

Acupuncture as Adjunctive Therapy for Chronic Stable Angina A Randomized Clinical Trial

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RobotReviewer report

Risk of bias table

trial	design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Zhao L, [unknown year]	RCT	+	+	+	+

Trial summaries

n	Participants	Interventions	Outcomes	punchline	finding
10	Chronic Stable Angina, 10 patients with class II-III chronic stable angina, patients had ischemic heart disease documented by coronary angiography and/ or an abnormal exercise test	placebo, Acupuncture, Diltiazem, diltiazem	weekly frequency of angina, safety and efficiency, exercise duration on treadmill, mean exercise time required to develop 1 mm ST depression, frequency of angina and exercise capacity	Significant differences in physical limitation score were found among the 4 groups only at weeks 8 and 16 within the follow-up period.	,Ä no diff

Characteristics of studies

Zhao L, [unknown year]

- Population
1. Patients with any of the following conditions were excluded: previous myocardial infarction; severe heart failure; valvular heart disease; severe arrhythmias; atrial fibrillation; primary cardiomyopathy; psychiatric, allergic, or blood disorders; poorly controlled or uncontrolled blood pressure or blood glucose; other severe primary disease not effectively controlled; heart disease treated with acupuncture within the previous 3 months; pregnancy or lactation; or involvement in other clinical trials.
 2. Copyright American Medical Association (AMA) Methods Study Population and Protocol We recruited patients with CSA from the outpatient and inpatient units of the departments of acupuncture and cardiology at clinical centers in 5 different regions in China.
 3. This randomized clinical trial that included 404 patients with chronic stable angina found that acupuncture on the acupoints in the disease-affected meridian significantly reduced the frequency of angina attacks compared with acupuncture on the acupoints

on the nonaffected meridian, sham acupuncture, and no acupuncture.

Intervention	1. Participants in all groups except the WL group received 12 sessions of acupuncture treatment (3 times weekly for 4 weeks); each session lasted 30 minutes.
	2. Patients in the WL group did not receive acupuncture but were instructed to schedule 12 sessions of acupuncture treatment free of charge after the 16-week study had concluded.
Outcomes	3. Copyright American Medical Association (AMA) Methods Study Population and Protocol We recruited patients with CSA from the outpatient and inpatient units of the departments of acupuncture and cardiology at clinical centers in 5 different regions in China.
	1. Secondary outcomes included mean severity of angina as assessed with a visual analog scale (score range, 0-10; higher scores indicate greater pain), the Seattle Angina Questionnaire, and rescue medication intake every 4 weeks for 16 weeks; the 6-minute walk distance test during weeks 1 through 4; and the Zung self-rating anxiety scale and the self-rating depression scale during weeks 1 through 4, 5 through 8, and 13 through 16.
Outcomes	2. Patients with any of the following conditions were excluded: previous myocardial infarction; severe heart failure; valvular heart disease; severe arrhythmias; atrial fibrillation; primary cardiomyopathy; psychiatric, allergic, or blood disorders; poorly controlled or uncontrolled blood pressure or blood glucose; other severe primary disease not effectively controlled; heart disease treated with acupuncture within the previous 3 months; pregnancy or lactation; or involvement in other clinical trials.
	3. Moreover, there were no differences among the 4 groups in Zung self-rating anxiety scale or self-rating depression scale scores at the end of treatment, but the DAM group showed significantly more improvement compared with the SA and WL groups at 5 to 8 weeks (DAM group vs SA group: effect size, 0.29; 95% CI, -0.57 to -0.01; $P = .04$; DAM group vs WL group: effect size, -0.32; 95% CI, -0.59 to -0.03; $P = .02$) and at 13 to 16 weeks (DAM group vs SA group: effect size, -0.36; 95% CI, -0.64 to -0.08; $P = .01$; DAM group vs WL group: effect size, -0.40; 95% CI, -0.68 to -0.12; $P = .005$) in self-rating anxiety scale (Table 2).

Bias	Judgement	Support for judgement
Random sequence generation	low	1. The randomization sequence was generated in blocks of varying sizes and stratified according to center under the control of a central computer system.
		2. Randomization and Blinding Eligible patients were randomly assigned in an equal ratio to the DAM, NAM, SA, or WL group via a central randomization system.
Allocation concealment	low	3. Allocation of participants was performed by an independent researcher at each clinical site who was not involved in outcome assessment.
		1. The randomization sequence was generated in blocks of varying sizes and stratified according to center under the control of a central computer system.
Blinding of participants and	low	2. Randomization and Blinding Eligible patients were randomly assigned in an equal ratio to the DAM, NAM, SA, or WL group via a central randomization system.
		3. Allocation of participants was performed by an independent researcher at each clinical site who was not involved in outcome assessment.
Blinding of participants and	low	1. The outcome assessors, data collectors, and statisticians were blinded to group allocations during the study.

personnel		2. Allocation of participants was performed by an independent researcher at each clinical site who was not involved in outcome assessment. 3. The parameters of acupuncture needles and electrical stimulation were identical to those in the DAM and NAM groups.
Blinding of outcome assessment	low	1. The outcome assessors, data collectors, and statisticians were blinded to group allocations during the study. 2. The heart rate variability data at the Yunnan center (69 cases) were recorded by a machine that was different from that used at the other centers, so those data were not included in analysis. 3. Allocation of participants was performed by an independent researcher at each clinical site who was not involved in outcome assessment.

References

1. Zhao L et al. Acupuncture as Adjunctive Therapy for Chronic Stable Angina Arch Inst Cardiol Mex [unknown year]. 56(4); 327-32 PMID: 2945527