Herbal acupuncture for type 2 diabetes: A meta-analysis

SEUNG-WOOK LEE¹*, MIN-HO NAM²* and BYUNG-CHEOL LEE¹

Departments of ¹Clinical Korean Medicine and ²Science in Korean Medicine, Graduate School, Kyung Hee University, Dongdaemun-Gu, Seoul 02447, Republic of Korea

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Abstract. Herbal acupuncture (HA) is a modern adjunctive technique in which natural herbs or biologic substances are injected into acupuncture points. The objective of this systematic review was to evaluate evidence of the effectiveness of HA for type 2 diabetes mellitus (T2DM). Three databases were searched. The included randomized controlled trials (RCTs) evaluated HA in controls and patients with T2DM and reported at least one of the following: Fasting blood glucose (FBG), postprandial (PP2hr) glucose and glycated hemoglobin (HbA1c). In a meta-analysis of seven RCTs (n=598 patients), HA significantly reduced levels of FBG, PP2hr glucose and HbA1c (P<0.0001, P=0.0005 and P=0.004, respectively). There was no significant effect of HA on total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol, or triglyceride level. High degrees of heterogeneity were present for all analyses except HDL-cholesterol and LDL-cholesterol. HA might have a beneficial effect on FBG, PP2hr glucose and HbA1c levels in patients with T2DM; however, because of several limitations, the results are inconclusive. Therefore, additional rigorous RCTs are warranted to overcome the limitations of previous studies.

Introduction

Diabetes is a metabolic syndrome associated with hyperglycemia, obesity, insulin resistance, hypertension, complex dyslipidemia, atherosclerosis and endothelial dysfunction (1-3). The global prevalence of diabetes is increasing. This trend has been attributed to numerous factors, including rapid changes in eating habits, increasingly sedentary lifestyles and genetic factors that determine body fat distribution (4). Appropriate interventions to control and prevent hyperglycemia are central to the management of diabetes (5-9). While drugs, diet and physical activity are key to treatment strategies, there is a growing interest in complementary and alternative medicine for diabetes, not only among the general public, but also among health care providers, researchers and educators (10). Herbal remedies and acupuncture could prove to be effective alternative and adjunctive treatments for diabetes. Recent clinical trials using herbal medicine (11,12) and acupuncture (13,14) have reported possible therapeutic value in diabetes, although these results are unreliable due to small sample sizes and low-quality methodologies.

Herbal acupuncture (HA), also known as pharmacopuncture, acupuncture point injection, acupoint injection, or point injection therapy, is a modern adjunctive technique that utilizes the injection of natural herbs or biologic substances into acupuncture points to promote, maintain or restore health (15,16). To date, this approach has been applied to relieve the pain associated with diseases such as rheumatoid arthritis, osteoarthritis and musculoskeletal disease. Only a small number of studies have been conducted to evaluate pharmacopuncture applications in various diseases, including obesity and digestive diseases (15,17). Thus, this systematic review summarizes the findings related to HA, focusing on its efficacy, safety and possible therapeutic value in the treatment of type 2 diabetes mellitus (T2DM).

Materials and methods

Search strategy. We performed a systematic literature search from January 2000 to February 2015. The following databases were included to identify relevant studies: MEDLINE through Pubmed, the Chinese National Knowledge Infrastructure (CNKI) and the Oriental Medicine Advanced Searching Integrated System (OASIS). The references in all located articles were searched manually for further relevant articles. Key terms were searched as follows: [(Diabetes OR diabetes mellitus) and (pharmacopuncture OR herbal acupuncture OR acupoint injection OR acupuncture point injection)]. CNKI and OASIS are databases from China and the Korea, respectively, so Chinese and Korean terms that corresponded to the original key words were also searched.

Study selection. The current review included all identified RCTs that assessed the efficacy of HA in diabetes treatment.
The quality and language of studies was not regarded at this stage of study analysis. Duplicate papers that reported the same or similar results were excluded. In particular, the same terms in different languages caused a number of paper duplications. Conference abstracts with no subsequent publication and dissertations were disregarded.

Studies that dealt with diabetes patients were included, while studies focusing on type 1 diabetes or other diseases with diabetes were not included. Studies that tested pharmacopuncture as part of a more complex intervention were also included if a control group used the same complex interventions. However, studies with acupuncture injection without herbal medicine were excluded; most of these studies used vitamins, scopolamine, loperamide, mecobalamin or metoclopramide.

In order to analyze efficacy, studies that included data on at least one of the following were included and assessed: Fasting blood glucose (FBG), postprandial (PP2hr) glucose or glycated hemoglobin (HbA1c). In the included studies, FBG, PP2hr glucose, HbA1c, total cholesterol, high-density lipoprotein (HDL) cholesterol, low-density lipoprotein (LDL) cholesterol and triglyceride (TG) levels were assessed.

Data extraction and quality assessment. Three reviewers independently selected relevant studies based on title and abstract. Full text versions of potentially eligible studies were retrieved and reviewed separately based on the aforementioned criteria. Data were extracted from original articles by the three reviewers. The results of each study were abstracted by a single reviewer and reassessed by the others. The Cochrane risk of bias assessment was used to evaluate methodological quality (18). Disagreements concerning the eligibility for inclusion were resolved through discussion.

Data synthesis. In order to summarize the effects of HA on each outcome, the risk estimates were abstracted. The standardized mean difference and 95% confidence interval (CI) were calculated using Review Manager version 5.3 (The Cochrane Collaboration, Oxford, UK). P<0.05 was considered to indicate a statistically significant result. The variance of change was imputed using a correlation factor of 0.4. Data was then pooled across studies, statistical heterogeneity was evaluated using χ² and Higgins I² tests and P<0.10 was considered significant. A random effects model was used if heterogeneity across studies was present.

Results

Description of studies. A total of 271 potentially relevant articles from the CNKI database were considered. After screening the abstracts and titles, 254 articles were excluded (Fig. 1). A detailed evaluation of the remaining 17 articles was performed by reading full texts, which determined that eight of the articles were duplicates. Full texts of two articles were not available. Consequently, seven RCTs met our inclusion criteria and were included in this review. The key data are summarized in Table I. All of the studies were performed and published in China, and reported positive effects of HA on T2DM.

Four studies used Western medical treatments such as gliclazide (19), metformin (20), glibenclamide (21) and insulin potentiation therapy (22) for both HA and control groups. One study (20) used oral administration of Yiqi Zishen decoction in addition to HA. These RCTs studied the effect of HA as an adjuvant therapy. While most of the studies evaluated HA effects compared to those of Western medical treatments, one study tested HA vs. Xiaoke Wan, a traditional Chinese medicine (TCM) decoction (23), and another tested HA vs. life-style interventions (24). Finally, one study tested the effect of HA treatment with various controls, such as saline injection into acupoints and muscle injection of herb extracts (21).

The seven included RCTs evaluated 628 (mean sample size, 90) patients with T2DM. A total of 300 patients received HA treatment for a range of 14 to 40 days (mean, 27 days). The outcome measures of these trials were FBG, PP2hr glucose, HbA1c, insulin resistance index, plasma insulin, total, HDL and LDL cholesterol, and TG. Baseline comparisons of major parameters related to diabetes were reported in all studies.

Herbal acupuncture treatments. Three types of herb extract were used for HA treatment in the reviewed RCTs: Astragalus propinquus (also known as Astragalus membranaceus), Salvia miltiorrhiza and a mixture of Angelica sinensis and vitamin B12. A. propinquus was used in four studies and S. miltiorrhiza was used in three studies. One study used these two herb extracts but alternated the herbs in the included patients. A mixture of A. sinensis and vitamin B12 was used in one study.

Six studies used multiple acupoints, whereas one study used a single acupoint (Table II) (21). There were 18 target acupoints, including 17 meridian points and one extra point. The most commonly used point was SP6, and the next most common was ST36. Among 18 acupoints, five were located on the lower extremities (ST36, SP6, SP9, SP10 and KI13), two on the upper extremities (LI4 and LI11), three on the abdomen (CV4, CV6 and CV12) and the remaining on the back (BL13, BL17, BL20, BL21, BL22, BL23, BL52 and Yishu). The majority of the acupoints were related to the gastrointestinal tract (ST36, SP6, SP9, SP10, LI4, LI11, CV4, CV6, CV12, BL20 and BL21) or kidneys (KI13, BL23 and BL52). All RCTs stated the rationale for acupuncture point selection from TCM theory.

Overall effects of herbal acupuncture. Seven RCTs (19-25) assessed the effects of HA on FBG, five RCTs on PP2hr
| Study                  | Country (language) | Patients (n) | Mean patient age ± standard deviation | Diagnosis       | Intervention                          | Additional therapy (both groups) | Outcome measures | Principal findings |
|-----------------------|-------------------|-------------|----------------------------------------|----------------|---------------------------------------|---------------------------------|------------------|--------------------|
| Wang and Wang (19)    | China (Chinese)   | HA: 30, CON: 30 | HA: 54.8±9.3, CON: 62.4±10.7           | Type 2 diabetes | Astragalus propinquus                | NA                              | 1) LC, Gliclizide 40-80 mg, 2) Gliclizide 0.25-0.5 mg (obese patients) | FBG, PP2hr glucose, HbA1C, FINS, TC, LDL-C, HDL-C, TG FBG, urine glucose |
| Zhang (23)            | China (Chinese)   | HA: 30, CON: 30 | HA: 57.4±9.6, CON: 56.7±9.76           | Type 2 diabetes | Salvia miltiorrhiza                  | Xiaoke Wan (3 times/day)        | NA               | NA                 |
| Liu et al (25)        | China (Chinese)   | HA: 50, CON: 48 | HA: 48.2±8.6, CON: 47.2±11.8           | Type 2 diabetes | Angelica sinensis and Vitamin B12   | Metformin 0.5 g (2 times/day)   | NA               | NA                 |
| Geng et al (24)       | China (Chinese)   | HA: 45, CON: 45 | HA: 51.98±5.73, CON: 51.47±6.12        | Pre-diabetes    | Astragalus propinquus                | NA                              | LC               | NA                 |
| Xie et al (20)        | China (Chinese)   | HA: 100, CON: 100 | HA: 49±8, CON: 47±9                    | Type 2 diabetes | 1) Yiqi Zishen with Astragalus propinquus 2) Salvia miltiorrhiza 1) and 2) used by turns | NA                              | 1) Metformin 0.25 g, 2) LC | FBG, PP2hr glucose, HbA1C, GH, TG |
| Wang et al (22)       | China (Chinese)   | HA: 30, CON: 30 | HA: 51±5, CON: 47±6                    | Type 2 diabetes | Salvia miltiorrhiza                 | NA                              | Insulin potentiation therapy | FBG, PP2hr glucose, FFA, HDL-C, LDL-C, CRP, HOMA-IR, HOMA-islet |

Table I. Summary of randomized clinical trials of HA for type 2 diabetes.
**Table I. Continued.**

| Study | Country (language) | Intervention | Mean patient age ± standard deviation | Patients (n) | Additional therapy (both groups) | Principal finding(s)* | Outcome measures | Other measures | Diagnoses | Subgroup analysis for outcomes of HA was performed based on the control types (sham treatment, conventional treatment or lifestyle intervention). |
|-------|-------------------|-------------|-------------------------------------|-------------|----------------------------------|-----------------------|-----------------|--------------|-----------|---------------------------------------------------------------|
| Li et al (21) | China (Chinese) | HA | 52.7±4.69 | 15 | HA (mus): | Fasting blood glucose, PP2hr glucose, HbA1c, FBG, GLU, HbA1c, CRP, CRP, C-reactive protein, HOMA-IR, GSP, 2h INS, FINS, TC, LDL-C, HDL-C, fasting insulin, HOMA-IR, HOMA-βcell function | FBG, PP2hr glucose, HbA1c, FBG, HbA1c | HA (mus): | Type 2 diabetes | No unanalyzed patients or dropouts for all studies. For these parameters, HA showed more significant improvement than control group(s). | No unanalyzed patients or dropouts for all studies. For these parameters, HA showed more significant improvement than control group(s). |
| LEE et al | China (Chinese) | HA (sal) | 52.5±4.69 | 15 | HA (sal): | Fasting blood glucose, PP2hr glucose, HbA1c, FBG, GLU, HbA1c, CRP, CRP, C-reactive protein, HOMA-IR, GSP, 2h INS, FINS, TC, LDL-C, HDL-C, fasting insulin, HOMA-IR, HOMA-βcell function | FBG, PP2hr glucose, HbA1c, FBG, HbA1c | HA (mus): | Type 2 diabetes | No unanalyzed patients or dropouts for all studies. For these parameters, HA showed more significant improvement than control group(s). | No unanalyzed patients or dropouts for all studies. For these parameters, HA showed more significant improvement than control group(s). |

*No unanalyzed patients or dropouts for all studies. For these parameters, HA showed more significant improvement than control group(s).*
Table II. Herbal acupuncture intervention details.

| Study          | Acupuncture points | Injection methods                  |
|----------------|--------------------|-----------------------------------|
| Wang and Wang (19) | S6, BL20, Yishu    | Bilateral, 1.5 ml, q.d. for 20 days |
| Zhang (23)      | ST36, K13, S6, P10, L14, BL20, BL21, BL22, BL23, BL13, Yishu | Bilateral, 1 ml, 2 sets of q.o.d. for 20 days with 1-week interval |
| Liu et al (25)  | ST36, SP6, K13, Yishu | Unilateral in turn, 0.5 ml, 2 sets of q.o.d. for 20 days with 5-day interval |
| Geng et al (24) | 1) CV12, ST36, Yishu | Alternating applications of 1) or 2) were applied. 3 sets of q.o.d. for 10 days with 5-day intervals |
| Xie et al (20)  | ST36, SP6, LI11, BL23, CV6 | 0.5 ml, q.d. for 4 weeks |
| Wang et al (22) | 1) left SP9, right ST36 | 1 ml, q.d. for 2 weeks. |
| Li et al (21)   | SP6                | Bilateral, 2 ml, every 3 days for 18 days |

q.d., every day; q.o.d., every other day.

A. FBG (mmol/l)

| Study name     | Sample size | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|----------------|-------------|---------|--------------------|--------|------------------------|------------------------|
| Liet al, 2002  | 15 15       | 10.6    | 2.22 [1.17, 3.27]   |        |                        |                        |
| Wang et al, 2012 | 30 30   | 13.0    | 2.20 [1.36, 3.04]   |        |                        |                        |
| Xie et al, 2012 | 100 100   | 16.0    | 1.30 [0.83, 1.77]   |        |                        |                        |
| Subtotal       |             |         | 1.49 [0.63, 2.32]   |        |                        |                        |

Heterogeneity: Tau^2 = 0.39; Chi^2 = 44.74, df = 6 (P < 0.0001); I^2 = 87%

B. PP2hrs glucose (mmol/l)

| Study name     | Sample size | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|----------------|-------------|---------|--------------------|--------|------------------------|------------------------|
| Li et al, 2000  | 15 15       | 9.3     | 4.82 [2.52, 6.52]   |        |                        |                        |
| Wang et al, 2012 | 30 30   | 17.3    | 2.42 [1.55, 3.29]   |        |                        |                        |
| Xie et al, 2012 | 100 100   | 23.3    | 1.10 [0.54, 1.66]   |        |                        |                        |
| Subtotal       |             |         | 1.80 [0.72, 2.87]   |        |                        |                        |

Heterogeneity: Tau^2 = 0.59; Chi^2 = 36.78, df = 4 (P < 0.0001); I^2 = 86%

C. HbA1c (%)

| Study name     | Sample size | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|----------------|-------------|---------|--------------------|--------|------------------------|------------------------|
| Li et al, 2000  | 15 15       | 16.6    | 2.30 [1.05, 3.25]   |        |                        |                        |
| Wang et al, 2012 | 30 30   | 22.9    | 0.97 [0.34, 1.60]   |        |                        |                        |
| Xie et al, 2012 | 100 100   | 29.0    | 0.77 [0.02, 1.52]   |        |                        |                        |
| Subtotal       |             |         | 1.13 [0.16, 2.09]   |        |                        |                        |

Heterogeneity: Tau^2 = 0.26; Chi^2 = 20.17, df = 3 (P = 0.0002); I^2 = 85%

Test for overall effects: Z = 2.85 (P = 0.004)

Figure 2. Forest plot depicting the meta-analysis results of randomized controlled trials that evaluated the effects of herbal acupuncture on (A) FBG, (B) PP2hrs glucose and (C) HbA1c. FBG, fasting blood glucose; PP2hrs, Postprandial 2 h; HbA1C, glycated hemoglobin; CI, confidence interval.
in a total of 145 cases; while one study (22) reported two cases of mild hypoglycemia out of a total of 30 cases. None of the studies reported any serious adverse events resulting from HA treatment.

**Discussion**

To our knowledge, this is the first systematic review and meta-analysis of RCTs that examines the effectiveness of HA for managing patients with T2DM. The results from meta-analysis indicated that HA may have a beneficial effect on FBG, PP2hr glucose and HbA1c levels in patients with T2DM, and suggest that HA may have clinical applications in the management of T2DM.

Understanding the respective efficacies of herbal remedies and acupuncture stimulation is necessary to understand the overall efficacy of HA because HA is a combination of these two approaches. HA therapy for improving conditions of patients with T2DM primarily used *A. propinquus*, *S. miltiorrhiza* and *A. sinensis*. *A. propinquus* is the most commonly used herb in anti-diabetic TCM decoctions and is known to contain rich anti-diabetic compounds, such as polysaccharides, saponins and flavonoids (26,27). It has been reported to reduce complications of diabetes such as increased

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**A. Total Cholesterol (mmol/l)**

| Study name          | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|---------------------|---------|--------------------|--------|--------------------------|--------------------------|
| Wang et al. 2002    | 30      | 30                 | 13.3   | 0.48 [-0.11, 1.07]       |                          |
| Wang et al. 2012    | 30      | 30                 | 29.5   | -0.10 [-0.33, 0.13]      |                          |
| Xie et al. 2012     | 100     | 100                | 21.8   | 0.60 [0.23, 0.97]        |                          |
| **Subtotal**        |         |                    |        |                          |                          |
| **Total**           |         |                    |        |                          | 0.18 [-0.09, 0.44]       |

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**B. HDL Cholesterol (mmol/l)**

| Study name          | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|---------------------|---------|--------------------|--------|--------------------------|--------------------------|
| Wang et al. 2002    | 30      | 30                 | 17.6   | -0.06 [-0.20, 0.18]      |                          |
| Wang et al. 2012    | 30      | 30                 | 9.8    | -0.05 [-0.22, 0.12]      |                          |
| **Subtotal**        |         |                    |        |                          |                          |
| **Total**           |         |                    |        |                          | -0.08 [-0.17, 0.01]      |

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**C. LDL Cholesterol (mmol/l)**

| Study name          | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|---------------------|---------|--------------------|--------|--------------------------|--------------------------|
| Wang et al. 2002    | 30      | 30                 | 27.6   | 0.04 [-0.24, 0.32]       |                          |
| Wang et al. 2012    | 30      | 30                 | 34.5   | 0.30 [0.07, 0.53]        |                          |
| **Subtotal**        |         |                    |        |                          | 0.18 [-0.07, 0.44]       |
| **Total**           |         |                    |        |                          | 0.11 [-0.09, 0.31]       |

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**D. Triglyceride (mmol/l)**

| Study name          | Control | Herbal Acupuncture | Weight | Mean Difference, 95% CI | Mean Difference, 95% CI |
|---------------------|---------|--------------------|--------|--------------------------|--------------------------|
| Wang et al. 2002    | 30      | 30                 | 17.0   | 0.46 [-0.05, 0.97]       |                          |
| Wang et al. 2012    | 30      | 30                 | 29.7   | -0.10 [-0.33, 0.13]      |                          |
| Xie et al. 2012     | 100     | 100                | 20.9   | 0.70 [0.27, 1.13]        |                          |
| **Subtotal**        |         |                    |        |                          | 0.33 [-0.22, 0.87]       |
| **Total**           |         |                    |        |                          | 0.25 [-0.05, 0.56]       |

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![Figure 3. Forest plot depicting the meta-analysis results of randomized controlled trials evaluating the effects of herbal acupuncture on (A) total cholesterol, (B) HDL cholesterol, (C) LDL cholesterol and (D) triglyceride. HDL, high density lipoprotein; LDL, low density lipoprotein; CI, confidence interval.](image-url)
urinary albumin excretion, plasma creatinine and blood urea nitrogen levels (28), as well as diabetic nephropathy (29,30). S. miltiorrhiza has also shown a significant anti-diabetic effect in animal studies; for instance, it decreases FBG and increases the insulin sensitivity index (31,32). It is effective for preventing and treating diabetic complications such as myocardial malfunction (33,34) and diabetic retinopathy (35). A. sinensis is also one of the most frequently used herbs for diabetes in China (36) due to evidence of its anti-diabetic properties (37). These previous findings align with the results of studies in the current review, which showed improvement in insulin sensitivity and microvascular diseases in animal and human studies following HA treatment.

In the clinical studies analyzed in this review, acupoints SP6, ST36, BL23, Yishu, BL20 and KI13 were selected for use in multiple studies. Classical (manual) acupuncture and electroacupuncture at these acupoints have previously been reported to be effective for improving diabetic conditions. For example, Wang et al. reported that manual acupuncture at multiple acupoints including SP6, BL23, BL20, Yishu and KI13 positively regulates glucose and lipid metabolism in T2DM patients (38). Additionally, electroacupuncture at ST36, BL20, BL23 and SP9 has been reported to reduce HbA1c and PBG2 h levels in impaired glucose tolerance patients (39). Similarly, Peplow and Baxter demonstrated that electroacupuncture at ST36 is beneficial for lowering blood glucose in T2DM rats (40). Altogether, these results suggest that the therapeutic effect of HA therapy on T2DM is attributable to a combination of anti-diabetic herbs and anti-diabetic acupuncture stimulation.

There were several limitations to the current review. First, the intervention methods used in the studies were not identical, although the acupoints SP6 (six studies), ST36 (five studies), BL23 (four studies) and Yishu (four studies) were typically used, and A. propinquus (four studies) and S. miltiorrhiza (three studies) were typically used as herbal material. Second, three different types of control group were used; however, HA showed positive effects regardless of the control group type. Third, although all of these studies were considered to have relatively homogenous T2DM patients, statistical pooling was difficult due to a lack of sufficient raw data. Another possible source of bias is the fact that the included trials were conducted in China. Fourth, the total number of trials included in our review and meta-analysis, and the total sample size, were too small to allow for definitive conclusions.

Nevertheless, the review demonstrated a comprehensive search strategy, included RCT designs only, and used suggested methods for systematic reviews of interventions for T2DM. Future studies of HA in T2DM should be of adequate sample size to allow for definitive conclusions. Third, although all of these studies were considered to have relatively homogenous T2DM patients, statistical pooling was difficult due to a lack of sufficient raw data. Another possible source of bias is the fact that the included trials were conducted in China. Fourth, the total number of trials included in our review and meta-analysis, and the total sample size, were too small to allow for definitive conclusions.

Based on the currently available literature, HA seems to have a beneficial effect on FBG, PP2hr glucose and HbA1c levels in patients with T2DM. However, HA does not have a statistically significant effect on lipid profiles. Caution should be exercised in applying the results of this analysis to patient care due to the limited quantity and quality of evidence regarding HA as a treatment for T2DM.

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