

行政院衛生署 93-94 年度科技研究發展計畫

中醫藥療效評估之文獻研究

A Literary Review of Curative Effects of Traditional Chinese Medicine

研究報告

計畫委託機關：中國醫藥大學

計畫主持人：林昭庚

研究人員：

- 止痛：劉旭然、梁智凱
- 免疫：江素瑛、謝長奇、侯庭鏞、趙德澂、林振蔚
- 神經：謝慶良、程錦宜
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- 新陳代謝：張世良、林榮宗、古欣平、蔡靜菽
- 總結：林昭庚、傅彬貴

執行期間：93 年 1 月 1 日至 94 年 12 月 31 日

** 本研究報告僅供參考，不代表本署意見 **

各機關研究計畫基本資料庫之計畫編號：

行政院衛生署 93-94 年度科技研究發展計畫

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行政院衛生署中醫藥委員會 93-94 年度
研究計畫成果報告

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執行機構：中國醫藥大學

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目 錄

壹、中文摘要	(2)
貳、英文摘要	(3)
參、前言	(4)
肆、材料與方法	(6)
伍、結果	(9)
陸、討論	(12)
柒、結論與建議	(14)
捌、參考文獻	(15)
玖、表一 針灸實證醫學目錄	(17)
壹拾、附件一 針灸實證醫學之現況與展望	(18)
壹拾壹、附件二 Critical Appraisal Method of Acupuncture Safety	(28)

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計畫主持人 林昭庚
執行單位 中國醫藥大學

摘要

中國醫學傳承至今已經有幾千年的歷史。最近十幾年來，世界各國對於傳統醫學日趨重視。世界衛生組織於 2002 年 5 月發表「2002-2005 世界衛生組傳統醫學策略」，「WHO TRADITIONAL MEDICINE STRATEGY 2002-2005」，WHO 建請各國將傳統醫學納入現有醫療政策體系中，並將透過提供技術指南來確保傳統醫學療法被適當、安全且有效地使用。然而現今中醫政策或醫療體系之推行，實證數據之有效與否便成為第一道門檻。由於世界各國對於傳統醫藥日趨重視，中醫藥療效評估之文獻也越來越多，過去各類中醫藥療效評估的報告分別發表在國際上的各類期刊中，但未能有效的整合。

本研究的目的是：將這些國際文獻作一有系統的回顧研究與資料整理，除了可與世界衛生組織所發表之傳統醫學策略相呼應，讓中醫藥重要療效評估與相關文獻中文化，加強中醫藥相關研究人員的國際觀，並有利於中醫政策之推展。研究的方法將以美國國家醫學圖書館 (National Library of Medicine, NLM) 提供每週更新的 PubMed (Medline + PreMedline) 資料庫所列的期刊為主，依照不同的生理系統之疾病分類來評讀整理針灸的療效評估。

本研究已於第一年初步依計劃完成了針灸之研究文獻匯整及分類總結，第二年並根據告專家建議，應對文獻之研究方法與質量進行深入研究，規劃文獻研析表，對於已收集完成的針灸文獻進行評讀，建立適合中醫藥文獻之評讀模式 (Appraising Model)。此一成果發現針灸療效積分較高者集中在骨骼肌肉系統疾病，如 OA、Low Back Pain 等，亦有部份非骨骼肌肉系統疾病有較佳的研究表現，如：Asthma、Vomiting 等，而對於針刺的安全性與經濟效益亦有較高積分，且獲較佳影響係數雜誌的支持，在所有主題排名前十名。

完成此一研究建立適合中醫藥文獻之評讀模式，除針灸之領域外，尚可運用此一模式，進行內科疾病的文獻療效評讀的工作，從藥物的療效角度而言，亦可進行療效證據之比較，作為選擇進一步研究開發之參考。

關鍵詞：中醫藥、針灸、實證醫學、文獻評讀

英文研究計畫題目**A Literary Review of Curative Effects of
Traditional Chinese Medicine**

計畫主持人英文名

Jaung-Geng Lin

執行單位英文名稱

China Medical University**ABSTRACT**

Objective: Traditional Chinese Medicine (TCM) has several thousand years' history of practice. For the past decade, the value of TCM has been increasing recognized in the world. According to a new World Health Organization (WHO) strategy 「WHO TRADITIONAL MEDICINE STRATEGY 2002-2005」 lunched on 16 May in 2002, it promoted that countries must integrate TCM into their national existing health care systems. WHO also asked government to evaluate the curative effects of TCM and by developing policies to regulate “alternative “ medical practices to make it safer to their people. Efficacy of TCM is the crucial basis and promise of its development. Many clinical trials have been conducted all over the world to evaluate the effectiveness of TCM; However, much of the information is incomprehensible to Traditional Chinese doctors. Acupuncture/moxibution will be discussed according to diseases in different physical systems.

Material and Method: A systematic literature review of Evidence-Based curative effects of TCM will be undertaken from the database of PubMed (Medline+PreMedline). This literature review not only responds to WHO TRADITIONAL MEDICINE STRATEGY, but also makes the importance international literatures comprehensible to Chinese doctor and promotes execution of Traditional Medical policy.

Result and Discussion: This project had established an new appraising model. The primary result was conducted that the more curative effect of acupuncture was on the diseases of skeletal muscle system e.g. OA, Low back pain, and the more performance of the diseases in non-skeletal muscle system was also conducted like asthma and vomit that was ranked in top ten of this study. The safety and cost effect of acupuncture was supported by international publications with higher performance in this appraising model.

Key Words : Traditonal Chinese Medicine 、 Acupuncture 、 Curative Evaluation 、 Evidence Basied Medicine

壹、前言

中國醫學傳承至今已經有幾千年的歷史。在西醫發展以前，中醫基礎理論和針灸、中藥幾乎是我們抵抗疾病、延年益壽、改善生活品質的唯一途徑。近百年來，隨著西方醫學之蓬勃發展與政府政策之相互影響，西醫成為醫學的主流，中醫藥被歸類在「傳統」醫藥或「輔助(替代)」醫藥的範疇。然而自古代隨著中華文化之傳播，中國醫學早已流傳於朝鮮、越南、日本等國；現代由於知識交流之普及更加速中國醫學之傳播。另一方面，西方醫學對某些疾病的控制仍然未臻完善，世界各國傳統醫學對這些疾病的治療經驗於是成為西醫遇到瓶頸時的重要參考依據。因此，最近十幾年來，世界各國對於傳統醫藥及替代醫藥日趨重視。世界衛生組織於 2002 年 5 月發表「2002-2005 年傳統醫學全球策略」，建請各國將傳統醫學納入現有醫療政策。美國國家衛生研究院(NIH)也特別撥款，並成立輔助與替代療法的專責機構²⁰。

中國醫學是累積先人智慧的一門「經驗醫學」，一開始就是以人為治療對象，並累積豐富的典籍供後代醫家參考。然而現今中醫政策或醫療體系之推行，實證數據之有效與否便成為第一道門檻，幾千年來中國醫學被我們認為有效並沿用至今的治療經驗必須經由現代醫學的科學化檢驗才能獲得認同。當初國家健康保險政策把傳統醫藥納入給付範圍的第一個最根本的問題就是：究竟中醫藥有無療效？因此，進行中醫藥療效評估是回答這個問題的唯一途徑。由於世界各國對於傳統醫藥日趨重視，中醫藥療效評估之文獻也越來越多²¹。自從 Pomeranz 在 1976 年發表針刺止痛機轉的論文之後¹，吸引國際研究者陸續進行針刺止痛的相關研究²⁻⁶，甚至應用在臨床手術後疼痛之緩解^{7,8}。針灸除了止痛作用之外，其他領域之

針灸研究也有很多，例如消化道疾病模式⁹、糖尿病的動物模式^{10, 11}或是增加運動生理¹²⁻¹⁴...等。中藥對於腦部缺血¹⁵、免疫反應^{16, 17}或是肝臟損傷之動物模式^{18, 19}也有療效。

本研究我們已依計劃完成針灸相關文獻的收集整理，初步集合成為針灸實證醫學專著，分成止痛、免疫、神經、呼吸循環、腸胃、泌尿、肌肉骨骼、婦兒、新陳代謝、總結十個類別，形成了二十七個有關針灸療效的問題與總結。根據學者專家的意見，認為應注意文獻之方法學及品質作評析；對於實際療效之文獻收集與分析，仍待加強。因此，延續計劃將根據此意見，修正研究之方向，由原本的廣泛收集，而改為精深之文獻評讀，建立可行之中醫藥文獻之評讀模式，期能使此一針灸實證醫學之新領域更加紮實。

貳、材料與方法

● 材料

本研究的主要資料搜尋來自每週更新的美國國家醫學圖書館 NCBI 透過全球資訊網提供使用者免費檢索的 PubMed 資料庫，內容包括 MEDLINE、PREMEDLINE。以 acupuncture, moxibustion、與相關疾病如：Hypertension、Diabetes、Asthma 等關鍵字進行搜尋。

● 研究方法與步驟

1. 資料分類	資料分類主要分成下列十組： 一止痛、二免疫、三神經、四呼吸循環、五腸胃、六泌尿、七肌肉骨骼、八婦兒、九新陳代謝、十總結。分組分類負責收集。
2. 資料蒐集	將相關之中英文摘要節錄、由各小組成員蒐集進行評讀。
3. 文獻研讀與整理	依EBM五個步驟進行研讀與整理 1. 問一個可以回答的問題 (formulating answerable clinical questions) 2. 尋找最佳的文獻證據 (searching for the best evidence) 3. 對文獻進行嚴格評讀 (critical appraisal) 4. 應用在個案患者身上 (applying evidence to patients) 5. 對以上四點進行稽核 (audit)
4. 資料分析歸納和比較	各組研讀資料，並以表格方式將其題目、研究目的與方法、結論簡單列出，分析歸納和比較，最後作總結，將資料作文獻回顧。

● 文獻評讀方式

建立文獻評讀表格內容包括:1.文獻基本資料、2.文獻簡要內容、3.評讀指標。依設計之表格，分組填寫，藉由評讀指標統計證據之強度。其評讀指標如下列文獻評讀表所示:

針灸證據醫學參考文獻評讀表

一、基本資料 (Basic Informations)	
A.編號(No)	由匯整者填寫，評讀者免填。
B.臨床問題 (Clinical problem)	依指定之題目填寫。
C.文獻來源(Source)	依 pubmed (http://www.pubmed.com/)所載，出版之雜誌名填入。
D.出版日期(Date)	西元年/月，例如: 2004/01。
E.卷(期):頁(Page)	Ex: 21(5):100-105。
F.作者(Authors)	依 pubmed 格式填寫。
G.出版型態 (Publication type)	依 pubmed 指定之 Publication type (Ex: clinical trial, editorial, letter, meta-analysis, practice guideline, RCT, review)
H.語言(Language)	Ex: English, Chinese....
二、文獻簡要內容 (Brief Contents of Reference)	
I.題目(Title)	依 pubmed 所載填寫
J.目的(Purpose)	■ 內容盡量精簡，條列方式。
K.材料與方法 (Material & Methods)	■ 以針灸實證醫學所載及 Pubmed 之摘要為主。 ■ 針灸實證醫學所載如有錯誤處請以紅字修改。
L.結論(Conclusions)	■ 材料請標明(人、動物、...) ■ 註明針灸之穴位、及治療方法。
三、評讀指標 (Appraisal Index)	
*M.影響係數 IF(Impact Factor)	搜尋方法如下 http://www2.cmu.edu.tw/~cmcrdc/doc/SCIsearch.doc 以圖書館收錄最新一期為準。
*N.問題支持度 SOQ(Supposition Of Question,-3-0-3)	■ 讀完整篇後，評讀者認為此文章此一臨床問題之支持度。 ■ (-3:非常否定/-2:否定/-1:不確定偏否定/0:與問題無關/1:不確定偏肯定/2:肯定/3:非常肯定)。
*O.證據積分 SOE(Score Of Evidence, 5-1)	RCT(5) > RCT/Cohort(4) > Case control(3) > Case series(2) > Experiences/ Case report(1)
P.評註(Comments)	■ 讀完整篇後，評讀者對本文的意見。
Q.評讀者(Reviewers)	中文名
S. 評讀日期(Appraisal Date)	西元年/月/日 Ex 2004/11/9

● 系統分組

依生理系統分為十組，完成了二十七個子題，進行文獻回顧，進行針灸療效之匯整與總結，形成探討針灸實證醫學專書，其主題如表一所列。

● 小組成員

- 一、 止痛：劉旭然、梁智凱
- 二、 免疫：江素瑛、謝長奇、侯庭庸、趙德澂、林振蔚
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- 十、 總結：林昭庚、傅彬貴

● 編寫方法

分為壹、臨床問題，貳、結果摘要(含參考文獻)，參、搜尋步驟，肆、文獻摘要(表格)-除題目外需翻成中文，伍、小組成員等五段落。依標準範例格式排版編寫。

● 證據強度計分方法

$$\text{Strength Of EBM (Score)} = \text{IF} * \text{SOQ} * \text{SOE}$$

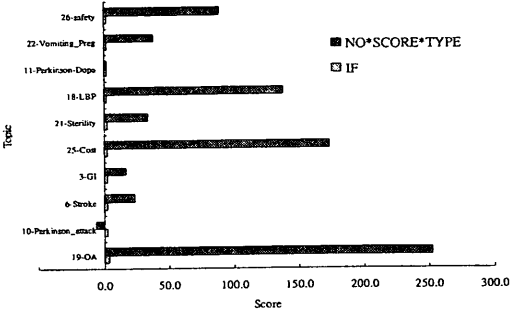
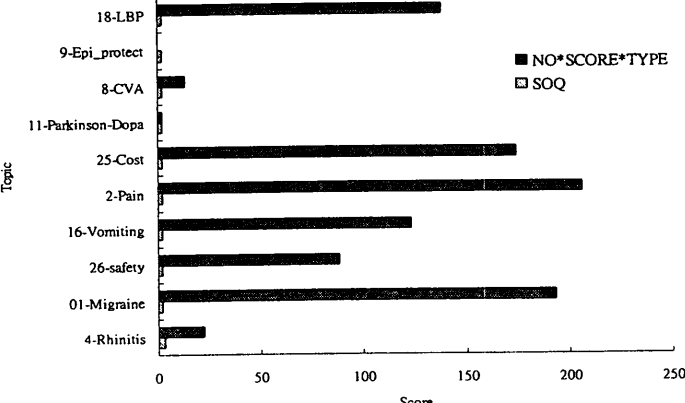
- IF: impact factor
- SOQ: Supposition Of Question
- SOE: Score Of Evidence
- Type: 1(clinical) 0.5(animal)
- Paper NO.*Type*Strength of EBM (score)

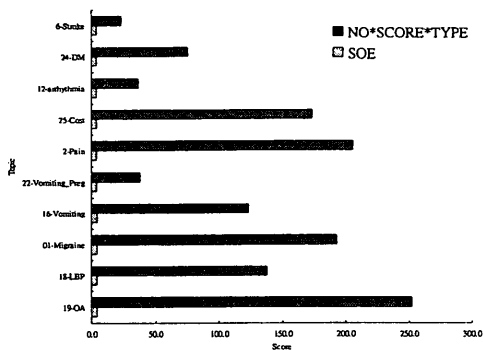
結果

為執行本計劃，已邀請國內各專題學有專精之專家學者參與，迄今共召開針灸實證醫學之研究與編輯會共六次，從系統分組，題目定訂，編寫方法等交換意見，最後定訂標準範例以為編寫之依據，進一步訂定文獻評讀指標，將文獻的療效程度量化，進行綜合比較。

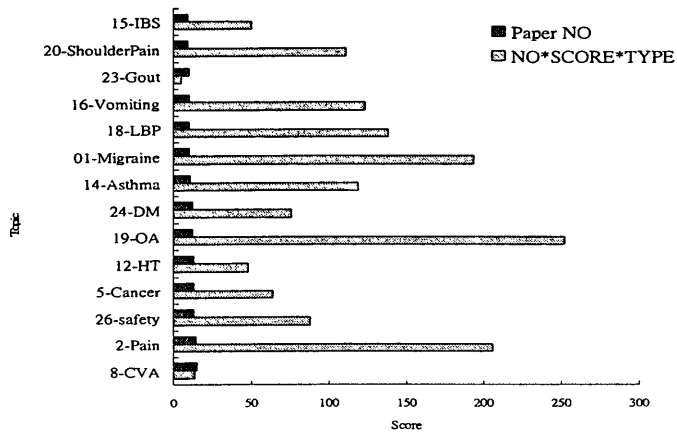
- 論文發表：完成針灸實證醫學之現況與展望如附件一，並投稿中華針灸醫學雜誌。及完成 Critical Appraisal Method of Acupuncture Safety 論文投稿國外期刊如附件二。並舉辦及發表針灸實證醫學研討會共四場次。

● 評讀結果

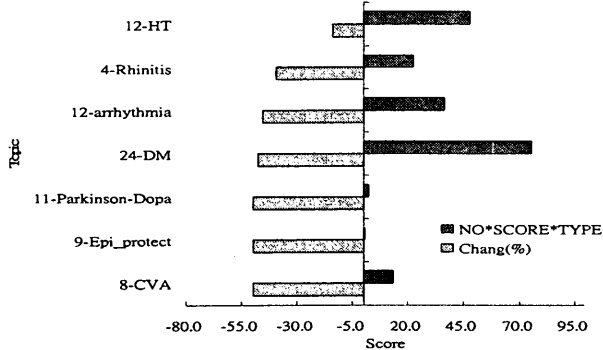
圖表	結果說明
	<ul style="list-style-type: none"> ● 較好 Impact Factor (IF)的學術期刊所支持的主題，大體上有較佳之績分表現。 ● 有較佳績分者為: OA、Cost、LBP、Safety
	<ul style="list-style-type: none"> ● Migraine、<u>Safety</u>、<u>Vomiting</u>、<u>Pain</u>、<u>Cost</u>等主題，在 SOQ 有較佳表現。 ● 對問題支持度較佳者，未必有較佳的積分。如 Rhinitis。



- Levels of Evidence 越高的主題，其績分有較高的表現。

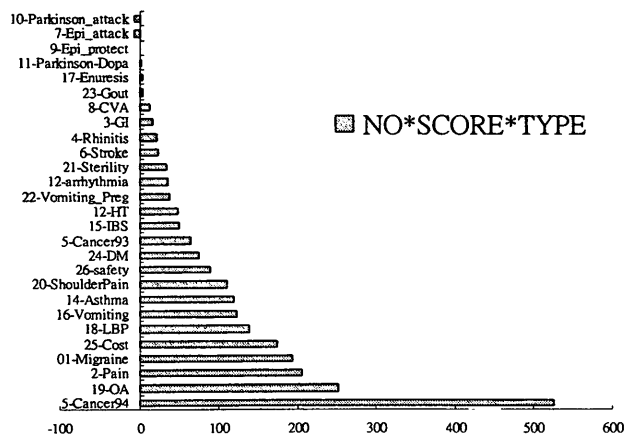
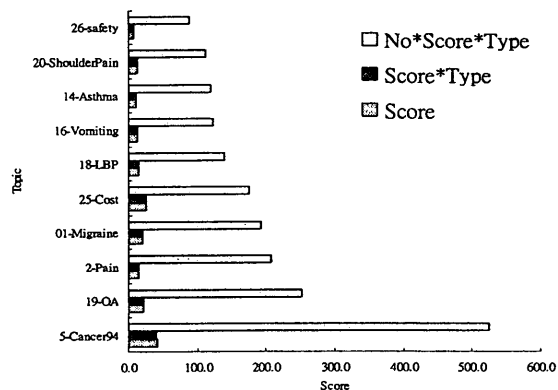


- Paper No. 較高者未必有較高績分之表現。
- CVA、Gout 等主題 Paper No. 為前十名，但其績分相對較低。



- 因受 Type 指標校正影響，績分下降越多則，非臨床試驗比例越高。
- 對於非臨床試驗之主題，針刺在 DM、Hypertension 等主題、相對有較好的研究表現。

Top Ten



- 初步成果發現針灸療效積分較高者集中在骨骼肌肉系統疾病，如 OA、Low Back Pain 等。
- 亦有部份非骨骼肌肉系統疾病有較佳的研究表現，如：Asthma、Vomiting 等，
- 對於針刺的安全性與經濟效益亦有較高積分，且獲較佳影響係數雜誌的支持，在所有主題排名前十名。
- 針對癌症副作用，94 年重新檢索發現其積分有顯著的提升。

參、討論

在第一年的研究中，我們已依計劃完成針灸相關文獻的收集整理，初步集合成為針灸實證醫學專著，分成止痛、免疫、神經、呼吸循環、腸胃、泌尿、肌肉骨骼、婦兒、新陳代謝、總結十個類別，型成了二十七個有關針灸療效的問題與總結，如附件。執行計劃中，根據學者專家的意見，認為應注意文獻之方法學及品質作評析；對於實際療效之文獻收集與分析，仍待加強。因此由原本的廣泛收集，而改為精深之文獻評讀。

完成此一研究能獲得下列之優點：1、針對主題收集相關文獻瞭解現況，便於學術之研究發展。2、評估數據化便於比較分析。3、分類整理文獻，較能系統性瞭解。4、可對不同證據等級之文獻進行統合。5、整理總結便於提供臨床醫師醫學新知。6、作為醫療衛生政策制定之參考。7、建立一全新的文獻評讀統合的方法，不僅僅局限於 RCT 之文獻統合，適合運用於中醫藥等 RCT 文獻較少的領域。雖然如此，仍有一些缺點值得進一步改進的，討論如下：1、問題支持度為評讀者較為主觀的認定，常常主觀的認定評分，必須由較資深且專業的研究人員認定。2、對於較有興趣的臨床問題反覆的以病例方式報導，有積少成多容易造成偏見 (bias) 之疑慮，因病例方式報導通常其 IF、與 SOE 均較低，相對可減低此一偏見。3、小樣本與大樣本的 RCT 研究其代表的不同的證據力，應否給予適當的加權以校正結果的偏見，通常大樣本的 RCT 能發表在較好的雜誌，其 IF 較高，應可避免此一偏見。4、動物實驗的結果對於臨床問題結論的影響，該如何加權以避免對臨床問題結論造成偏見，也是值得討論的問題。5、對於常見

的偏見如：發表偏見 (publication bias)、資料庫偏見 (database bias)、英語偏見 (English bias)、選擇偏見 (selective bias) 等應加以控制，避免誤導統合分析的結論。

肆、結論與建議

本研究已初步依計劃完成了針灸之研究文獻匯整及分類總結，並根據專家建議，應對文獻之研究方法與質量進行深入研究，規劃文獻研析表，對於已收集完成的針灸文獻進行評讀，建立適合中醫藥文獻之評讀模式 (Appraising Model)。初步成果發現針灸療效積分較高者集中在骨骼肌肉系統疾病，如 OA、Low Back Pain (LBP) 等，亦有部份非骨骼肌肉系統疾病有較佳的研究表現，如：Asthma、Vomiting 等，而對於針刺的安全性與經濟效益亦有較高積分，且獲較佳影響係數雜誌的支持，在所有主題排名前十名。

值此實證醫學方興未艾的時代中，西醫紛紛設立實證醫學中心，中國大陸亦設有中醫藥專屬的循證醫學中心，反觀台灣在中醫的實證醫學卻未見開展，本研究期望能結合有共識的專家學者，在有限的資源底下，貢獻綿薄，期能拋磚引玉，在實證醫學的評讀上建構一個簡便可行的模式，以供後續研究參考。

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陸、圖、表

表一、針灸實證醫學目錄

組別	臨床問題	頁數
一.止痛	1. 針灸是否能改善偏頭痛？	1~16
	2. 針灸是否能改善手術後疼痛？	17~33
二.免疫	3. 針灸對發炎性腸炎是否具有療效？	34~44
	4. 針灸對鼻炎是否具有療效、改善鼻炎症狀、或降低用藥之效果？	45~55
	5. 針灸對於癌症患者的治療及對化放療後副用的療效？	56~74
三.神經	6. 針灸對腦中風神經學缺陷及運動功能是否具有療效？	75~96
	7. 針灸對癲癇發作症狀是否具有緩解之療效？	97~106
	8. 針灸對暫時性中大腦動脈梗塞模型是否具有神經保護作用？	107~115
	9. 針灸對致發癲癇動物模型是否具有腦神經細胞保護之療效？	116~120
	10. 針灸對巴金森氏病發作症狀是否具有緩解之療效？	121~124
	11. 針灸對致發巴金森氏病動物模型是否具有提升度巴明激導性神經元之療效？	125~127
四.呼吸 循環	12. 針灸是否具有降血壓治療高血壓之效果？	128~147
	13. 針灸是否具有治療心律不整的效果？	148~157
	14. 針灸是否具有治療氣喘之效果？	158~174
五.腸胃	15. 針灸對大腸激燥症是否有療效？	175~186
	16. 針灸是否具有止嘔吐之效果？	187~199
六.泌尿	17. 針灸是否能改善小兒遺尿症	200~209
七.肌肉 骨骼	18. 針灸是否針灸是否緩解下背疼痛？	210~225
	19. 針灸是否緩解退化性關節炎所引發之疼痛？	226~242
	20. 針灸對於肩膀疼痛的治療效果？	243~256
八.婦兒	21. 針灸是否可提高女性不孕患者的懷孕率？	257~266
	22. 針灸或穴位按摩是否可緩解妊娠噁心嘔吐？	267~277
九.新陳 代謝	23. 中醫師使用針灸治療痛風性關節炎，能否改善其發炎疼痛的症狀？	278~291
	24. 中醫師使用針灸治療，能否改善糖尿病？	292~307
十.總結	25. 針灸治療與減少醫療支出、保險給付的關係	308~331
	26. 使用針灸治療的安全性評估	332~350
新增	27. 使用針灸治療類風濕性關節之評估	351~361

針灸實證醫學之現況與展望

林昭庚¹ 張世良²

¹中國醫藥大學 中國醫學研究所

²中國醫藥大學 中西醫結合研究所

摘要

世界衛生組織 (WHO) 在2002-2005年傳統醫藥策略，鼓勵各國傳統醫學納入現有醫療政策體系，並促進傳統醫學療效評估與安全性之研究。而實證醫學 (evidence-based medicine, EBM) 的概念漸被擴展到整個保健系統，因此提出實證保健 (evidence-based healthcare, EBHC) 的全新理念，對健保支付制度有一定的影響。EBM或EBHC被視為新的典範，取代建立在權威之上的傳統醫學。它仰賴隨機對照試驗 (RCT)，一系列試驗之系統性回顧(Systematic Review, SR)及綜合分析(Meta-analysis)；然而它不僅受限於此，也強調資訊的傳播和收集。

運用實證醫學觀念整理傳統針灸醫學，依生理系統分類，對針灸的療效進行整理，並運用評讀表建立指標，對個別文獻之影響因子 (impact factor)、問題支持度 (supposition of question)、證據等級積分 (score of evidence)、進行量化綜合比較，期能瞭解針灸對各生理系統疾病療效的程度差異，借此將針灸相關的文獻收集與傳播。

展望未來，應將具有較佳證據力的主題，進一步的運用 Meta-analysis的方法進一步分析，一方面也要注意偏見 (Bias) 的產生與控制，才能有較為客觀具體的結論。

關鍵詞：針灸、實證醫學、隨機對照試驗、綜合分析

壹、背景

中國醫學傳承至今已經有幾千年的歷史。在西醫發展以前，中醫基礎理論和針灸、中藥幾乎是我們抵抗疾病、延年益壽、改善生活品質的唯一途徑。近百年來，隨著西方醫學之蓬勃發展與政府政策之相互影響，西醫成為醫學的主流，中醫藥被歸類在「傳統」醫藥或「輔助(替代)」醫藥的範疇。然而自古代隨著中華文化之傳播，中國醫學早已流傳於朝鮮、越南、日本等國；現代由於知識交流之普及更加速中國醫學之傳播。另一方面，西方醫學對某些疾病的控制仍然未臻完善，世界各國傳統醫學對這些疾病的治療經驗於是成為西醫遇到瓶頸時的重要參考依據。因此，最近十幾年來，世界各國對於傳統醫藥及替代醫藥日趨重視。世界衛生組織於2002年5月發表「2002-2005年傳統醫學全球策略」，建請各國將傳統醫學納入現有醫療政策。美國國家衛生研究院(NIH)也特別撥款，並成立輔助與替代療法的專責機構。

中國醫學是累積先人智慧的一門「經驗醫學」，一開始就是以人為治療對象，並累積豐富的典籍供後代醫家參考。然而現今中醫政策或醫療體系之推行，實證數據之有效與否便成為第一道門檻，幾千年來中國醫學被我們認為有效並沿用至今的治療經驗必須經由現代醫學的科學化檢驗才能獲得認同。當初國家健康保險政策把傳統醫藥納入給付範圍的第一個最根本的問題就是：究竟中醫藥有無療效？因此，進行中醫藥療效評估是回答這個問題的唯一途徑。由於世界各國對於傳統醫藥日趨重視，中醫藥療效評估之文獻也越來越多。自從 Pomeranz 在 1976 年發表針刺止痛機轉的論文之後，吸引國際研究者陸續進行針刺止痛的相關研

究，甚至應用在臨床手術後疼痛之緩解 [1]。針灸除了止痛作用之外，其他領域之針灸研究也有很多，例如消化道疾病模式、糖尿病的動物模 [2,3]式或是增加運動生理 [4]...等。

台灣在針灸之相關文獻的收集整理方面，目前初步集合成為針灸實證醫學專著，分成止痛、免疫、神經、呼吸循環、腸胃、泌尿、肌肉骨骼、婦兒、新陳代謝、總結共十個類別，形成了二十七個有關針灸療效的問題與總結，其目的在於運用實證醫學方法整理針灸對於疾病治療研究的現況並總結成果，進一步運用指標如雜誌影響因子 (impact factor)、問題支持度 (supposition of question)、證據等級積分 (score of evidence)、進行量化綜合比較，期能瞭解針灸對各生理系統疾病療效的程度差異，借此將針灸相關的文獻收集與傳播。

貳、實證醫學之起源

實證醫學 (evidence-based medicine, EBM) 之觀念並非突然出現，早在70-80年代，臨床流行病學的發展及其對提高臨床研究及醫療品質的貢獻，為 EBM 之興起奠定了重要的基礎。因此 EBM 可說是臨床流行病學的運用及發展，同時 Archie Cochrane 等之系統評介及衛生技術評估和管理醫療的出現均為 EBM 的迅速發展起了重要的推動作用。十九世紀中期，英國的流行病學者 Archie Cochrane 教授，他的著作「療效和效益：醫療保健中的隨機對照試驗」首次討論了醫療保健如何作到既有療效又有效益的問題，在健康服務上引起回響及後來的提倡促進了實證醫學觀念的接受度。而 EBM 概念和命名的正式形成，是以 1992 年加拿大 McMaster 大學的 Gordon Gnyatt 博士在美國醫學雜誌 (JAMA, 1992,

268(17):2420-2425) 發表的文章為里程碑 [5]，同年在英國牛津，Iain Chalmers及其同事們正式創建了英國的 Cochrane 中心，次年成立了國際 Cochrane 協作網，正式開始了實證醫學實踐提供可靠證據-系統評介 (systematic review, SR 或 Meta-analysis) 的協作工作，主旨在開展國際性 EBM 之研究 [6]。然而它不僅受限於此，也強調資訊的傳播和收集，所以實證及於臨床實務，它也因此具有研究基礎實務的概念。

參、實證醫學之基本概念簡介

著名的臨床流行病學家 David Sackett 教授將 EBM 定義為：慎重、準確和明智地運用所獲得的研究依據來確定病患的治療措施 [7]。醫師的治療處置，制定治療指南 (guideline)，政府機構制定衛生政策。而 EBM 的實踐是既重視個人的臨床經驗又強調現有的、最好的研究依據。此一最佳的研究依據乃是指臨床研究、基礎理論或動物實驗。但人體是複雜的，單憑動物實驗及理論推演，其並不等於病人實際的效果，這種實際的效果需要人體試驗加以證明。

EBM 對臨床醫學工作者提出了更高的標準，除了專業技能的要求外；現代的臨床醫師應具備文獻檢索的能力，從臨床研究中獲得最新的、可靠的訊息以指導自己的治療決策；另外臨床醫師應以病人為中心，考量病人實際的需求與利益，採取利大於弊的治療措施，而不是僅從理論或醫師自己的觀點來處理病人。除了病人本身的治療外，實證醫學的概念也漸被擴展到整個保健系統，因此提出實證保健 (evidence-based healthcare, EBHC) 的全新理念，對健保支付制度有一定的影響 [8]。EBM或EBHC被視為新的典範，實證醫學實質義函是指：醫師對病人的診

斷、治療、預防、復健和其他決策應建立在當前最佳臨床證據、臨床專業知識及病人需求三者結合之基礎上，體現以病人為中心的醫療模式。改變以往依據個人經驗作為醫療決策選擇治療方法的經驗醫學。

臨床流行病學認為，大樣本、多中心、隨機對照臨床實驗 (randomized controlled trial, RCT) 是評介一種治療措施的最佳方法，也是該療法有效性和安全性最可靠的依據。在缺乏大樣本 RCT 的情況下，對 RCT 進行系統性回顧 (SR) 也可以達到類似於大樣本、多中心 RCT 的效果。西方國家推行 EBM 以來，引起了醫學實踐模式及觀念巨大的變革，使人們意識到長期、廣泛的臨床治療方法並非都是有效的，而有一些似為無效的治療方法經大樣本、多中心 RCT 或 RCT 的 SR 後被證實為真正有效或利大於弊而被推廣應用。

肆、針灸醫學引入實證醫學之現況

針灸學是傳統中醫學的重要組成部分，但以往的研究對科學的方法學重視程度不夠，缺乏高品質的臨床研究依據，影響針灸學在防病治病中作用的發揮。為瞭解針灸臨床研究品質，在 2000 年吳濱等以 EBM 標準收集，中國大陸針灸臨床隨機對照試驗 (RCTs) 之期刊論文，檢索出 1991-1998 年《中國針灸》、1983-1998 年《上海針灸》以及 1990-1999 年《針灸臨床雜誌》刊載的臨床研究性文章和其中的 RCT 文章、CCT 文章 (Controlled Clinical Trail CCT, 半隨機對照試驗)，並分析 RCT 文章的品質，以期瞭解針灸臨床科研方法學的應用狀況及存在問題。結果令人堪憂，三種雜誌的 RCT 文章占臨床研究性文章比率均不到 20% 且存在品質問題 [9]。

在台灣 2004 起中國醫藥大學 林昭庚教授及其所領導的研究團隊，曾以 EBM 之臨床實踐上主要五個步驟：(1)問一個可以回答的問題 (formulating answerable clinical questions) (2)尋找最佳的文獻證據 (searching for the best evidence) (3)對文獻進行嚴格評讀 (critical appraisal) (4)應用在個案患者身上 (applying evidence to patients) (5)對以上四點進行稽核 (audit)。整理針灸在國際發表的期刊文獻，依生理系統分類，對針灸的療效進行整理，並運用評讀表建立指標，對個別文獻發表雜誌之影響因子 (impact factor, IF)、問題支持度 (supposition of question, SOQ)：此為評讀者對該文章所屬臨床問題經評讀後之評估量化指標。如果為 "0"則表示該文獻與所屬臨床問題完全無關，其支持度分正面與負面各三等級，依所認定之等級填入；證據等級積分 (score of evidence, SOE)：根據不同的證據等級給予(5-1)

不同的積分，RCTs 給予 5 分，臨床經驗或病歷報告則給予 1 分，其中 IF*SOQ*SOE 則稱為證據強度，進行量化綜合比較，期能據瞭解針灸對各生理系統疾病療效的程度差異，如研究非為人體試驗者則乘 0.5 以校正其影響證據強度的情況，借此將針灸相關的文獻比較、收集整理與傳播，並提供衛生單位制訂健康保險政策之參考。

伍、如何運用實證醫學促進針灸學之發展

傳統的針灸醫術乃是長期以來治療疾病的經驗結晶，取得了相當的寶貴的經驗法則，但是要取信於人仍須要有客觀的科學研究證據，在實證醫學概念方興未艾之同時，針灸工作者除專業知識外，應加強對《臨床流行病學》、《醫學統計學》、WHO《針灸臨床研究規範》及實證醫學知識的學習，展開有系統之培訓，以增強科學研究方法之概念，提高科學研究水準。推廣 RCT 研究法的認識，集中研究能量，持續地進行相關之研究，進一步進行個別 RCT 主題的 SR 為臨床醫師提供更有用的訊息，減少誤導。

對針灸臨床研究論文要求方面 (1) 治療標的或分組情況應明確；(2) 診斷及納入\排除和療效評判標準需客觀；(3) 研究選用的經絡、腧穴、針灸工具、針灸手法、針刺技術（包括進針方向、角度、深度、留針時間、病人體位、行針情況如捻轉提插的頻率與幅度以及其他的輔助行針方法）應敘明；(4) 針刺得氣情況的描述與認定；(5) 使用的各種輔助針灸設備，如鐳射、電針等治療儀器，進行詳細描述，以使針灸臨床研究的結果更具說服力，提高研究的真實性、可靠性與可重複

性 [10]。此外，組間起始點情況、研究結果等資料應進行嚴謹的統計學處理以提高研究科學性。以上各環節都涉及到臨床流行病學的研究方法學知識。希望針灸工作者能意識到規範使用臨床研究方法學的意義並正確實施於科學研究中，使針灸療法的確切臨床療效能得到充分的科學證實，而提高針灸臨床研究品質。

陸、針灸實證醫學發展之困境與展望

一般而言，針灸的研究論文普遍存在以下的問題：(1) 真正有描述具體隨機的方法者、盲法 (blind) 的使用較少。絕大多數只是文中提到隨機採用"隨機分組"，但沒有說明具體隨機的方法，缺乏可信度。盲法是消除觀察性或測量性偏見 (bias) 所必須借助的方法原則，在針灸臨床研究中不易做到單盲 (single blind)、雙盲 (double blind)，整體而言盲法使用率偏低。(2) 診斷、納入\排出標準不明確，療效評判標準未採用黃金標準，影響了實驗的準確性。(3) 某些組間起始值未進行描述、組間樣本數分配比例不合理、研究結論等資料未經規範的統計學處理，以致組間可比性和資料準確性差，影響實驗品質。(4) 針灸術語使用沒有標準化。(5) 論文中對方法學描述較少甚至沒有，影響實驗的可重複性。(6) 治療結果有效率偏高，有效率多在90%以上甚至有100%的報導。(7) 還存在病例來源無說明，且無多數無臨床試驗委員會 (IRB) 審查，無病人臨床試驗同意書簽屬；納入實驗的全部樣本是否完成了全部治療、試驗組和對照組有無中途退出和不依從病例未作說明，致使研究結果不夠準確等問題。以上均提示目前針灸臨床研究絕大多數的設計方法普遍存有待改進的問題。

由於具嚴謹 RCT 架構的針灸臨床研究原本就不多，因此在同一主題上嚴謹

的針灸臨床研究更是不足，因此高品質的研究文獻進行 統合分析 (Meta-analysis) 的文章並不多見。另一方面有許多的文獻是較低品質或低證據等級的病歷報導，如何與高品質的針灸臨床研究統合。目前採用先前所提文獻品質的評估法，於分析中給予研究權重，如先前所提的 SOQ、SOE 等指標，可獲得對每個研究證據強度的評分，藉以量化統合比較，此一方式較為實際而容易執行，但是亦有其方法本身的缺點：(1) 問題支持度為評讀者較為主觀的認定，常常主觀的認定評分；(2) 對於較有興趣的臨床問題反覆的以病例方式報導，積少成多容易造成偏見 (bias)；(3) 小樣本與大樣本的 RCT 研究其代表的不同的證據力，應給予適當的加權以校正結果的偏見；(4) 動物實驗的結果對於臨床問題結論的影響，該如何加權以避免對臨床問題結論造成偏見，也是值的討論的問題；(5) 對於常見的偏見如：發表偏見 (publication bias)、資料庫偏見 (database bias)、英語偏見 (English bias)、選擇偏見 (selective bias) 等應加以控制，避免誤導統合分析的結論 [11]。

雖然針灸實證醫學之發展，初步有一定之困境，但經過實地整理文獻的過程，能較嚴謹地釐清臨床有興趣之主題，收集相關資訊進而傳播做為政府制訂醫療政策之參考。另一方面，使醫學新知能為臨床醫師所運用，提升醫療品質，使更能瞭解該主題科學研究之進展，讓學術研究更能往下紮根，而科學進展正是站在前人的基礎上往前邁進。實證醫學如果是一股不可擋的醫學新潮，傳統的針灸醫術自無法置身潮流之外，因此瞭解目前的進展與可能的困境，才能進一步策劃未來。

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附件二

Critical Appraisal of Acupuncture Safety

Jaung-geng Lin¹, Pin-kuei, Fu¹, Rong-Tsung Lin², Shih-Liang Chang²

1. Graduate Institute of Chinese Medical Science, China Medical University, Taichung City, Taiwan, R.O.C.

2. Graduate Institute of Integration of Chinese and Western Medicine, China Medical University, Taichung City, Taiwan, R.O.C.

Corresponding Author: Shih-liang Chang MD PhD

Tel: +886-4-22053366 ext 1647

Fax: +886-4-8346349

E-mail: slchang@mail.cmu.edu.tw

List of Abbreviations: evidence-based medicine (EBM); supposition of question (SOQ); score of evidence (SOE); impact factor (IF)

Running Title:

J.G. Lin et. al., Appraisal method in Acupuncture Safety

Abstract

In recent years, more and more importance has been placed on traditional medicine around the world. In May 2002, the World Health Organization (WHO) launched its Traditional Medicine Strategy 2002-2005, suggesting traditional therapies were included in existing national health policy systems, while also providing clinical guidelines to ensure appropriate, safe and effective application of these established treatment modalities. The concept of evidence-based medicine (EBM) proposed by British Professor Archie Cochrane has also gained gradual acceptance and even gained health insurance approval. Given these developments, evidence-based medical study of literature relating to traditional Chinese medicine is both timely and significant.

As acupuncture is an invasive treatment, safety in clinical application should be closely monitored. The safety issue remains largely unresolved, however, and given its rising prominence and acceptance, a resolution is urgently required. Study of the relevant literature may provide a relatively rapid way to evaluate the safety of acupuncture statistically. At the same time, establishing a critical appraisal model will provide a reference for relative intensity study of evidence-based medicine in Traditional Chinese Medicine.

The PubMed and Medline database search using the terms “acupuncture” and “safety” selected relevant publications. Based on this critical evaluation of the literature and the derivation of these indicators, we conclude that acupuncture safety is supported with certain evidence in research relative to conventional and accepted therapies without evidence.

Key words: acupuncture safety, evidence-based medicine, critical appraisal method

Introduction

Over the past two decades, traditional medicine and alternative therapies have increasingly become a focus of attention worldwide. In May 2002, the World Health Organization (WHO) launched its Traditional Medicine Strategy 2002-2005, suggesting that these complementary practices are included in existing national health policy systems, while also providing clinical guidelines to ensure their appropriate, safe and effective application ⁽¹⁾. Further, the American National Institutes of Health (NIH) has appropriated funds for traditional medicine, establishing the National Center for Complementary and Alternative Medicine (CAM). Traditional Chinese medicine (TCM) is a medical science that is based on experience and the accumulation of the wisdom of ancestors. From the earliest records, people were the object of treatment, and abundant records were handed down as reference for later generations of doctors. The first obstacle encountered in present day Chinese medical policies and systems, however, are the related issues of effectiveness and safety. For thousands of years, the efficacy of TCM has been accepted. With the rapid rise and predominance of medicine based on the western deterministic paradigm, however, these age-old treatment practices must now be subjected to scientific and medical scrutiny before they can be recognized, while their safety requires even more-rigorous verification.

The EBM concept has evolved since it was first proposed in the 1970's, and has been growing in popularity in recent years. British Professor Archie Cochrane, his book "Effectiveness and Efficiency" won acclaim among health practitioners after its publication in 1972, with later referral to it establishing the concept. Nowadays, evidence-based medicine and health care are regarded as new concepts, replacing authority-based traditional medicine. EBM relies on randomized controlled trials (RCT), systematic review of test series, and meta-analysis. The collection and dissemination of information are also emphasized, so it is comparable to clinical practice, while also incorporating research and practice ⁽²⁾. In general, EBM consists of five steps: (1) formulation of answerable clinical questions; (2) literature search for the best evidence; (3) critical appraisal of the relevant material; (4) clinical application of the evidence; and, (5) audit of the above ⁽¹⁶⁾.

In this study, the EBM concept was applied to literature related to acupuncture safety, and an attempt was made to construct a synthesized model of papers in different EBM levels which allows critical appraisal ⁽¹⁵⁾. The principal aims of the investigation were: to gain an overall understanding of acupuncture safety studies worldwide; to produce a summary of the material and reach a consensus; in-depth study of acupuncture safety; and, to search the literature for the best evidence. Secondly, the relevant literature was subjected to critical appraisal and a simple, easy-to-use and practicable appraisal model developed for use as a reference in the study of problems related to evidence-based medicine.

Materials and Method

1. Data Source

The main source for the information used in this study was the PubMed database. This resource is updated weekly and accessible from the National Center for Biotechnology Information (NCBI) of the US National Library Medicine via the internet, where users may retrieve data without charge. Medline database was also used with the same search strategy for correcting the database bias.

2. Data Selection

The results of studies relating to acupuncture safety, the findings of systematic reviews, and relevant clinical cases were collected from a PubMed search following a search strategy, for the words “acupuncture” and “safety”, and the search limits as following conditions: publication date to 2004/05/30, only items with abstracts and English. In general, each included paper was reviewed by two members or more of a subgroup in our research team; the conflicts were resolved by discussions among the members of the subgroup.

3. Data Extraction

Collected data were subjected to critical appraisal, and the five EBM steps applied to the main study results and conclusions. The three main categories of the critical appraisal are: (1) basic informations of included paper: items were defined in Table 1; (2) brief contents of the reference section; and, (3) appraisal index for which a form was designed (see Table 1). Through the establishment of an appraisal model and various indexes, insight was gained into the quality and general condition of the reference literature relating to acupuncture safety.

In the table, the impact factor (IF) is based on latest issue of journal citation report (JCR) available in the library of China Medical University. It is indicated by 0.1 when the issues were unable to find. The supposition of question (SOQ; -3-0-3) is a quantification index given by the appraiser

after study of the texts and the described clinical problems. Score of “0” indicates the reference is unrelated to the described clinical problem. The SOQ is divided into 3 positive and 3 negative scores and completed by and according to the appraiser. The scoring method of Evidence (SOE; 5-1) was designed as below: ⁽¹⁵⁾

- (1) RCTs: reference consists of multiple randomized controlled trials e.g., meta-analysis or systemic review; accredited with a score of 5.
- (2) RCT/Cohort: reference consists of single randomized controlled trials or cohort studies; a cohort study compares populations exposed to different factors; usually applied for etiology study or to evaluate disease progress e.g., comparison of smoking and non-smoking as causes of lung cancer; accredited with a score of 4.
- (3) Case control: reference consists of case control studies comparing patients to a control group; historical data are collected to search for between-group differences; accredited with a score of 3.
- (4) Case series: reference consists of reports of multiple cases; accredited with a score of 2.
- (5) Experiences/Case report (1): reference consists of a single case; accredited with a score of 1.

Finally, we multiply the indexes, IF, SOQ and SOE as evidence score and rank this score in the name of the quality of evidence.

Results

Seventy four titles were found from the initial search, but only 12 reports exploring the safety and side-effects of acupuncture were selected and one paper investigated safe needling depth⁽¹⁰⁾ was also included for our analysis and discussed safety of acupuncture, six were systematic reviews^(3-5,7-9), and five related to clinical testing^(6,12,14,17,18), with one evaluating the safety of acupuncture electro stimulation⁽¹¹⁾. In the other hand, we did not include the article that was only appeared in Medline database finally after consideration. After collection and critical appraisal of the reference literature on the safety of clinical acupuncture, a mean value of 2.1 for Supposition of Question (SOQ; -3-0-3) was demonstrated. Additionally, mean post-appraisal Score of Evidence (SOE; 5-1) and magazine publication Impact Factor (IF) values of 2.6 and 1.8, respectively, were derived. Each included paper was list in Table 2, that was illustrated the brief summary of each article based on the evidence analyzed in this study. The evidence score and rank of each paper were also derived in table 2. The mean value of 11.7 for this evidence score was also demonstrate. This score and rank help us to realize the degree of evidence in accordance with the problem of acupuncture safety.

Summarizing the various investigations of safe acupoint depth, the needle depth recorded in the modern reference literature is generally greater than described in the classic medical records, with safe acupoint depth for chest and back areas was not the same for each acupoint. In adults, but not infants, a positive correlation was demonstrated with the length of the second section of the middle finger. Comparing gender, safe acupoint depth in the chest area was greater for females; however, no significant between-gender difference was demonstrated for the back area. This gender variation should be considered, therefore, when deciding on the safe depth for acupoint, and, unless the subject is an infant, the length of the middle section of the second finger may be used as a reference value⁽¹⁰⁾.

Study of the reference literature for side effects found that most researchers deemed the risk of acupuncture causing severe side effects, such as pneumothorax, infectious hepatitis or septicemia, to be extremely low^(3-5,7-9). Filshie (2001), however, opines that where palliative treatment is applied for

control of tumor pain, and if neither the clinical stage of the disease nor the status of the modern medical treatment thereof is known, acupuncture treatment is not safe ⁽⁷⁾. Severe potential side effects include spinal instability, severe coagulation, neutropenia and lymphoedema ⁽⁹⁾. Valvular heart disease patients and those who are prone to neutropenia should avoid acupuncture for control and management of pain. Common side effects recorded in the six systematic reviews include epidermal haemorrhage, hypotension, dizziness, and vomiting. (Lao et al., 2003), needle pain during treatment (1-45%), fatigue (2-41%), and haemorrhage (0.03-38%). (Ernst et al., 2001) ⁽⁵⁾. Summarizing the six reviews, we conclude that acupuncture is safe and has relatively few severe side effects, with five of these indicating that that the traditional therapy is safe to a certain degree.

In the studies of clinical evaluation, large samples were used to test whether acupuncture has any side effects. In one investigation, 900 patients were divided into three groups which were assessed using multicenter RCTs ⁽¹⁴⁾. Also, comprehensive evaluation was performed for tens of thousands of patients who had averaged several acupuncture sessions each ^(6,12,17,18). Ernst et al., (2003) found that the main side effects of acupuncture were haemorrhage (2.9%), haematoma (2.2%), dizziness (1%) and other systemic symptoms (2.7%). They conclude that although acupuncture, like other therapies, sometimes causes a bad reaction, if it is applied accurately in accordance with set safety standards and with attention to differences in acupoint anatomy, it can be regarded as a safe treatment modality ⁽⁶⁾. In their prospective study of 34,407 treatments, MacPherson et al., (2001) studied the side effects of acupuncture performed by certified members of the British Acupuncture Association and Registration (BAAR), identifying no severe side effects. Some 43 different types of relatively minor side effects were noted, however, giving an occurrence rate of 1.3/1000 treatment sessions (95% CI: 0.9-1.7). These included severe nausea and acute dizziness (n=12), unanticipated symptoms that increased and prolonged the initial feeling of discomfort (n=7), prolonged and unacceptable pain and hematoma (n=5), and emotional and psychological reactions (n=4). The results Of the BAAR study were obtained from a survey of one-third of the members. Assuming the accuracy of the proffered annual total of 1.5-2 million acupuncture sessions nationally, this constitutes important evidence for

determination of public health and safety policies. Compared to treatments commonly applied during outpatient consultations in conventional medical practice, namely administration of oral agents, acupuncture is a relatively safe method of physical therapy ⁽¹²⁾. In their evaluation of 12,172 acupuncture sessions for 1128 patients treated at an acupuncture research center in a Singapore medical center, Yong et al., (1999) found that about 70% of these individuals believed that acupuncture was safe, with 54% satisfied with the treatment results, 51% believing it was beneficial, and 54% willing to recommend acupuncture to others with similar problems. In regard to side effects, near-fainting only occurred in two patients (0.18%; 0.02% of treatment sessions), with complications caused by acupuncture not reported⁽¹¹⁾. Yamashita et al., (1999) studied 65,482 sessions performed by 84 specially trained professors and interns at the Institute of Clinical Medicine of the Tsukuba College in Japan, with side effects reported in 94 of these treatments (0.14%). Severe complications, such as pneumothorax, infection or spinal injury, were not observed. It appears reasonable to suggest, therefore, that if acupuncture is performed by well-trained professionals according to standard procedures, the risk of severe complications is extremely low. Further, in the reports that mentioned severe complications after acupuncture, the cause was ascribed to the negligence of the practitioner. In future, complications of this type may be minimized by improved medical education and technical training of acupuncturists ⁽¹⁷⁾.

Discussion and Conclusion

Analysis of the relevant safety-evaluation literature worldwide indicates that acupuncture is a safe treatment modality with certain evidence supported. Although a slight possibility of severe complications such as pneumothorax and infectious hepatitis is mentioned in some of the reports, gradual establishment of standard operating procedures (SOP) for acupuncture, popularization of disinfection practices, enhancement of anatomy training as part of acupuncture education, and increasing the professionalism of acupuncturists have led to reduced incidence of side effects.

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients⁽¹³⁾. Although randomized controlled trails (RCTs) are the gold standard for evidence, it is also important to synthesize the available evidence when there is no or few RCT in interesting area. The main purpose of this study try to develop a synthesized method of different study designs not only RCT. Through this study, literature based on scientific evidence may be collected and appraisal indexes (IF, SOQ, SOE) developed, also, extended indexes (IF*SOQ*SOE) may also be used to help us to synthesize the degree of evidence in the problem of acupuncture safety. This appraisal model will enhance efforts towards understanding of the degree of evidence among the curative effect of acupuncture treatment in various diseases. For the convenience to abstract data of evidence levels, we change commonly used quality of evidence levels measure in systemic reviews from 5 to 1. The highest quality of evidence levels like meta-analysis in RCT study that was gave 5 in SOE. Similarly, the lowest quality of evidence levels like case report that was gave 1 in SOE⁽¹⁵⁾.

We excluded 62 initial searched titles because the focus of each articles not close relationship to acupuncture safety. Excluded titles had been reviewed by a team of research in Chinese Medical College, China Medical University of Taiwan, and though the supposition of question (SOQ) equal to zero which was defined in Table 1. In order to minimize the bias, Medline database was also used. However, if publications supporting acupuncture safety predominated in Pubmed database, we did not

include the article that was only appeared in Medline database finally, thus the database bias may have lowered by this consideration. Another important aspect of evidence-based medicine is the collection and dissemination of information to help guide decisions by clinicians, patients and other decision makers.

In their study of acupuncture performed by BAAR members, MacPherson et al., (2001) assumed an annual total of 1.5-2 million sessions, providing an important and substantial body of evidence applicable to public health and safety policies. Compared to treatments commonly applied during outpatient consultations in western medicine, namely oral administration of pharmaceuticals, acupuncture is a relatively safe therapy ⁽¹²⁾. We trust future investigations will be quantitatively and qualitatively improved, and that clinical trials are conducted in accordance with the principles of multi-center and randomized controlled trials. This will allow consensus to be established with respect to the safety and efficacy of acupuncture, allowing this important traditional complementary therapy to keep pace with conventional medical practice and its emergence as a mainstream treatment.

Acknowledgments

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Table 1. Critical Appraisal Form – Reference Literature on Acupuncture and Evidence-Based Medicine

1. Basic Information	
A. Ref. No.	Literature reference number
B. Clinical problem	Is clinical use of acupuncture safe?
C. Reference Source	Name of magazine recorded in PubMed (http://www.pubmed.com/)
D. Publication Date	YY/MM, ex. 2004/01
E. Volume (Issue): Page	Ex: 21(5):100-105 °
F. Author(s)	Use PubMed format
G. Publication type	Publication type as categorized by PubMed (Ex: clinical trial, editorial, letter, meta-analysis, practice guideline, RCT, review)
H. Language	Ex: English, Chinese....
2. Brief Contents of Reference	
I. Title	As in PubMed
J. Purpose	<ul style="list-style-type: none"> ■ As briefly as possible, point by point ■ Clearly indicate material (people, animals, ...)
K. Material & Methods	
L. Conclusion	
3. Appraisal Index	
*M. Impact Factor (IF)	1. Based on latest issue available in library. Search method: http://www2.cmu.edu.tw/~cmcrdc/doc/SCIsearch.doc 2. Unable to find issues indicated by 0.1
*N. Supposition of Question (SOQ; -3-0-3)	1. Score awarded by the appraiser after study of text. 2. (-3: extremely negative; -2: negative; -1: uncertain leaning to negative; 0: not relevant ; 1: uncertain leaning to affirmative; 2: affirmative; 3: extremely affirmative)
*O. Score of Evidence (SOE; 5-1)	RCTs (5) > RCT/Cohort (4) > Case control (3) > Case series (2) > Experiences/ Case report (1)
P. Comments	Comments of appraiser on text after study
Q. Reviewers	Name of Reviewers
S. Appraisal Date	YY/MM/DD Ex: 2004/11/9

Table 2 Appraisal indexes of each included references

No.	Year	Journal	Author	Study Design	IF	SOQ	SOE	Evidence Score	Rank
10201	1997 Feb.	Chin Med J (Engl).	Lin JG.	Historic al Article	0.1	2	2	0.4	11
10202	2003 Aug.	Can Fam Physician.	Chung A et. al.	Review, Tutorial	0.41	3	3	3.69	6
10203	2003 Jan.	Ann Intern Med	Cherkin DC et. al.	Review, Academ ic	11.41	3	2	68.46	1
10204	2003 Jan.	Altern Ther Health Med	Lao L et. al.	Review, Academ ic	0.92	3	1	2.76	7
10205	2001 Dec.	Acupunct Med.	Filshie J	Review, Tutorial	0.1	-3	1	-0.3	13
10206	2001 Apr.	Am J Med.	Ernst E & White. AR.	Review	4.9	3	2	29.4	2
10207	1995 Jan.	J Altern Compleme nt Med	Jobst KA	Review	1.26	3	5	18.9	3
10208	2004 Mar.	BMC Compleme nt Altern Med.	Streitbe rger K et. al.	Multi-c entre clinical RCT	0.29	2	1	0.58	10
10209	2003 Jun.	Compleme nt Ther Med.	Ernst G et. al.	Multi-c entre Study	1.51	3	4	18.12	4
10210	2001 Dec.	Acupunct Med	MacPhe rson H et. al.	Prospec tive studies	0.1	3	4	1.2	8
10211	1999 Apr.	Singapore Med J	Yong D et. al.	Case series	0.1	2	4	0.8	9
10212	1999 Jun.	J Altern Compleme nt Med.	Yamash ita H et. al.	Case series	1.26	3	2	7.56	5
10213	2000 Feb.	J Altern Compleme nt Med.	Lytle CD et. al.	Equipm ent	1.26	0	3	0	12

IF = Impact Factor, SOQ = Supposition of Question, SOE = Score of Evidence, Evidence Score = IF*SOQ*SOE

Reference Literature

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16. Yamashiro S: Practice and application of evidence-based medicine. *Rinsho Byori* 2000, 48 (12):1149-1155.
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包括整廠輸出、對外投資、對外技術合作及顧問服務等四種。

技術擴散：指政府引導式的技術移轉方式，即由財團法人、國營事業或政府研究機構將其開發之技術擴散至民間企業之一種單向移轉（政府移轉民間）。

技術創新：指研究執行中產生的技術，且有詳實技術資料文件者。

（二）研究成果發表情形【若為 SCI 論文，請註明 Impact factor】

列出貴計畫於本年度中所有計畫成果產出於下表，包含已發表或已被接受發表之文獻、已取得或被接受之專利、擬投稿之手稿（manuscript）以及專著等。「計畫產出名稱」欄位請依「臺灣醫誌」參考文獻方式撰寫；「成果產出形式」欄位則填寫該產出為期刊、專利、手稿或專著等，舉例如下：

序號	計畫產出名稱	產出形式	SCI*
1	針灸實證醫學 (再版)	手稿或專著	
2	<u>林昭庚, 張世良, 針灸實證醫學之現況與展望.</u> <u>中華針灸醫學會雜誌 2005;1-5.</u>	期刊	
3	<u>Lin JG, Fu PK, Lin RT, Chang SL. Critical Appraisal of Acupuncture Safety. Chinese Medicine; submitting.</u>	期刊 手稿	
4	針灸實證醫學與臨床應用	研討會	
5			

範例：

序號	計畫產出名稱	產出形式	SCI*
1	Travell JG, Rinzler S, Herman M. Pain and Disability of Shoulder and Arm. J Am Med Asso 1942 ; 120:417-422.	期刊	√

* SCI: Science Citation Index，若發表之期刊為 SCI 所包含者，請打「√」。

附件 5

行政院衛生署中醫藥委員會 93-94 年度委辦研究計畫成果報告自我評估表

計畫名稱	中醫藥療效評估之文獻研究	計畫編號	CCMP93-RD-017 CCMP94-RD-104
執行機構	中國醫藥大學	主持人	林昭庚
<p>自我評估項目：</p> <p>一、研究方法是否與原計畫之設計相同</p> <p><input checked="" type="checkbox"/> 完全相同 <input type="checkbox"/> 少部分不同 <input type="checkbox"/> 大部分不同 <input type="checkbox"/> 完全不同</p> <p><u>未"完全相同"者請說明不同之項目與原因：</u></p> <p>二、研究成果內容與原計畫書目的之相符程度</p> <p><input checked="" type="checkbox"/> 完全相符 <input type="checkbox"/> 少部分不符 <input type="checkbox"/> 大部分不符 <input type="checkbox"/> 完全不符</p> <p><u>未"完全相符"者請說明不符之項目與原因：</u></p> <p>三、研究成果是否達成預期目標</p> <p><input type="checkbox"/> 已達成且超過預期目標 <input checked="" type="checkbox"/> 已達成預期目標 <input type="checkbox"/> 部分未達成 <input type="checkbox"/> 均未達成</p> <p><u>均請說明，未達成目標請務必說明原因：</u></p> <p>四、對該研究成果應用價值之自我評估：(可複選)</p> <p><input checked="" type="checkbox"/> 可列為中醫師或中藥從業人員在職繼續教育專題演講之內容</p> <p><input checked="" type="checkbox"/> 具出版專籍參考之價值</p> <p><input checked="" type="checkbox"/> 具發表於學術期刊之價值</p> <p><input type="checkbox"/> 具備申請專利或技術移轉之潛力</p> <p><input checked="" type="checkbox"/> 其他 <u>有利於中醫總額費用之協商，及政策訂定之參考</u></p> <p>五、其他</p>			
計畫主持人簽章		日期	95/04/18

註：本表電腦檔案可於"<http://www.ccmp.gov.tw>"上取得