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Effects of needling at Sanyinjiao (SP6) acupuncture point on blood glucose levels and cardiovascular functions in patients with type 2 diabetes mellitus: a randomized placebo-controlled study

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ABSTRACT

Objective To determine the effect of needling at Sanyinjiao (SP6) on random blood glucose (RBG) levels and cardiovascular function in patients with type 2 diabetes mellitus (T2DM).

Methods In this randomized placebo-controlled study, T2DM patients (aged 35 – 65 years) were recruited from the Government Yoga and Naturopathy Medical College and Hospital, Chennai, India, between January 5, 2022 and March 15, 2023. Participants were randomly assigned to either acupuncture group or sham acupuncture group. The acupuncture group received bilateral needling at Sanyinjiao (SP6) while sham acupuncture group received needling at a non-acupuncture point [1.5 cun lateral to Sanyinjiao (SP6)] for 30 min. Primary outcome was RBG, and secondary outcomes included systolic blood pressure (SBP), diastolic blood pressure (DBP), pulse rate (PR), pulse pressure (PP), mean arterial pressure (MAP), rate pressure product (RPP), and double product (Do-P). All parameters were assessed immediately before and after intervention.

Results A total of 100 patients with T2DM were enrolled in the study, and blinded to acupuncture group (n = 50) and sham acupuncture group (n = 50). Intergroup analysis showed that significant reductions in RBG (P < 0.001), SBP (P = 0.035), DBP (P = 0.008), and MAP (P = 0.009) were found in acupuncture group compared with sham acupuncture group. Within-group analysis showed significant reductions in RBG (P < 0.001), SBP (P < 0.001), DBP (P = 0.008), PP (P = 0.023), MAP (P < 0.001), RPP (P < 0.001), and Do-P (P = 0.002) in acupuncture group, whereas sham acupuncture group showed a significant decrease in PR (P = 0.023) only in the post-test assessment compared with pre-test assessment.

Conclusion A period of 30 min of needling at the Sanyinjiao (SP6) acupuncture point reduces RBG and promotes cardiovascular function in patients with T2DM as compared with needling at non-acupuncture points. Sanyinjiao (SP6) acupuncture may offer an immediate, non-pharmacological intervention to strengthen glycemic control management and cardiovascular health in T2DM patients.

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1 Introduction

Type 2 diabetes mellitus (T2DM) is a group of metabolic disorders characterized by chronic hyperglycemia due to defects in insulin secretion, insulin resistance, or a combination of both [1]. The prevalence of diabetes was 9.6% (463 million people) in the world in 2021 and is expected to reach 10.4% (578 million) in 2030, and 10.9% (700 million) in 2045 [2, 3]. Uncontrolled diabetes is linked to both microvascular and macrovascular disorders, including diabetic retinopathy, diabetic nephropathy, diabetic neuropathy, peripheral artery disease, and cerebrovascular disease [4]. The conventional line of treatment includes biguanides (metformin), sulfonylureas (glimepiride, glipizide, and glyburide), thiazolidinediones (rosiglitazone and pioglitazone), and insulin. The long-term use of these drugs generates potential side effects, such as lactic acidosis, constipation, vitamin B-12, and folic acid deficits, as well as other gastrointestinal problems in 30% of patients [5]. The non-pharmacological methods involve glycemic control through diet, exercise, acupuncture, massage therapy, biofeedback, yoga, and herbal medications, which play a crucial role in the reduction of blood glucose levels [6].

Acupuncture is considered a treatment modality grounded in traditional Chinese medicine (TCM) which is based on the meridian system, that encompasses proper insertion and manipulation of needles of various gauges and lengths into the skin at specific acupoints [7, 8]. The classic TCM theory holds that diabetes is caused by Yin deficiency and dryness-heat. Sanyinjiao (SP6), one of the acupuncture points in the spleen meridian, which is a three-Yin intersecting point (where three-Yin meridians, namely liver, kidney, and spleen), strengthens the spleen and stomach energy while nourishing the Yin and blood [9]. Numerous studies have demonstrated that acupuncture at Sanyinjiao (SP6) along with other acupuncture points for a short or long duration has blood sugar-lowering effects [10, 11]. However, no studies have explored the effects of acupuncture at Sanyinjiao (SP6) alone on blood glucose levels in patients with T2DM. Thus, the aim of this study was to determine the immediate effect of bilateral needling at Sanyinjiao (SP6) on random blood glucose (RBG) levels and cardiovascular function in these patients.

2 Materials and methods

2.1 Study design

A randomized placebo-controlled study was conducted between January 5, 2022, and March 15, 2023, at the Government Yoga and Naturopathy Medical College and Hospital, Chennai, India. The protocol was approved by the Institutional Ethics Committee (RES/IEC-GYNMC/2021/133), and written informed consent was obtained from all participants.

2.2 Participants

2.2.1 Inclusion criteria Males and females aged 35 to 65 years with a history of T2DM for at least one year, receiving regular anti-diabetic medications (biguanides and sulphonylureas), and willing to participate in the study were included.

2.2.2 Exclusion criteria Participants were excluded if they had: other types of diabetes or T2DM complicated by diabetic neuropathy, Grade III nephropathy, end-stage renal disease, or diabetic ulcers; any psychological conditions; open wounds or skin diseases at the needling sites; autoimmune disorders or who underwent insulin therapy; needle phobia; or were pregnant or lactating.

2.3 Randomization and blinding

Eligible participants were randomly assigned in a 1 : 1 ratio into acupuncture group and sham acupuncture group using a simple random method by computerized randomization. Allocation concealment was conducted using sequentially numbered opaque sealed envelopes. Sealed envelopes were prepared in advance, indicating each participant's allocation based on their recruitment number. These envelopes were handed to the researcher responsible for enrolling participants. Participants who met the inclusion and exclusion criteria and provided informed consent were sequentially assigned a unique recruitment number. The corresponding sealed envelope for that recruitment number was then opened, and participants were allocated to either the acupuncture or sham acupuncture group based on its contents. Randomization was performed by one of the authors who was not involved in intervention or outcome assessments.

2.4 Intervention

All interventions were performed by a qualified acupuncturist with three years of clinical experience who was pursuing a doctor of medicine in acupuncture and energy medicine. Treatments were conducted in a well-ventilated, noise-free, temperature-controlled room between 9:00 am and 12:00 pm after they had breakfast. In both groups, sterile disposable stainless steel filiform needles (0.25 mm × 13 mm, TX-PinPai, Suzhou Tianxie Acupuncture Instruments Co., Ltd., China) were used. All patients were on their regular anti-diabetic medications and informed about the procedure and potential sensations of needle insertion before treatment. The needles were retained for 30 min without manual or electrical stimulation, and no other treatments were administered during the study period.

2.4.1 Acupuncture group Participants received bilateral needling at Sanyinjiao (SP6) (located 3 cun proximal to the tip of the medial malleolus). Needles were inserted perpendicularly to a depth of 1 cun and retained for 30 min without manipulation or electrical stimulation.

2.4.2 Sham acupuncture group Participants received bilateral needling at non-acupuncture points [located 1.5 cun lateral to Sanyinjiao (SP6)] with identical needle type, insertion depth, and retention time as acupuncture group.

2.5 Outcome measures

All outcomes were assessed at the baseline before the intervention and immediately after the intervention.

2.5.1 Primary outcome variables RBG was measured using a calibrated portable glucometer (Accu-Chek Instant Blood Glucose Glucometer, Roche Diagnostics India Pvt. Ltd., Mumbai, India). Following standard aseptic procedures, capillary blood samples were obtained by finger prick using disposable lancets. The measurement was performed according to the manufacturer's instructions.

2.5.2 Secondary outcome variables Systolic blood pressure (SBP), diastolic blood pressure (DBP), and pulse rate (PR) were evaluated using a digital BP monitor (HEM-8712, Omron Healthcare Co., Ltd., Kyoto, Japan). Assessments including pulse pressure (PP), mean arterial pressure (MAP), rate pressure product (RPP), and double product (Do-P) were calculated using the following formulas: PP = SBP – DBP; MAP = DBP + (1/3 × PP); RPP = (PR × SBP)/100; Do-P = (PR × MAP)/100 [12].

2.6 Statistical analysis

Data analysis was performed using SPSS 16.0. The Kolmogorov-Smirnov test was used to assess data normality. Baseline demographic and clinical characteristics between groups were compared using independent samples *t* test for normally distributed data and Mann-Whitney *U* test for non-normally distributed data. As baseline RBG values differed significantly between groups, univariate analysis of covariance (ANCOVA) with Bonferroni adjustment was conducted for between-group comparisons, using baseline values as covariates. Within-group differences were analyzed using paired samples *t* test for normally distributed data and Wilcoxon signed-rank test for non-normally distributed data. Data were represented as mean ± standard deviation (SD) for normally distributed data and median (interquartile range) for non-normally distributed data. Two-tailed tests were used for all analyses, and $P < 0.05$ was considered statistically significant. No data were missing, and no subjects were lost to follow-up.

3 Results

3.1 Participant characteristics

A total of 120 patients were assessed for eligibility, and 100 patients with T2DM who met the inclusion criteria were enrolled in the study. All participants were blinded to acupuncture group (n = 50) and sham acupuncture groups (n = 50). All participants completed the study with no dropouts, resulting in complete data for analysis (Figure 1). The baseline demographic and clinical characteristics of both groups are presented in Table 1. The results showed no statistically significant difference in all demographic and outcome measures except RBG between acupuncture and sham acupuncture groups at baseline ($P > 0.05$).

3.2 Primary outcome variable

Between-group analysis showed a statistically significant reduction in RBG ($P < 0.001$) in acupuncture group

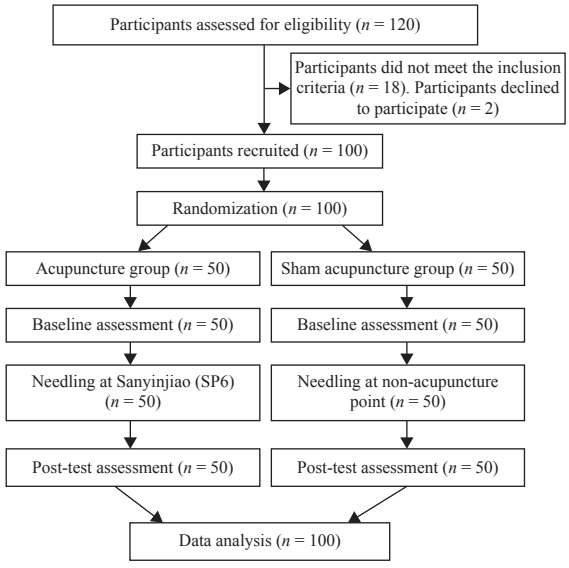

Figure 1 Trial profile of the study

Table 1 Demographic variables of the acupuncture and sham acupuncture groups

Group	Age (year)	Gender (*n*)		Height (m)	Weight (kg)	BMI (kg/m²)	RBG (mg/dL)	SBP (mmHg)	DBP (mmHg)
		Female	Male						
Acupuncture	55.08 ± 8.08	29	21	1.59 ± 0.05	62.79 ± 10.37	24.86 ± 3.72	260.78 ± 73.18	125.88 ± 19.91	80.64 ± 10.78
Sham acupuncture	54.90 ± 7.86	31	19	1.60 ± 0.06	63.49 ± 8.99	24.92 ± 3.79	224.60 ± 50.02	129.44 ± 18.80	84.50 ± 10.85
P value	0.870	/		0.430	0.388	0.793	0.005	0.360	0.077

BMI, body mass index. RBG, random blood glucose level. SBP, systolic blood pressure. DBP, diastolic blood pressure.

compared with sham acupuncture group. Within-group analysis revealed that acupuncture group demonstrated a significant decrease in RBG ($P < 0.001$) from baseline to post-intervention, while sham acupuncture group showed no significant change ($P > 0.05$) (Figure 2).

3.3 Secondary outcome variable

Between-group analysis showed a statistically significant reduction in SBP ($P = 0.035$), DBP ($P = 0.008$), and MAP ($P = 0.009$), with a trend toward reduction in Do-P ($P = 0.095$), and no significant changes were noted in PR, PP, and RPP in acupuncture group compared with sham acupuncture group ($P > 0.05$). Within-group analysis, for acupuncture group showed a statistically significant reduction in SBP ($P < 0.001$), DBP ($P = 0.008$), PP ($P = 0.023$), MAP ($P < 0.001$), RPP ($P < 0.001$), and Do-P ($P = 0.002$) after acupuncture treatment, but no significant changes were found in PR ($P > 0.05$). In contrast, sham acupuncture group showed a significant decrease only in PR ($P = 0.023$), with no significant changes noted in other variables ($P > 0.05$) (Table 2). No adverse events were observed from the participants.

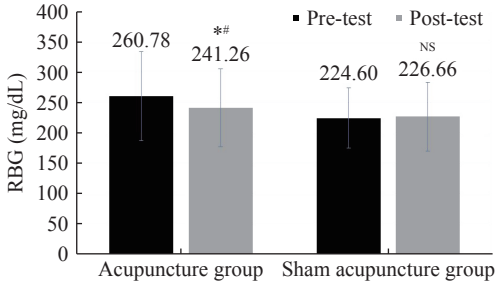

Figure 2 Pre-test and post-test RBG of acupuncture and sham acupuncture groups

*$P < 0.001$ in within-group group analysis (Wilcoxon signed ranks test with $Z = 5.359$). #$P < 0.001$ in between groups analysis using analysis of covariance (ANCOVA with $F = 17.647$). NS, $P > 0.05$ in within and between groups analysis (Wilcoxon signed ranks test with $Z = 1.303$).

Table 2 Baseline and post-test assessments of acupuncture and sham acupuncture groups

Group	SBP (mmHg)			
	Baseline	**Post-test**	***t*/*z*/*F* value**	***P* value**
Acupuncture	125.88 ± 19.91	121.20 ± 18.00	$t = 4.070$	< 0.001
Sham acupuncture	129.44 ± 18.80	129.38 ± 19.16	$z = 0.856$	0.392
t/*z*/*F* value	$t = 0.919$	$z = 2.107$		
P value	0.360	0.035		
Group	**DBP (mmHg)**			
	Baseline	**Post-test**	***t*/*z*/*F* value**	***P* value**
Acupuncture	80.64 ± 10.78	78.62 ± 9.78	$t = 2.755$	0.008
Sham acupuncture	84.50 ± 10.85	84.04 ± 10.07	$t = 0.473$	0.639
t/*z*/*F* value	$t = 1.785$	$t = 2.730$		
P value	0.077	0.008		
Group	**PR (bpm)**			
	Baseline	**Post-test**	***t*/*z*/*F* value**	***P* value**
Acupuncture	86.18 ± 12.98	84.56 ± 12.88	$t = 1.946$	0.057
Sham acupuncture	84.92 ± 9.74	83.62 ± 9.45	$t = 2.343$	0.023
t/*z*/*F* value	$t = 0.549$	$t = 0.416$		
P value	0.584	0.678		
Group	**PP (mmHg)**			
	Baseline	**Post-test**	***t*/*z*/*F* value**	***P* value**
Acupuncture	45.24 ± 13.59	42.58 ± 12.76	$z = 2.277$	0.023
Sham acupuncture	44.94 ± 13.26	45.34 ± 13.96	$z = 0.205$	0.838
t/*z*/*F* value	$z = 0.017$	$z = 1.204$		
P value	0.986	0.229		
Group	**MAP (mmHg)**			
	Baseline	**Post-test**	***t*/*z*/*F* value**	***P* value**
Acupuncture	95.72 ± 12.98	92.81 ± 11.68	$t = 3.943$	< 0.001
Sham acupuncture	99.48 ± 12.54	99.15 ± 12.11	$t = 0.277$	0.783
t/*z*/*F* value	$t = 1.473$	$t = 2.664$		
P value	0.144	0.009		

Table 2 Continued

Group	RPP (mmHg·b/min)			
	Baseline	Post-test	*t*/*z*/*F* value	*P* value
Acupuncture	107.68 ± 18.77	101.93 ± 18.55	*t* = 3.743	< 0.001
Sham acupuncture	109.77 ± 18.94	107.87 ± 17.95	*t* = 1.144	0.258
t/*z*/*F* value	*t* = 0.555	*t* = 1.627		
P value	0.580	0.107		
Group	**Do-P (mmHg·b/min)**			
	Baseline	**Post-test**	***t*/*z*/*F* value**	***P* value**
Acupuncture	82.06 ± 14.12	78.26 ± 14.05	*t* = 3.219	0.002
Sham acupuncture	84.41 ± 13.62	82.86 ± 13.17	*t* = 1.442	0.156
t/*z*/*F* value	*t* = 0.847	*t* = 1.688		
P value	0.399	0.095		

Data were represented as mean ± SD. In within-group analysis, *z* value of Wilcoxon signed rank test, and *t* value of Paired samples *t* test. In between group analysis, *z* value of Mann Whiteney *U* test, *t* value of independent samples *t* test, and *F* value of analysis of covarance (ANCOVA).

4 Discussion

The present study was conducted to determine the effect of bilateral needling at acupuncture point Sanyinjiao (SP6) on blood glucose levels and cardiovascular function in patients with T2DM. The results showed a significant reduction in RBG, SBP, DBP, and MAP, with a trend toward a decrease in Do-P in acupuncture group compared with sham acupuncture group.

Consistent with our findings, a study that investigated the effect of self-acupressure at four points of Taichong (LIV3), Zusanli (ST36), Sanyinjiao (SP6), and Taixi (KD3) showed a decrease in the FBS and an increase in serum insulin levels in acupuncture group [13]. Another research that provided acupuncture at 15 acupoints which included Sanyinjiao (SP6), showed a drop in fasting plasma glucose and glycated hemoglobin (HbA1c) after acupuncture [11]. The findings of another study show that acupuncture at seven points [Sanyinjiao (SP6), Yinlingquan (SP9), Laogong (PC8), Jianshi (PC5), Neiguan (PC6), Ximen (PC4), and Quze (PC3)] lowered SBP and DBP in hypertensive patients [14]. These studies are in line with the findings of the present study. In T2DM, Sanyinjiao (SP6) points are often used together with other points, which highlights the importance of Sanyinjiao (SP6). However, there are limited controlled clinical trials to evaluate the effects of Sanyinjiao (SP6) acupuncture point on blood sugar levels in patients with diabetes.

4.1 Glycemic control

The results of the present study suggest that acupuncture at Sanyinjiao (SP6) for 30 min reduces RBG effectively compared with needling at non-acupuncture points. This could be attributed to the following mechanism of action: the classic TCM theory holds that diabetes is caused by Yin deficiency and dryness-heat. As a Yin intersecting point where three-Yin meridians meet (liver, spleen, and kidney), Sanyinjiao (SP6) strengthens the spleen and stomach while nourishing the Yin and blood [9]. The parasympathetic nervous system promotes insulin secretion, as evidenced previously by the impaired insulin secretion observed in vagotomized rats [15]. Moreover, it also inhibits the gluconeogenic pathway in the liver, which may contribute to the reduction in blood glucose levels. Acupuncture increases para-sympathetic tone which decreases the blood glucose level, SBP, and DBP [16].

The hypothalamic-pituitary-adrenal axis and glucose regulation are closely correlated. Hypothalamic-pituitary-adrenal (HPA) axis dysregulation in diabetes appears to include complex interactions between impaired glucocorticoid negative feedback sensitivity and factors including hyperinsulinemia, hyperglycemia, and hyperleptinemia. Acupuncture regulates the HPA axis by regulating the expression of glucocorticoid receptors and negative feedback regulation of glucocoriticoid recepotor (GR). This, in turn, decreases the levels of glucocorticoids from the adrenal cortex, lowers the HPA axis excitability, and indirectly reduces the circulating blood glucose level as well as blood pressure [17]. Several studies have shown the effectiveness of Sanyinjiao (SP6) in addition to other acupuncture points in decreasing blood glucose levels [10]. Thus, the results of the present study are consistent with the findings of previous research.

4.2 Cardiovascular functions

Further, the results showed a significant reduction in SBP, DBP, PP, MAP, RPP, and Do-P in acupuncture group, but no such significant changes were observed in sham acupuncture group compared with its respective baseline. Results of this research indicate that 30 min of

needling at Sanyinjiao (SP6) is effective in strengthening cardiovascular function, as evidenced by a decrease in blood pressure, myocardial oxygen consumption, and cardiac workload [18], in contrast to the control intervention involving needling at a non-acupuncture point. Additionally, impaired endothelial function lowers nitric oxide (NO) levels. Whereas, acupuncture improved endothelial dysfunction by inducing the synthesis and activation of endothelial-derived nitric oxide, which acts as a vasodilator, inhibits growth and inflammation, and has an anti-aggregate effect on platelets [19]. Previous study also suggest that acupuncture increases NO levels, and vascular permeability, which in turn decreases SBP and DBP [20]. This is in line with our findings, which demonstrate that acupuncture at Sanyinjiao (SP6) potentiates the cardiovascular variables. Also, based on the theories of acupuncture, stimulation at Sanyinjiao (SP6) stabilizes the reverse ascending of Chong Qi and guides the Qi downward. At the same time, it can also nourish Yin to suppress Yang and regulate Qi and blood, which is conducive to decreasing blood pressure [21].

4.3 Strength and limitation of the sdudy

The study indicated the effect of a single acupuncture point Sanyinjiao (SP6) on blood glucose levels and expanded the scope of application of single-point needling in the treatment of T2DM. None of the patients reported any adverse effects during the intervention. However, the study only found the immediate effect of the intervention and failed to demonstrate the short-term and long-term effects. Next, the sample size was small and sample size calculation was not performed based on previous research. Besides, parameters including continuous blood glucose monitoring, continuous blood pressure monitoring, autonomic functions testing, NO, and other biochemical analyses should have been performed for a better understanding of its effect. Hence, further studies with large sample sizes and long-term follow-up with more objective variables are warranted to validate the results of the study.

5 Conclusion

Single-session bilateral needling at Sanyinjiao (SP6) acupuncture point for 30 min demonstrated immediate beneficial effects on glycemic control and cardiovascular parameters in patients with T2DM. Specifically, this intervention significantly decreased blood glucose levels and improved cardiovascular functions compared with needling at non-acupuncture points. These findings suggest that Sanyinjiao (SP6) acupuncture could serve as a safe and non-pharmacological adjunctive intervention for T2DM management.

Competing interests

The authors declare no conflict of interest.

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三阴交穴位针刺对 2 型糖尿病患者血糖水平和心血管功能的影响：一项随机安慰剂对照研究

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【摘要】目的 本研究旨在确定三阴交（SP6）穴位针刺对 2 型糖尿病患者（T2DM）随机血糖（RBG）水平和心血管功能的影响。**方法** 在这项随机安慰剂对照研究中，期间从印度金奈政府瑜伽和自然疗法医学院和医院招募 T2DM 患者（年龄 35 – 65 岁），时间跨度为 2022 年 1 月 5 日至 2023 年 3 月 15 日。参与者被随机分配到针灸组或假针灸组。针灸组接受双侧三阴交（SP6）穴位针刺，而假针灸组接受非穴位点（距三阴交侧位 1.5 寸处）针刺，每次 30 分钟。主要观察指标为 RBG，次要观察指标包括收缩压（SBP）、舒张压（DBP）、脉搏率（PR）、脉压（PP）、平均动脉压（MAP）、心率血压乘积（RPP）和心率血压双乘积（Do-P）。所有参数在干预前后立即进行评估。**结果** 共有 100 名 T2DM 患者参与研究，被随机分配至针灸组（$n = 50$）和假针灸组（$n = 50$）。组间分析显示，针灸组与假针灸组相比，RBG（$P < 0.001$）、SBP（$P = 0.035$）、DBP（$P = 0.008$）和 MAP（$P = 0.009$）显著降低。组内分析显示，针灸组 RBG（$P < 0.001$）、SBP（$P < 0.001$）、DBP（$P = 0.008$）、PP（$P = 0.023$）、MAP（$P < 0.001$）、RPP（$P < 0.001$）和 Do-P（$P = 0.002$）显著降低，而假针灸组仅在脉搏率（PR）上表现出显著降低（$P = 0.023$）。**结论** 与非穴位点针刺相比，30 分钟的三阴交（SP6）穴位针刺可以降低 T2DM 患者的 RBG 并改善其心血管功能。三阴交（SP6）穴位针刺可能作为一种即时、非药物干预手段，加强 T2DM 患者的血糖控制管理和促进心血管健康。

【关键词】针灸；糖尿病；三阴交；2 型糖尿病；血糖