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Systematic Review

Assessment of the safety and efficacy of acupuncture in erectile dysfunction treatment

针刺治疗勃起功能障碍安全性及疗效的评价

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Abstract
Objective: To assess the safety and efficacy of acupuncture in erectile dysfunction treatment.
Methods: A systematic literature search was conducted to identify relevant studies. Seven electronic databases including Popline, World Health Organization (WHO) Global Health Library (GHL), System for Information on Grey Literature in Europe (SIGLE), Scopus, Institute for Scientific Information (ISI) Web of Science, PubMed and Virtual Health Library (VHL) were utilized to carry out the search. A manual search was further conducted for relevant publications from references of the included articles, relevant papers in PubMed and Google Scholar, and primary studies that had cited the included papers. Hand-search using each keyword to avoid missing any relevant publications was also carried out.
Results: The literature search yielded 2 818 reports after removing duplicates using Endnote software. There were 21 studies eligible for full-text screening and five of which were subsequently included. After two studies identified from the manual search were added, a total of seven studies were found suitable to carry out the systematic review and meta-analysis. Five of them were used for quantitative and qualitative analysis, while two were only used for qualitative analysis. There were four clinical trials, one pilot study, one case report, and one animal study.
Conclusion: Acupuncture can improve male erectile function.
Keywords: Acupuncture Therapy; Traditional Chinese Medicine; Erectile Dysfunction; Men; Systematic Review

【摘要】目的：评价针刺治疗勃起功能障碍的安全性及疗效。**方法：**采用文献检索法对相关研究进行系统检索。利用Popline、世界卫生组织(WHO)全球卫生图书馆(GHL)、欧洲灰色文献信息系统(SIGLE)、Scopus、美国科学信息研究所(ISI) Web of Science、PubMed和VHL 7个电子数据库进行检索。通过从收录文章的参考文献、PubMed和谷歌学术的相关论文以及引用收录论文的初步研究中搜索相关刊物，并进行进一步人工搜索。此外，对每个关键词都进行手动检索以避免遗漏相关文献。**结果：**用Endnote软件剔除重复文献后，共得到2 818篇文献。有21项研究符合全文筛选的条件，其中5项随后被纳入。加上从手动检索中确定的2项研究后，共有7项研究适合进行系统性回顾和meta分析。其中5项用于定量和定性分析，2项仅用于定性分析。共有4项临床试验、1项初步研究、1份病例报告和1项动物研究。**结论：**针刺治疗能够改善男性勃起功能。

【关键词】针刺疗法；中医学；勃起功能障碍；男性；系统评价
【中图分类号】R246.2　　**【文献标志码】**A

Erectile dysfunction (ED) is an extremely prevalent health problem that has been reported to affect about 30 million men in the USA. It is a common worldwide clinical problem, with tens of thousands of new cases being reported per year[1]. Worldwide, the affected people are predicted to increase from 152 million in 1995 to 322 million in 2025[1]. Some of the significant risk factors for ED include age, smoking, hypertension, obesity, coronary artery disease, lifestyle, hyperlipidemia, trauma, prostatic hypertrophy, diabetes, and depression[2]. Moreover, approximately 20% of the cases have added psychological reasons[2]. ED is recognized to impact the psychological, social, and physical health of the families and their quality of life[3-4]. In some cases, pharmacological treatment options for ED are available. Therapeutic options in the form of specific orally-administered pharmacological agents (e.g., sildenafil, vardenafil, and tadalafil) and intracavernous injection are available to manage ED. However, some individuals prefer to avoid using these therapeutic options for a variety of reasons including side effects, drug interactions, and cost of medication[4].

Complementary and alternative medicine (CAM) has been extensively used to treat ED[5]. Acupuncture, defined as the insertion of needles into the skin and underlying tissues at acupoints for preventive or therapeutic purposes, is one of the most important components of CAM[6]. Contemporary researches proposed that the neurophysiological influence of acupuncture, as a result of neurotransmitter modulation

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and central nervous system activation, may positively affect the pathophysiology of ED[7-8]. The present study is a review of the relevant available published literature serving as a meta-analysis to assess the therapeutic role of acupuncture in the management of ED.

1 Methods

1.1 Databases

A systematic search was carried out to identify relevant studies using seven electronic databases including Popline, World Health Organization (WHO) Global Health Library (GHL), System for Information on Grey Literature in Europe (SIGLE), Scopus, Institute for Scientific Information (ISI) Web of Science, PubMed and Virtual Health Library (VHL). A manual search was further conducted for relevant publications from references of the included articles, relevant papers in PubMed and Google Scholar, and primary studies that had cited the included papers. The literature list was further augmented by hand-searching using each keyword to avoid missing any relevant publications.

1.2 Search methods

1.2.1 Search strategy

The search term used was 'Acupuncture' AND ('Erectile Dysfunction' OR 'Sexual Dysfunction' OR 'Impotence'). There were no restrictions for the study design, age, area, and publication year. Only English articles were chosen.

1.2.2 Inclusion criteria

Original publication reporting acupuncture for ED patients despite it was the main treatment or in combination; animal studies were included; no restriction made for the area, study design, and publication year.

1.2.3 Exclusion criteria

Unreliably extracted data; only abstract studies or studies where the full paper was not available; books, conference, and thesis; overlapped data sets; *in vitro* studies; previous systematic reviews, meta-analyses and literature reviews on our topic of interest; non-English studies.

1.2.4 Screening

Duplication was removed using EndNote version X8. An initial eligibility assessment of the retrieved titles and abstracts was performed. Full texts of the eligible articles were then retrieved and reviewed for inclusion in the systematic review and were further screened for inclusion in the meta-analysis. In both steps of the screening, inclusion or exclusion of a study was considered conclusive. Any queries during the process were resolved by discussion and consensus with the supervisor.

1.3 Data extraction

Based on a pilot review and extraction, a data extraction form was developed using Microsoft Excel file. I extracted data from the included studies using the excel sheet. Before the initiation of analysis, rechecking was carried out by me and re-checked again for accuracy. All the queries were resolved by discussion and consensus with the supervisor. Papers published by the same research group and studying the same factors were checked for potential duplicate data based on the year of patient recruitment and the hospital where the patients were recruited and confirmation from the authors.

1.4 Quality assessment

Risk of bias in the included studies was evaluated. Methodological quality assessment was done using the National Institutes of Health (NIH) quality assessment tool for cohort and cross-sectional studies (2014)[9]. Quality assessment of each study was obtained through a scoring system, including 14 questions. The criterion was judged as following: a score of 13 to 14 was good, 9 to 12 was fair, and studies scored below 9 were considered to have poor quality for cohort and cross-sectional studies[10]. Furthermore, the Cochrane quality assessment tool was used to determine the quality of randomized studies[11]. Any queries were solved by consulting the supervisor.

1.5 Statistical analysis

Meta-analysis was performed using the comprehensive meta-analysis software version 3 when there was more than one study. The adjusted and non-adjusted hazard ratios (HR) were pooled for mortality events. Also, raw data were used to calculate the pooled risk ratio (RR) for mortality. Mean difference (MD) was used to analyze continuous outcomes. Odds ratio (OR) was used to pool other outcomes. Fixed effect model with the method of Mantel N, *et al*[12] was used when there was no evidence of heterogeneity between studies. Otherwise, the random effects model was chosen. Heterogeneity between studies was estimated using the *Q*-test, and *I*-squared (I^2) test which describes the percentage of variability in effect estimates that is because of heterogeneity beyond sampling error[13-14]. Significant heterogeneity was considered when $P<0.10$, or the $I^2>50\%$[11]. Further sensitivity analysis was carried out by removing one study each time to investigate their impact on the effect size magnitude. Furthermore, meta-regression and subgroup analyses were performed when there were ten or more studies in the analysis and comparable groups, respectively. Begg CB, *et al*[15] used funnel plot and Egger M, *et al*[16] used regression test to evaluate the presence of publication bias, when there were ten or more studies in the analysis[17]. The publication bias was significant when $P<0.10$. If publication bias was found, the trim and fill method of

Duvall and Tweedie was done by adding studies that seemed to be missing[18-19] to enhance the symmetry[20]. The adjusted pooled effect size and its 95% confidence interval (CI) were computed after the addition of potential missing studies.

2 Results

2.1 Literature search

The literature search yielded 2 818 reports after removing duplicates using Endnote software. There were 21 studies eligible for full-text screening and five of which were subsequently included. After two studies that were identified from the manual search were added, a total of 7 studies were included for the systematic review and meta-analysis. Five of these were used for quantitative and qualitative analysis, while two were only used for qualitative analysis (Figure 1 and Table 1)[21-26]. These publications included four clinical trials, one pilot study, one case report, and one animal study.

2.2 Study and patient characteristics

The characteristics of studies included for quantitative analysis are summarized in Table 1. A total of 167 patients were included. Of these, 60 had sexual dysfunction of a non-organic cause, 39 had a psychogenic ED, 19 had ED caused by medication, one had ED caused by type 2 diabetes mellitus and one because of hypertension. Three studies reported the outcome measurement according to the patients' perception. One study reported outcome according to the sexual function visual analog scale (SFVAS) and the Arizona sexual experience questionnaire (ASEXQ)[24]. Another study reported outcome according to the international index of erectile function 5 (IIEF5)[26]. The treatment duration varied between 6 weeks and 30 months; the 20-minute session was the most common duration.

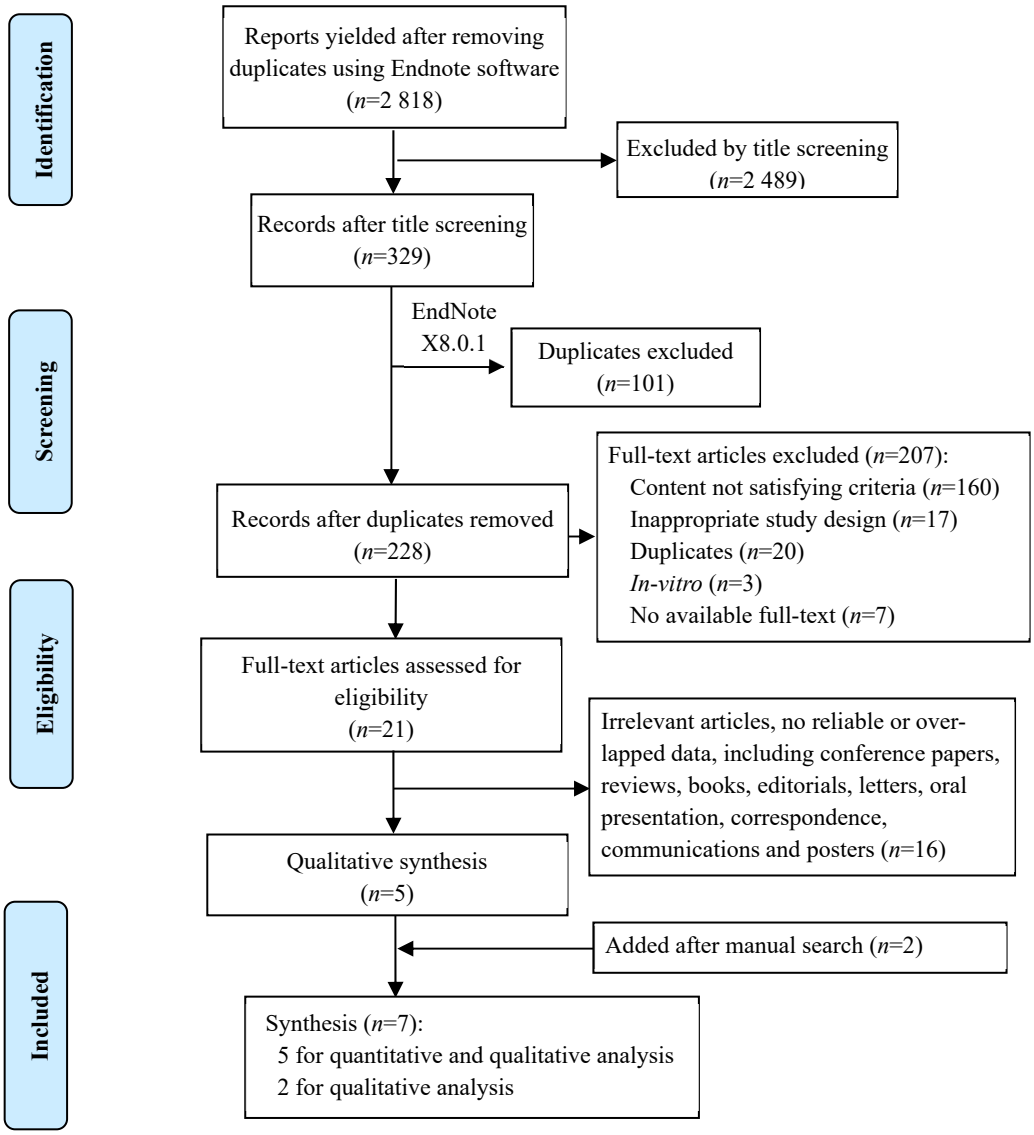

Figure 1. Flow chart of study selection

Table 1. The characteristics of studies included for quantitative analysis

Study	Study design	Type of ED	Compared group	Sample size	Average age (year)	Treatment duration	Outcome measurement
Aydin S 1997[21]	RCT	Non-organic cause	Acupuncture	15	36.7±10.4[1)]	20 min, twice a week for six weeks	The patients who reported that they felt happy and had no problem with sexual activity were considered as 'cured' or having 'good results'
			Hypnosis	16	38.4±10.8[1)]	Three days per week later decreased to one per month for 6 months	
			Needle placebo	14	35.3±11.5[1)]	NA	
			Oral placebo	15	36.2±11.4[1)]	NA	
Kho HG 1999[22]	Pilot study	Nine psychogenic, two caused by hyper-tension, one caused by medication and one because of type 2 diabetes mellites	Acupuncture	13	53.2±6.9[1)]	Twice a week over four weeks for a total of eight sessions	Patient interview
Engelhardt PF 2003[23]	RCT	Psychogenic erectile dysfunction	Acupuncture	19	38.9 years (range 20-61 years)	20 min, once or twice weekly for 15 sessions	When erections became sufficient for penetration and sexual intercourse
			Placebo acupuncture	11			
Khamba B 2013[24]	Clinical trial	Sexual dysfunction secondary to antidepressant	Acupuncture	18	NA	12 weeks	The sexual function visual analogue scale (SFVAS) and the Arizona sexual experience questionnaire (ASEXQ)
Liu P 2017[26]	RCT	NA	WNM	24	43.0±12.4[1)]	(28.2±6.2) months[1)]	The international index of erectile function 5 (IIEF-5)
		NA	Acupuncture	22	45.0±10.2[1)]	(27.5±7.1) months[1)]	

Note: 1) Data represented as median ± standard deviation; RCT=Randomized controlled trial; NA=Not available; WNM=Warm needling moxibustion

2.3 Quality assessment

Results of quality assessment are summarized in Table 2. There were two studies with overall risk of bias as low, one study with overall risk of bias as moderate and two studies with overall risk of bias as high.

2.4 Quantitative results

2.4.1 Acupuncture in comparison with placebo needles

Two studies of total 59 patients studying the effectiveness of acupuncture for ED in comparison with placebo needles showed that acupuncture had significantly positive results against placebo needle with [OR (95% CI)=4.06 (1.177-14.030), P=0.027], (Figure 2).

2.4.2 Acupuncture in comparison with hypnosis for ED

One study of 31 patients reported the comparison between acupuncture and hypnosis as methods for ED treatment[21]. Interestingly, there was no significant between-group difference with P=0.375.

2.4.3 Acupuncture in comparison with warm needling

One study with 46 ED patients compared warm needling with acupuncture[26]. Interestingly, the overall effective rate in the warm needling group was 91.3%, versus 75.0% in the traditional acupuncture group, and the between-group difference was statistically significant with P<0.05.

2.4.4 Acupuncture for sexual dysfunction caused by antidepressant

One study reported 18 patients with ED due to antidepressant were treated with acupuncture[24]. The study showed significant improvement in all areas of sexual functioning, as well as in both depressive and anxiety symptoms.

2.4.5 Acupuncture for sexual dysfunction of psychogenic cause

Engelhardt PF, *et al*[23] reported a study of 19 ED patients with psychogenic cause treated with acupuncture; surprisingly the results were satisfactory with 68.4% effective rate and a significant difference with the placebo group (P=0.0017).

Table 2. Quality assessment of the included studies

Quantitative study	Risk of bias	Quality score (out of possible 14 points)
Aydin S 1997[21]	High	7
Kho HG 1999[22]	High	8
Liu P 2017[26]	Moderate	10
Engelhardt PF 2003[23]	Low	13
Khamba B 2013[24]	Low	13

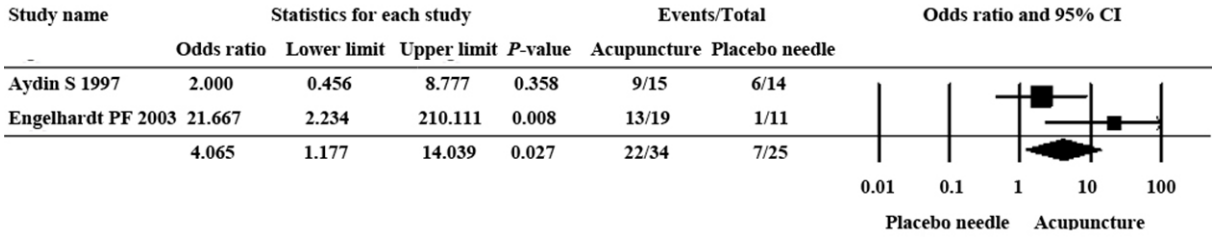

Figure 2. Acupuncture in comparison with placebo needle for ED

2.5 Qualitative analysis

2.5.1 Acupoint used for acupuncture

Different acupoints were used in the different studies[21-24]. Aydin S, *et al*[21] in their study used disposable sterile No. 30 needles at Qichong (ST 30), Zusanli (ST 36), Zhaohai (KI 6), Guanyuan (CV 4) and Qihai (CV 6). Qichong (ST 30) is found two fingerbreadths lateral to the symphysis on the lower edge of the pubic bone and the needle is inserted downwards. Zusanli (ST 36) lies on the point of intersection of the lines half a fingerbreadth lateral to the linea interossei of the tibia and two fingerbreadths below the head of fibula. Zhaohai (KI 6) lies one fingerbreadth below the internal malleolus. Guanyuan (CV 4) lies three fingerbreadths above the symphysis. Qihai (CV 6) is found two fingerbreadths below the navel[21]. Liu P, *et al*[26] in their study used Qihai (CV 6), Guanyuan (CV 4), Zhongji (CV 3), Yaoyangguan (GV 3) and bilateral Taixi (KI 3), Shenshu (BL 23), Ciliao (BL 32) and Yanglingquan (GB 34). Kho HG, *et al*[22] used Guanyuan (CV 4), Baihui (GV 20), bilateral Sanyinjiao (SP 6), Taixi (KI 3) and Shenmen (HT 7). Interestingly, Khamba B, *et al*[24] used 34-gauge disposable stainless-steel needles bearing and retained the needles for 15 min at nine common acupoints for 12 sessions. According to the traditional Chinese medicine technique, five of the acupoints were reinforced using thrusting and rotation manipulations in the clockwise direction at 5-minute and 10-minute for Mingmen (GV 4), bilateral Taixi (KI 3) and Shenshu (BL 23). The even reinforcing-reducing manipulation during which the needles were retained untouched for the duration of treatment, was applied to bilateral Shenmen (HT 7) and Neiguan (PC 6).

2.5.2 Other narrative data

Hiroshi T, *et al*[25] reported a 61-year-old man who suffered from ED for two years since his diagnosis with type 2 diabetes mellitus. Initially, sildenafil citrate, which is a phosphodiesterase type 5 inhibitor, efficiently treated his ED. Nonetheless, the patient's response to this medication deteriorated over time, until he was no longer able to achieve an erection, despite treatment. The authors used manual acupuncture at Zhongliao (BL 33) which induced beneficial effects according to the IIEF5. The patient reported an improvement suggesting that the combination of acupuncture and sildenafil had a good impact. Huang AC, *et al*[27] investigated the interactive activity of electroacupuncture (EA) on the pharmacokinetics of sildenafil and their synergistic effect on penile blood flow in rats. The pharmacokinetic studies confirmed that sildenafil was significantly increased by the administration of low-frequency EA. Moreover, the pharmacodynamic studies using Doppler imaging revealed an elevated blood flow in the rat penis compared with the lower body during combined treatment of sildenafil and low-frequency EA. These data show a potential synergistic therapeutic effect of EA and sildenafil for the treatment of ED.

3 Discussion

3.1 Summary of the main results

A total of seven studies have been included in this systematic review and meta-analysis. According to these studies, sexual dysfunction of non-organic cause is the major cause for ED. The acupuncture treatment duration varied between 6 weeks to 30 months; the 20-minute session was the most common duration of treatment. Regarding quality assessment, there were two studies with an overall risk of bias as low. Acupuncture showed significantly positive results compared with placebo needling; no significant association has been shown between acupuncture and hypnosis as methods for ED treatment; while a statistically significant association was

reported when comparing warm needling with acupuncture. Of particular concern to ED causes, since antidepressant drugs are a significant cause for ED, acupuncture appeared to be an effective method for the treatment of psychogenic ED. The present analysis included five different studies which considered the acupoints used for acupuncture with different acupoints being used as detailed earlier. Combination of acupuncture appeared to show a beneficial effect of acupuncture as adjunctive therapy for ED participants with type 2 diabetes mellitus when compared with other conventional therapies (initially treated with sildenafil citrate). The present review also suggested a synergistic therapeutic effect of EA and sildenafil for the treatment of ED.

3.2 Comparison with previous studies

There are three published review studies on this topic. One included 3 RCTs, including 183 participants with ED[28], comparing acupuncture and psychological therapy with acupuncture and psychological therapy. The included RCTs in this review failed to present a specific therapeutic effect of acupuncture and had methodological flaws as observed by the authors. Another recent study included only a Chinese database and involved 6 RCTs. In these studies, the control treatment included only Chinese herbal medicine and the details of treatment information were not specified[29]. The third review was performed using analyses depending on different comparisons and reported that although the strength of the evidence was weak, the findings revealed there was a potential add-on effect of acupuncture for ED patients. A total of 31.8% of the included trials had reported adverse information from acupuncture. This review provided the latest evidence published of acupuncture for ED[30]. The findings of these three reviews were not finally pooled because of clinical and statistical heterogeneity, which failed to show a definite therapeutic effect of acupuncture for ED. Compared to the previous two reviews, this updated review covered a broader combination of studies, including acupuncture with moxibustion, acupoint injection and different comparisons, and additional outcome assessments.

3.3 Limitations

The present study possesses some limitations of note. Firstly, there is a possibility that relevant research papers were missed (e.g., those not written in English), resulting in selection bias. Secondly, although the Cochrane Library was checked, grey literature in other databases may have been missed. Thirdly, although the review and extraction processes were conducted independently and double-checked, it was still subjective and dependent on the reports of articles, rather than the direct assessment of the studies. The analysis was further limited by the fact that the methods used for the assessment of ED varied between studies. Furthermore, there was limited information in the reported studies regarding the use of medications such as beta-blockers, diuretics, phosphodiesterase inhibitors, testosterone, and antihypertensive agents that may have contributed to ED. Finally, the studies on acupuncture treatment of ED have the deficiency of small sample size and low overall quality, which may affect the authenticity of this review and its conclusions. It is therefore essential that there need to be more rigorous and reasonable multicenter RCTs to explore the clinical efficacy of acupuncture for ED to make the conclusions more objective and reasonable.

Conflict of Interest

There is no potential conflict of interest in this article.

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