to those of Western medications in diminishing vesical complications (VC, $p<0.0001$) and rectal complications (RC, $p=0.08$) caused by CT; (4) top 15 herbs used frequently to improve SR or TRR and to treat VC or RC in the retrieved trials were identified.

Conclusions: Adjuvant PT may improve the efficacy and safety of CT in clinical treatments of cervical cancer, although this result needs to be further verified by more high-quality trials.

Introduction

CERVICAL CANCER IS the most common malignant tumor threatening women, especially those over 40 years old.¹ Worldwide deaths due to cervical cancer were estimated at 0.25 million per year and expected to rise by 25% over the following decade.² Current conventional therapies (CT) including surgical therapy, radiotherapy, chemotherapy, hormone therapy, and others may be helpful to treat patients at the early stage of cancer, but so far it is still very difficult to cure advanced-stage patients, especially those with cancer relapse or metastasis. Moreover, CT may result in significant adverse effects; for example, about 16% patients who are treated with radiotherapy may develop rectal complications.³ Searching for more effective and safer therapies to treat cervical cancer as well as other cancers is one of the important targets in oncologic studies.

Phytotherapy (PT) has been used to treat malignant tumors in women for thousands of years in China and some other countries. During the past decades, a number of clinical trials have been conducted to investigate the value of natural

herbs in the treatment of cervical cancer. In the present study, we performed a systematic review and meta-analysis to (1) assess the quality and data of retrieved trials; (2) compare the therapeutic effects and adverse effects of CT plus PT (CT-PT) to those of CT alone in clinical treatments; (3) compare the effects of PT to those of Western medications (WM) such as anti-infective drugs, vitamins, and other drugs in the treatment of vesical and rectal complications caused by CT; and (4) identify herbs used commonly in clinical trials. We hypothesized that the adjuvant PT might play a valuable role in the treatment of cervical cancer by increasing efficacy and safety of CT; and certain natural herbs and their effective components could become new reagents in future preclinical and clinical studies to overcome cervical cancer.

Methods

Inclusion and exclusion criteria

All randomized controlled trials (RCTs) and controlled clinical trials (CCTs)⁴ that compared the effects and/or adverse events of CT-PT with those of CT alone were included.

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目前研究 **Further research**

中药复方作用机理 -- 中药相互作用机理

The current best evidence from this study should also be valuable to analyze complex mechanisms and herb-herb interactions of formula therapies in traditional Chinese medicine.



致谢 Acknowledgement

**We would sincerely give our thanks to the sponsorship
from the Hospital Authority of Hong Kong**

**Zhong-Zhen ZHAO, Liang LIU, Chen QI, Bin DENG, Xiao-Ying TIAN
Ping-Xiang DENG, Dong-Ying XU, Ching-Mei CHOI, Hiu-Lai KONG
Ling-Ling CHONG, Wing-Chi LO, Sheung-Fung YU, Lok-Fu LUK
Chi-Man NG, Tak-Wai CHAN, Shek-Fai CHUNG
Chun-Tung WONG, Kit-Ying HO**

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Thanks!

