Self-Administered Moxibustion of Dyslipidemia in Diabetic Patients: A Randomized, Double-Blind, Controlled Trial

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Received 4 March 2022 • Revised 30 March 2022 • Accepted 15 April 2022 • Published online 1 May 2022

Abstract:

Background: Dyslipidemia is a common disease and a public health problem. Dyslipidemia is one of the leading risk factors of cardiovascular diseases that reduce quality of life, and cause premature deaths. Acupuncture and Moxibustion is a part of Traditional Chinese Medicine that has much research for their effectiveness in lowering blood lipid levels.

Objective: We aimed to study the effectiveness of Fenglong (ST 40) acupoint in lowering blood lipid level.

Methods: A randomized controlled clinical trial in 30 diabetes type II with dyslipidemia subjects was performed. Subjects were randomized into 2 group with 15 subjects in each group. The case group received box-moxibustion at Fenglong (ST 40) acupoint bilaterally and the control group received box-moxibustion at Shangjuxu (ST 37) bilaterally for 8 weeks under the instruction and supervision of a medical acupuncturist and a TCM practitioner for how to locate and apply the device. All subjects were prescribed to continue their individual antidiabetic drugs and take regular diet as usual. Subjects were assessed at the beginning and 8 weeks later. Fasting blood sugar (FBS) levels were also assessed.

Results: A significant reduction of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), and FBS were observed only in cases.

Conclusion: Self-administration moxibustion in only Fenglong (ST 40) acupoint is effective in lowering TC and LDL-C.

Keywords: Acupuncture, Moxibustion, Dyslipidemia

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GMSMJ 2022; 2 (2): 109-120

Background

Dyslipidemia is a common disease and a public health problem. Dyslipidemia is one of the leading risk factors of cardiovascular diseases that reduce quality of life, and cause premature deaths.[1] Statin drugs are needed to treat dyslipidemia if lifestyle changes do not work. Statins are prescribed for such treatment in order to reduce LDL-C levels, but statins can cause some adverse effects, which are intolerable by some patients such as elevated liver enzymes, rhabdomyolysis, etc.[2] Serious side effects such as intracerebral hemorrhage, cancer can eventually develop.[2,3] Moreover, in observational studies by Unai et al., clinical trials and meta-analyses indicated an increased risk of developing new-onset type 2 diabetes mellitus (T2DM) after long-term statin treatment. It has been shown that statins can impair insulin sensitivity and secretion by pancreatic β-cells and increase insulin resistance in peripheral tissues.[4]

Acupuncture & Moxibustion is a part of Traditional Chinese Medicine (TCM) that has much research for their effectiveness in lowering blood lipid levels.[5,6] Liu et al. analyzed the frequency of acupoints employed in 65 research articles by retrieving the main database of Chinese and English version clinical research literature on the acupoints for hyperlipidemia treated with acupuncture and moxibustion. It was found out that the first five top acupoints with high frequency use include Fenglong (ST 40), Zusanli (ST 36), Sanyinjiao (SP 6), Neiguan (PC 6) and Tianshu (ST 25). No any article included Shangjuxu (ST 37) within the composition of the acupoints.[7] It would be desirable to control dyslipidemia by safe and effective treatment modality. Among different methods, acupuncture & moxibustion is one of the most popular complementary treatments. Acupuncture & moxibustion is performed by stimulating particular points on the skin called acupoints. Thus, we aimed to perform a randomized controlled clinical trial in diabetic patients who suffer from dyslipidemia in order to examine its effectiveness in changing the lipid profile by moxibustion.

Figure 1 Warm-needling acupuncture

Figure 2 Box-moxibustion

Material and Methods

This was a prospective double-blind randomized controlled trial that was conducted between case and control group. Diabetic patients at DM clinic, Lansak hospital, Uthai Thani, Thailand, that was diagnosed dyslipidemia from blood test screening. Dyslipidemia in diabetic patient is defined as LDL-C level from 100 mg/dL and up.

Patients who had a history of bleeding disorders or were receiving anticoagulant or anti-platelet medications, had epilepsy, uncontrolled hypertension, diabetic neuropathy and active dermatological lesions at the area of moxibustion, as well as pregnant women or those patients whose mental disabilities made their participation in the study difficult were excluded from the study.

Written informed consents were obtained from all participants before their enrollment into the study. Participants were informed that they would be randomly assigned to one of the 2 study groups below by a statistician who was not involved in the implementation phase of the study using a Block of Two Randomization.

The TCM practitioners in Lansak hospital did not have any idea about using acupuncture & moxibustion to treat dyslipidemia before that, because they were new graduate and no lesson was taught for this disease, they just practice in very common diseases that known to be of help, so both doctors and participants were concealed about which acupoint was belong to real or sham. The moxibustion boxes were the same model with the width of the base measured 7.8 cm from both outer walls.

The study was done according to the principles of the Declaration of Helsinki. The study protocol was approved by the ethics committee of the Medical Science Ethics Committee of Dhurakij Pundit University.

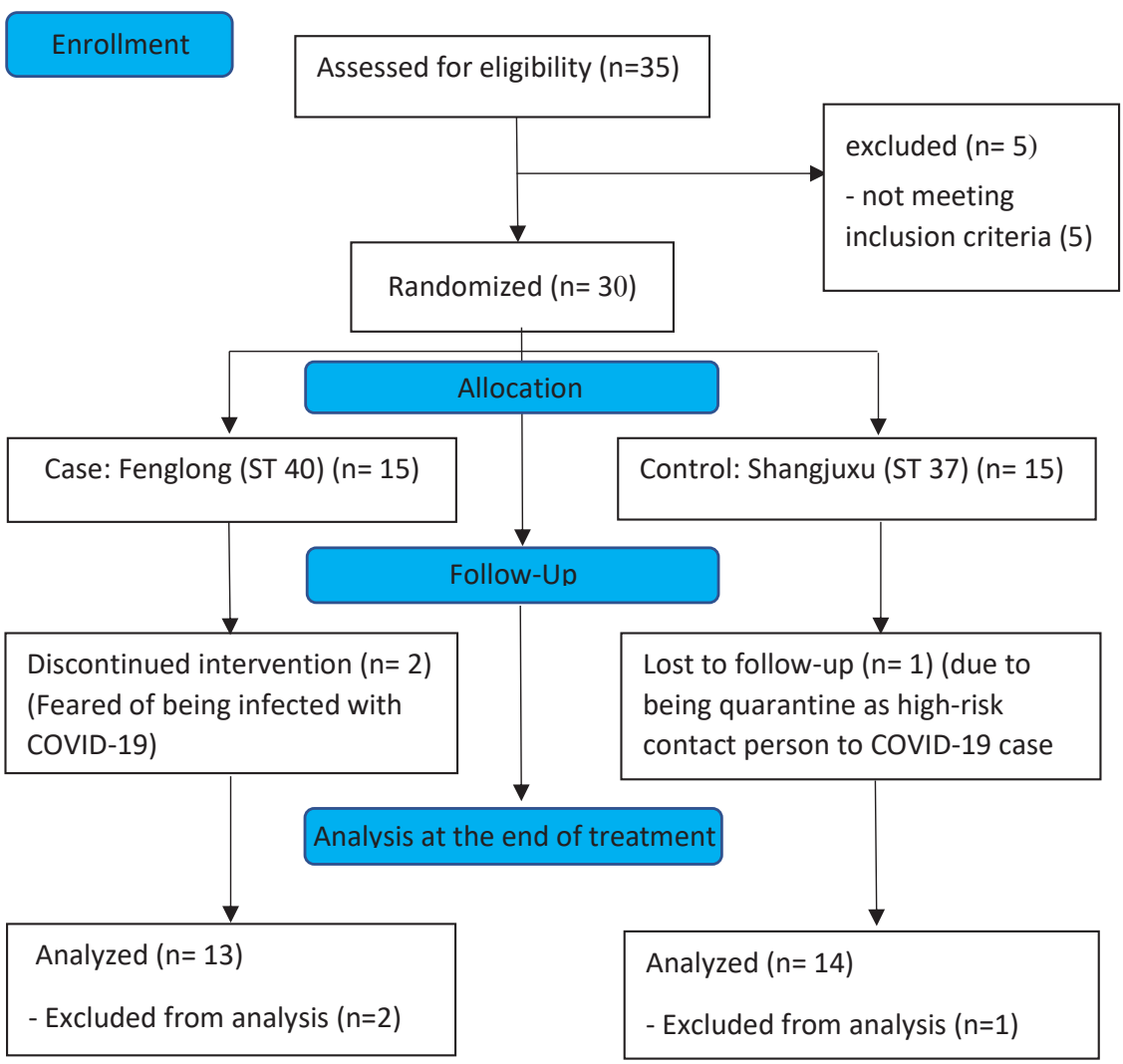

Figure 3 Flow diagram

Study Design and Subjects

Thirty subjects aged between 35-60 years old with LDL-C level 100-189 mg/dL, who denied to start with statin drugs firstly were recruited in this study, they were requested to visit twice a week for eight weeks of the study. Lipids profile and fasting blood sugar were measured before and after the experiment.

Sample Size Estimation and Statistical Analysis

The sample size was calculated based on a study of Rerksuppaphol & Rerksuppaphol.[6] Stata Software, Version 12.0 was used to calculate sample size, Estimated sample sizes for a two-sample means, based on the two-sided test, 5% α error and 90% power, the number of patients needed for the study was calculated to be 10 for each group. We considered p-value of less than 0.05 to establish the level of significance. All statistical analyses and graphics were performed using Stata Software, Version 15.0 (StataCorp). Data was presented as number, percentage and mean ± SD.

Moxibustion method

In the case group. Bilateral Fenlong (ST 40) on both lower legs were selected. The subjects were instructed by a medical acupuncturist and a TCM practitioner to locate the acupoints and strap the device correctly while they were sitting on bed and flexing the knees (Figure 1). After moxa stick (Han Yi) was lighted up, it was inserted into the hole of the moxibustion box (Figure 2). Subjects then placed the cap on the box body and adjusted the deepness needed to maintain the heat as much as they could tolerate. Each moxibustion treatment lasted for 20 minutes. After finishing the treatment, the device was released and the remaining moxa stick was pressed in a stainless-steel container to put out the flame of moxa stick and for further uses. All subjects were asked to receive two treatment sessions per week for a total of 8 weeks. During the treatment, subjects were allowed to stretch their knees or lie down for relaxation. In the control group, bilateral Shangjuxu (ST 37) on both lower legs were used and all the procedures were in the same manner as the case group. Adverse effects and satisfaction rate were evaluated. Although both Fenglong (ST 40) and Shangjuxu (ST 37) acupoints are in the Stomach Meridian and located between the groove of Tibia and Fibula (the passage of the meridian), they only have common effects on gastrointestinal tract disorder and local effects nearby. Fenglong (ST 40) is a special acupoint that can reduce all kinds of phlegm, but not for Shangjuxu (ST 37). Adverse effects and satisfaction rate were evaluated.

Anthropometric Measurements. Body weight (BW) and height were measured. The body mass index (BMI) was calculated as weight (kg) divided by height in meters squared (m^2). The distances between the two acupoints in each subject were measured in straight longitudinal line perpendicular to the foot with the range of 4.9 to 6.0 cm. (min.-max.). As a result, the two acupoints of each subject were not covered within a moxibustion box when applied to the individual of the two groups given the distance from the center of the moxibustion hole to the outer wall is 3.9 cm.

Collection of Blood Samples. Blood samples were taken from each patient for analysis after a 12-hour fasting, 2 times during the study (at the beginning and 8 weeks later). After venipuncture, blood samples were collected into Vacutainer tubes.

Biochemical Analysis. Lipid profile composed of total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-C), and low-density lipoprotein cholesterol (LDL-C) including fasting blood sugar (FBS) level were measured at the laboratory of Lansak Hospital, which was certified by Department of Medical Science, Ministry of Public Health, Thailand.

Statistical Analysis. Data was checked for normality and homogeneity of variances. Values were expressed as percentage and mean ± SD. Independent t-test was analyzed for comparison between two groups. A two tailed P value of < 0.05 was considered statistically significant. Per protocol analysis was done for the better reflection to the effect of treatment with adequate statistical power.

Evaluation. The ability to locate acupoint and apply the device was correctly evaluated by our staffs.

Results

Demographic Data. Thirty participants fulfilled the inclusion criteria. Then, they were divided into 2 groups (cases and controls), by Block of Two Randomization, including 15 subjects in each group. By the end of the study, 3 subjects withdrew from the study; two subjects in case group declined to continue treatment for fear of COVID-19. One subject in control group was not available to get her blood sample after cessation at 8-week treatment given she was requested to self-quarantine as a high-risk contact person to a COVID-19 patient, so 27 participants completed the study (Figure 3). The analysis showed that sex, age, and BMI were not significantly different between cases and controls ($P > 0.05$) as shown in Table 1.

Table 1 Comparison of characteristics between case group and control group with Chi-square and Independent t-test

Group	Case	Control	Statistic used	p-value
Sex (M: F) n (%)	4:9 (30.8: 69.2)[a]	6:8 (42.9:57.1)[a]	0.695[c]	0.402
Age	52.77 (7.42)[b]	55.57 (5.45)[b]	-1.125[d]	0.271
Height	159.77 (7.34)[b]	160.07 (7.65)[b]	-0.105[d]	0.918
BW	74.10 (19.46)[b]	75.26 (16.45)[b]	-0.167[d]	0.868
BMI	29.04 (7.72)[b]	29.19 (4.86)[b]	-0.060[d]	0.953

M = Male; F = female; [a] Presented as n and percentage in proportion; [b] Presented as mean (SD); [c] Chi-square test; [d] Independent t-test

Comparison of lipid profile and FBS levels between the case and control Group at baseline. The analysis showed that lipid profile and FBS were not significantly different between cases and controls ($P>0.05$). Biochemical levels of participants were summarized in Table 2.

Table 2 Comparison of the mean (SD) of FBS, TC, TG, HDL-C and LDL-C between case group and control before study with independent t-test

Group	Case	Control	p-value
FBS	176.69 (66.81)	155.14 (59.92)	0.385
TC	209.08 (52.02)	222.57 (41.07)	0.460
TG	203.46 (103.70)	160.93 (73.62)	0.228
HDL-C	44.15 (9.13)	48.43 (7.53)	0.195
LDL-C	137.38 (36.20)	141.93 (38.66)	0.756

FBS: fasting blood sugar; TC: total cholesterol; TG: triglyceride; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol

Comparison of the changes in different parameters between the case and control group. The analysis showed that TC, LDL-C, and FBS were significantly reduced ($P<0.05$). (Table 3)

Table 3 Comparison of the mean (SD) of FBS, TC, TG, HDL-C and LDL-C before and after in case group at the end of the study with Paired t-test

Group	Before	After	p-value
FBS	176.69 (66.81)	121.54 (31.65)	0.047
TC	209.08 (52.02)	174.54 (28.42)	0.018
TG	203.46 (103.70)	187.69 (119.04)	0.437
HDL-C	44.15 (9.13)	42.46 (13.54)	0.529
LDL-C	137.38 (36.20)	98.85 (21.69)	0.000

FBS: fasting blood sugar; TC: total cholesterol; TG: triglyceride; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol

Comparison of the changes in parameters before and after the intervention within the control group. The analysis showed that there was no significant change in any of the parameters ($P > 0.05$). (Table 4)

Table 4 Comparison of the mean (SD) of FBS, TC, TG, HDL-C and LDL-C within control group at the end of the study with Paired t-test

Control	Before	After	p-value
FBS	155.14 (59.92)	164.50 (78.39)	0.515
TC	222.57 (41.07)	221.71 (44.95)	0.930
TG	160.93 (73.62)	155.07 (72.45)	0.746
HDL-C	48.43 (7.53)	46.36 (8.49)	0.234
LDL-C	141.93 (38.66)	144.36 (46.72)	0.795

FBS: fasting blood sugar; TC: total cholesterol; TG: triglyceride; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol

Comparison of the changes in different parameters between the case and control group. In the case group, significant changes were found in TC (P = 0.003) and LDL-C (P = 0.004) but not in the control group. However, the other parameters namely TG, HDL-C, and FBS were not significantly changed between the case and control group (P > 0.05). (Table 5).

Table 5 Comparison of the mean (SD) of FBS, TC, TG, HDL-C and LDL-C between two groups at the end of the study with Independent t-test.

Group	Case	Control	p-value
FBS	121.54 (31.65)	164.50 (78.39)	0.078
TC	174.54 (28.42)	221.71 (44.95)	0.003
TG	187.69 (119.04)	155.07 (72.45)	0.394
HDL-C	42.46 (13.54)	46.36 (8.49)	0.375
LDL-C	98.85 (21.69)	144.36 (46.72)	0.004

FBS: fasting blood sugar; TC: total cholesterol; TG: triglyceride; HDL-C: high-density lipoprotein cholesterol; LDL-C: low-density lipoprotein cholesterol

The ability to locate acupoint and apply device. The subjects could locate acupoint and apply the device correctly at the range between 3 to 5 session of the experiment.

Discussion

The study showed that there is no significant difference in sex, age, BMI, and blood chemistry between the two groups (P > 0.05). When compared the result before and after intervention within the case group, a significant reduction in FBS (P = 0.047), TC (P = 0.018), and LDL-C (P = 0.000) were observed, whilst in the control group, no significant change in the blood chemistry levels (all P > 0.05) was observed. When compared the result after intervention between two groups, there were significant reductions in TC (P = 0.003) and LDL-C (P = 0.004) in cases, but no significant reduction in FBS level. Table 3-5 summarizes the levels of the parameters.

Consistent with our results, which indicated the efficacy of moxibustion therapy for reduction of lipid parameters in cases compared to controls, Liu et al. performed a meta-analysis on comparison of the effects of moxibustion and lipid-lowering drugs for primary hyperlipidemia. He concluded that in comparison with statins and fibrates, moxibustion had advantages in lowering TC and LDL-C.[7,8] Other studies had found the same result as ours regarding the reductions in TC and LDL-C. Rerksuppaphol and Rerksuppaphol performed a randomized controlled trial to compare the efficacy of electroacupuncture (EA) of body acupoints and Fenglong (ST 40) in controlling serum lipids in patients with dyslipidemia. Patients were randomized into two treatment groups (body acupuncture with 20 acupoints group and Fenglong group) and a control group. At the end of the treatment (week 8), TC and LDL-C in both active treatment groups were significantly lower than their baseline levels; meanwhile, in the control group, TC and LDL-C at the end of treatment were higher than baseline ($P < 0.01$). There was no statistically significant difference between TC and LDL-C levels between body acupuncture and Fenglong groups.[6] Li and Wang also reported significant changes in TC and LDL-C in acupuncture therapy compared with control subjects.[9]

Some studies reported the inability of acupuncture to increase HDL-C level and some other do not. M.T. Cabioglu and Ergene reported significant decreases of TG, TC, and LDL-C, but no changes in HDL-C in electroacupuncture group compared to controls. It had been suggested that these changes in lipid metabolism might be caused by increase in the serum beta-endorphin levels.[10]

While many studies showed favorable outcome for 4 major parameters of lipid profile (decrease of TG, TC, LDL-C, and increase of HDL-C). Abdi et al. performed a randomized controlled clinical trial in obese subjects to examine the effectiveness of body acupuncture on lipid profile and other parameters. Subjects received acupuncture for 6 weeks in combination with a low-calorie diet for a total of 12 weeks. After 6 weeks, significant reductions of TC ($P<0.001$), TG ($P<0.001$), HDL-C ($P<0.05$), and LDL-C ($P < 0.001$) were observed in authentic (cases) acupuncture subjects. In the sham (controls) acupuncture group, TC ($P < 0.01$), HDL-C ($P < 0.001$), and LDL-C ($P < 0.01$) were reduced significantly. At week twelfth, in the authentic group, there was significant reduction of TG ($P < 0.01$) and LDL-C ($P < 0.001$) but increased in HDL-C ($P<0.001$). In the control group, significant reduction was observed in TG ($P < 0.01$) and LDL-C ($P < 0.05$) but increase in HDL-C ($P < 0.001$). This meant both acupuncture and diet control played roles in significant changes in lipid profile and produced a sustained effect, which was more significant in cases compared to controls.[11] Yuan et al. reported a clinical study in obese adults with dyslipidemia, which participants were categorized by TCM syndrome differentiation into 6 different types. Acupoints were selected for acupuncture and moxibustion according to the syndrome differentiation, with additional warm-needling acupuncture in 2 acupoints being applied to the 3 of the 6 types (those with dampness or deficient syndrome). Treatment was performed every other day for 3 months to examine lipid profile before and after the study, it revealed that the mean difference of TC, TG, and LDL-C decreased significantly ($P<0.01$), and HDL-C increased significantly ($P < 0.01$).[12] The same result was obtained in other study, Huang et al. reported study in cases of severe obesity complicated with hyperlipidemia by categorized the subjects into 6 types of syndrome differentiation which was similar to Yuan et al. By performed warm-needling acupuncture

30 minutes every other day for 3 months.[13]

Chen et al. recruited 76 cases of hyperlipidemia patients to be treated with moxibustion at the same acupoints in different time, 3 times per week for 8 weeks. They were randomly divided into three groups: 10-minute group (group A, 25 cases), 20-minute group (group B, 25 cases) and 30-minute group (group C, 26 cases). Blood lipid and fasting blood glucose were observed before and after treatment. There was significant decrease in TC, TG, LDL-C, and FBS (all $P < 0.001$), but no significant difference of HDL-C ($P>0.05$) after treatment. The group C played more prominent role than group A in regulating TC ($P < 0.01$) and LDL-C ($P < 0.05$), there was no significant difference between group C and group B ($P > 0.05$). In conclusion, the degree of lowering lipid level varies with time of moxibustion, and moxibustion for 20-30 minutes was significantly better than that of 10 minutes.[14]

Zhang et al. studied the effect of electroacupuncture (EA) and its mechanism at "Fenglong" (ST 40) on rats with hyperlipidemia. After the treatment of EA at "Fenglong"(ST 40), the contents of TC, LDL-C significantly decreased (all $P < 0.01$), and the contents of TG, HDL-C did not change materially (all $P > 0.05$). So, EA at "Fenglong" (ST 40) had some therapeutic effects on decreasing the content of TC, LDL-C in rats of hyperlipemia and improve the gene expression of ABCA1, PPAR-alpha, LXR-alpha and RXR-alpha mRNA by promoting reverse cholesterol transport.[15] However, it should be noted that this could be a part of the mechanism of how acupuncture works and there could also be some other explanatory mechanism.

In our study, there was also significant reduction for TC ($P < 0.05$) and LDL-C ($P < 0.001$), but not TG and HDL-C. This may be explained by application of different acupoints in most studies whilst we employed only Fenglong (ST 40) acupoints in clinical trial regardless of syndrome differentiation, diet control program, duration of intervention, follow up visit to observe the sustained effects, etc. During the study, no side effect was detected. The satisfaction was rated with full scores of 5 by all participants. In subjects' point of view, these may be due to new intervention they experienced, without adverse effect, and the impression from the hospitality staffs.

In comparative experiments, Chen demonstrated that after acupuncture of "Sanyinjiao" (SP 6) for 2 - 4 hours, the blood sugar level of type-II DM patients decreased significantly, while in control group, acupuncture of non-acupoint had no obvious effect on blood sugar.[16] He also found that the effects of Sanyinjiao (SP 6), Diji (SP 8), and Yinlingquan (SP 9) used together can modulate blood sugar level via exiting vagal nerve-pancreatic islet system and reduce insulin resistances.[17] Chen et al. (2001) presented papers that compared the effects of simple acupuncture, simple herbal medicine recipe, and acupuncture plus herbal medicine recipe in type-II DM patients on serum glucagon, insulin sensitivity index, immune-cytokine, high coagulation state. The results showed that the best remedy was a combination of acupuncture and herbal medicine recipe.[18,19]

Hui et al. (2011) performed a study of 80 type-II DM, which patients were randomized into acupuncture and medication groups. Acupuncture was applied to Yishu (EX), Feishu (BL 13), Pishu (BL 20), and additional acupoints according to syndrome identification. The treatment was given once every other day for 12 weeks. For patients in the medication group, Glibenclamide (2.5-7.5 mg/time, 1-2 times/day according to blood sugar level) was given for 12 weeks. Fasting blood glucose (FBG), fasting insulin (FINS) and fasting leptin (FLP) were detected. Insulin sensitivity index (ISI) and homeostasis

model assessment-insulin resistance (HOMA-IR) were calculated. In comparison with pre-treatment, FBG levels and HOMA-IR in both acupuncture and medication groups, and FINS and FLP levels in the acupuncture group were decreased significantly ($P < 0.01$), while ISI in both acupuncture and medication groups, and FINS level in the medication group were increased remarkably after the treatment ($P < 0.01$). Comparison between two groups showed that after the treatment, FINS and FLP levels, and HOMA-IR of the acupuncture group were considerably lower than those of the medication group ($P < 0.01$), while ISI of the acupuncture group was significantly higher than that of the medication group ($P < 0.01$). It implied that acupuncture therapy is effective in lowering FLP level, which may contribute to its clinical effect in improving type-II DM.[20] In terms of traditional medicine, it is believed that acupuncture regulates the qi and blood in the body via meridian and acupoints to normalize the internal organs' functions, thus reversing the pathology induced by the imbalance of the body homeostasis.

We could not find any study that had evaluated the effects of moxibustion therapy on diabetic patients comorbid with dyslipidemia, by searching keywords in PubMed, Google scholars, China National Knowledge Infrastructure (CNKI), VIP database, Science Direct, Oxford Open, Springer Open, Cambridge Care, Hindawi Publishing Corporation, DOAJ, Thai JO, and CUJO.

Conclusion

Self-administration moxibustion is found to be effective for reduction of TC and LDL-C in diabetic patients with dyslipidemia. It is safe, convenient and economical. Moxibustion can be used as a proffered or synergic treatment option for lipid control. Moreover, moxibustion can be administered by patients themselves at home after practicing under supervision of acupuncturist for 4-5 times.

Abbreviations

BMI: body mass index; DM: diabetes mellitus; EA: electroacupuncture; FBS: fasting blood sugar; FINS: fasting insulin; FLP: fasting leptin; hr.: hour; ISI: Insulin sensitivity index; kg: kilogram; LDL-C: low-density lipoprotein cholesterol; m^2: square meter; TC: total cholesterol; TG: triglycerides; HDL-C: high-density lipoprotein cholesterol; HOMA-IR: homeostasis model assessment-insulin resistance; SD: standard deviation; TCM: Traditional Chinese Medicine.

Conflict of interest statement

The authors have no conflict of interest to report.

Role of funding source

The study sponsor had no role in the planning, execution or analysis of the study

Acknowledgments

The authors would like to thank our consultants: Assistant Professor Mart Maiprasert, Department of Anti-aging and Regenerative Medicine, College of Integrative Medicine, Dhurakij Pundit University. Associate Professor Krit Pongpirul, Department of Preventive and Social Medicine, Faculty of Medicine, Chulalongkorn University, and Assistant Professor Dr. Somkiat Sangwatanaroj, Division of Cardiovascular Medicine, Department of Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand. We also are particularly grateful to the patients and their family members who volunteered to participate in this study.

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