



## Clinical Research

# Effect of *Tinospora cordifolia* on physical and cardiovascular performance induced by physical stress in healthy human volunteers

Bharat A. Salve, Raakhi K. Tripathi, Anup U. Petare, Ashwinikumar A. Raut<sup>1</sup>, Nirmala N. Rege

Department of Pharmacology and Therapeutics, Seth GS Medical College and KEM Hospital,

<sup>1</sup>Department of Clinical Research and Integrative Medicine, Kasturba Health Society, Medical Research Centre, Mumbai, Maharashtra, India

### Abstract

**Introduction:** In Ayurveda *Tinospora cordifolia* (Willd.) Miers., has been used for its *Rasayana*, *Deepana*, *Jwaranashana*, *Tridosha Shamaka* properties. It is an immunomodulator, useful in stress, hyperlipidemia, pyrexia. *T. cordifolia* was evaluated for adaptogenic activity in healthy volunteers during exercise. **Aims:** The primary objective of this study was to evaluate the effect of *T. cordifolia* on physical performance, and secondary objectives were to evaluate muscle power, maximal oxygen consumption, and sympathetic activity in comparison with placebo when subjected to physical stress. **Materials and Methods:** A total of thirty participants were randomly assigned into three groups ( $n = 10$  each) namely placebo, TC 150 and TC 300. Placebo group received maize starch capsule, TC 150 and TC 300 received 150 mg and 300 mg, respectively of *T. cordifolia* aqueous extract in capsule form once daily in the morning for 28 days. The assessment was performed at baseline visit, day 14 and 28. Physical stressors were cycle ergometer exercise, Jammer's hand-held dynamometer, and cold pressor tests. Physical performance evaluated was maximum distance and speed, oxygen consumption ( $VO_2$  max), and hand grip strength. Cardiovascular response was assessed by multiple heart rate (HR) and blood pressure (BP) measurements during each test. **Results:** On day 28, TC 150 mg group showed a significant increase in mean maximum speed compared to placebo. On day 14 and 28, TC 300 mg group showed a significant decrease in mean systolic BP (SBP) and HR on fixed workload exercise compared to placebo. There was significant increasing dose effect of both TC groups on SBP on day 14 and 28 and on HR on day 28 only. On day 14 and 28, TC 300 mg showed a significant decrease in mean HR on the cold pressor test, compared to placebo. **Conclusion:** *T. cordifolia* improved physical performance and suppressed over activation of the sympathetic nervous system showing its adaptogenic property.

**Key words:** Antistress, cold pressor test, cycle ergometer, *Tinospora cordifolia*,  $VO_2$  max

## Introduction

Stress is a biological response controlled by the brain as a reaction to challenging stimulations of physical or emotional nature.<sup>[1]</sup> Stressors are any agent or event that threatens homeostasis and causes stress. Individual when exposed to a stressor, a physiological compensatory response to stress is launched by the body that is activation of the sympathetic nervous system

and release of cortisol, epinephrine, and norepinephrine occurs from adrenal medulla via hypothalamic–pituitary–adrenal axis.<sup>[2]</sup> Prolonged exposure to stressors can manifest regarding emotional, behavioral, and even physical symptoms and these symptoms of stress vary enormously among different individuals.

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**Address for correspondence:** Dr. Anup U. Petare, Department of Pharmacology and Therapeutics, Seth GS Medical College and KEM Hospital, Parel, Mumbai - 400 012, Maharashtra, India.  
E-mail: [anuppetare@gmail.com](mailto:anuppetare@gmail.com)

Such kind of chronic stress is implicated in the pathogenesis of various diseases such as hypertension, stroke, ulcers, coronary heart diseases, decreased immunity, and metabolic disorders, and also mental imbalance which may lead to anxiety and depression.<sup>[3,4]</sup> There are no drugs available currently in modern medicine which modulate the compensatory mechanism to stress with minimal adverse effects.

In Ayurveda, the herb *Guduchi* (*Tinospora cordifolia* (Willd.) Miers.) has been used since long for its *Rasayana* properties to increase the vigor and immunity. The term “*Amrita*” is attributed to its ability to impart youthfulness, vitality, and longevity. Pharmacological properties of *T. cordifolia* are *Deepana* (ability to facilitate metabolism), *Jwaranashana* (to alleviate fever) and *Tridosha Shamaka* (helps to maintain homeostasis of *Doshas* during stressful situations). It is found to be safe on hematological and biochemical organ function tests and has muscle strengthening, lipid lowering action in healthy individuals.<sup>[5,6]</sup> It has been shown that the immune system can function as a neuroendocrine organ since it can synthesize not only hormones and neuropeptides but also cytokines that have an impact on the neuroendocrine system.<sup>[7]</sup> Stress is responsible for physiological compensatory mechanism via neuroendocrine axis. *T. cordifolia* currently used as cardiogenic, but its effect on physical performance is not reported.<sup>[8]</sup> The hypothesis of the study was that drugs which modulate immunity should have an impact on individual's physiological compensatory mechanism so along with cardiovascular performance does any changes in physical performance occurs. Hence in this study, evaluation of the effect of *T. cordifolia* aqueous extract in healthy participants when subjected to physical stress on physical performance and sympathetic activity is done.

## Materials and Methods

This was a pilot study, designed as prospective, open-label, randomized, placebo-controlled comparative study in healthy male adult volunteers with fixed dosage regimen. The study was conducted after the permission of Institutional Ethics Committee (Ref. No.: EC/172/2011; Date: April 16<sup>th</sup>, 2014). Male participants between the age of 18 and 45 years and body mass index (BMI) between 18.5 kg/m<sup>2</sup> and 24.9 kg/m<sup>2</sup> were selected for the study and written informed consent was obtained from each participant. The participants were screened for their healthy status from clinical history, physical examination, blood investigations, chest radiography and electrocardiogram (ECG) and eligible participants were randomized into one of the three groups.

### Grouping and posology

The total thirty participants were randomized into three groups ( $n = 10$  each) as placebo, TC 150, and TC 300. TC 150 and TC 300 group received 150 mg and 300 mg respectively of *T. cordifolia* aqueous extract in the capsule form once daily in the morning for 28 days while the placebo group received the maize starch capsule in the same dosage frequency. The study medication was dispensed after the baseline visit evaluation.

As mentioned in Ayurvedic literature, the therapeutic dose of *T. cordifolia* is 1–3 g of crude pulverized stems, aqueous extract of *T. cordifolia* in powder form in a dose of 150 mg and 300 mg

was studied, which was equivalent to 1.5 g and 3 g of crude pulverized stem of, *T. cordifolia* respectively (manufacturing by - Ixoreal Biomed Private Limited, Abids, Hyderabad, Telangana, India and packaged as capsules by Shivangi Pharmaceuticals, Mumbai, Maharashtra, India).

### Criteria for assessment

The evaluation consisted of three visits viz., baseline, day 14, and day 28. At each visit after 20 min of initial rest to assess effect on physical performance participant was asked to perform:

- 6 min cycle ergometer exercise with fixed resistance and no speed limit<sup>[9,12]</sup>
- After 20 min the hand grip strength was assessed by Jammers handheld dynamometer average of three reading taken with 1 min gap in between each reading<sup>[12,13]</sup>
- Following this, Young Men's Christian Association cycle ergometer submaximal test was performed with 3–4 increasing workload (25, 75, 100, 125 watt workload) for 9–12 min after each of these test participant was instructed to rest for 20 min<sup>[14,15]</sup>
- Then to assess effect on sympathetic nervous system, fixed workload exercise on cycle ergometer test was performed for 6 min with fixed speed of 50 rpm and resistance of 75 watt after 20 min rest<sup>[14,16]</sup>
- Cold pressor test participants were asked to immerse hand in 0–1°C water bath for 3 min.<sup>[17]</sup>

The whole procedure took 4–5 h. Variables assessed in these test during study procedure are mentioned in Table 1 All tests and exercises were done in ambient temperature range of 24–26°C during 9 am to 1 pm in an air-conditioned room. The participants were instructed to fast for at least 1 h before testing and were asked to refrain from ingesting beverages containing caffeine.

### Statistical analysis

Repeated measure of ANOVA used for within group analysis, *Post hoc* Tukey test and unpaired *t*-test was used.

### Observations

A total of 38 participants were screened of which 7 did not meet the inclusion and exclusion criteria and one participant was dropped out from placebo group due to inability to follow-up.

The mean age of the thirty volunteers was  $27.37 \pm 2.48$  years (range: 22–36). The mean height was  $170.73 \pm 6.77$  cm (range: 158–186). The mean weight was  $67.00 \pm 7.21$  kg

**Table 1: Variable assessed at each visit**

Number	Exercise/test	Parameter assessed
I	6 min cycle ergometer exercise test	Distance travelled, maximum speed
II	Hand grip strength by Jammers' hand held dynamometer	Muscle power (kg)
III	The YMCA cycle ergometer submaximal test	VO <sub>2</sub> max
IV	Fixed workload exercise on cycle ergometer	SBP and DBP, HR
V	Cold pressor test	SBP and DBP, HR

YMCA: Young Men's Christian Association, HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

(range: 52–81). The mean BMI was  $22.92 \pm 1.44 \text{ kg/m}^2$  (range: 19.37–24.7). The general and clinical examinations of the volunteers were normal. All volunteers were nonsmokers, nondrinkers, and nontobacco chewers. The chest X-ray posterior-anterior view and 12 lead ECG of all the volunteers were normal. All volunteers were HIV and hepatitis B surface antigen negative. The laboratory values of all the included participants were in normal range.

## Results

In the placebo group, on day 28, the increase in mean distance travelled was statistically significant. In TC 150 group, on day 28, the mean maximum speed, mean hand grip strength and mean  $\text{VO}_2$  max increased significantly. In TC 300 group, on day 28, statistically significant increase seen in mean distance travelled and mean  $\text{VO}_2$  max [Table 2].

Effect on sympathetic system by fixed workload exercise in TC 300 significant decrease was observed in mean systolic blood pressure (SBP) on day 14 and day 28 and heart rate (HR) at day 28 when compared to placebo. TC 150 showed significant decrease in mean SBP and diastolic BP (DBP) on day 14 and 28 and HR at day 28. There was significant increasing dose effect of *T. cordifolia* on SBP on day 14 and day 28 while the increasing dose effect on HR was significant on day 28 only [Table 3].

In cold pressor test, TC 150 and TC 300 showed a significant decrease in SBP on day 14 and 28. TC 150 showed a significant decrease in DBP on day 14 and day 28, and TC 300 showed a significant decrease on day 28. Both groups showed a significant decrease in HR at day 28 [Table 4].

## Discussion

The effect of the study drug was evaluated after baseline visit on day 0, day 14 and day 28 i.e. last visit (day 28). Day 14 visit was kept to see if the effect can be observed early also. The adaptogenic/anti-stress activity was evaluated regarding physical performance in the presence of physical stress and the effect on the sympathetic nervous system (cardiovascular parameters) was assessed in the presence of physical stress in healthy adults. The study was conducted on healthy adult volunteers to avoid the confounding effect of diseases and physical deformity. In addition, this study was planned to evaluate the prophylactic use of the herbal drug in healthy individuals as adaptogen/anti-stress agent. As per this study objective, *T. cordifolia* was compared with placebo and lower dose was compared with the higher dose of respective herb to evaluate incremental dose effect.

*T. cordifolia* is known as an adaptogen, as it increases the resistance of the body to physical, chemical, and biological stress and builds energy and general vitality.<sup>[18]</sup> *T. cordifolia* is mentioned as *Tridosha Shamaka* and a *Rasayana* plant. Rasayanas are known to impart strength to the tissues. As mentioned in the Ayurvedic text, it has cardio-tonic and hematopoietic activity and is effective in cardiac debility.<sup>[6]</sup> In many preclinical and clinical studies, *T. cordifolia* has shown following properties, such as anti-stress, immunostimulatory, anti-inflammatory, antidiabetic, antihyperlipidemic, antioxidant,

**Table 2: Effect on physical performance on exposure to physical stress**

Parameters	Placebo			TC 150			TC 300		
	Day 0	Day 14	Day 28	Day 0	Day 14	Day 28	Day 0	Day 14	Day 28
Maximum distance travelled in km	3.260±0.4186	3.292±0.3923	3.352±0.4123*	3.522±0.1960	3.628±0.2576	3.700±0.2366	3.210±0.6499	3.337±0.5753	3.440±0.5411*
Maximum speed reached in km/h	43.983±2.363	44.800±2.459	44.588±2.197	45.583±2.036	47.053±2.131*	47.683±2.695*	43.350±6.980	44.273±6.437	43.883±6.377
Hand grip strength (muscle power in kg force)	40.767±5.842	41.045±5.690	40.983±5.619	40.312±4.912	40.712±4.989	41.133±4.907*	41.055±5.107	41.327±5.119	41.550±4.918
YMCA cycle ergometer submaximal test ( $\text{VO}_2$ max in mL/kg/min)	34.202±1.615	34.425±1.47	34.553±1.631	35.075±0.5883	35.347±0.6134*	35.620±0.699*#	34.055±1.431	34.700±1.474*	35.502±1.15*#

Data: Mean±SD, on post hoc Tukey test. \*P<0.05 compared to baseline visit, #P<0.05 compare to visit 1. TC: *Tinospora cordifolia* aqueous extract, YMCA: Young Men's Christian Association, SD: Standard deviation

**Table 3: Comparative effect of *Tinospora cordifolia* during fixed workload exercise**

Parameters	Study group	Mean±SD		
		Day 0 (baseline)	Day 14 (visit 1)	Day 28 (visit 2)
Difference of HR at start and end of exercise	TC 300	47±4.3	44.17±3.6*	39.83±2.8*#
	TC 150	53.67±5	49.83±1.1	49.33±1.4
	Placebo	50.5±3.4	50.67±2.8	51±3.1
Difference of SBP at start and end of exercise	TC 300	16±1.2	14.66±1.4	11.33±1.1*#
	TC 150	20.67±2.1	19±1.1	16±1.8
	Placebo	20.33±1.4	20±1.6	21.33±2.2
Difference of DBP at start and end of exercise	TC 300	14±2.1	10.34±1.7	10±1.8
	TC 150	14±1.8	11.67±2.6	9±1.4
	Placebo	13.33±1.4	11±2.5	12.66±1.7

Data: Mean±SD on *post hoc* Tukey test, \*P<0.05 compared to baseline visit, #P<0.05 compare to visit 1. HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, TC: *Tinospora cordifolia* aqueous extract, SD: Standard deviation

**Table 4: Comparative effect of *Tinospora cordifolia* during cold pressor test**

Parameters	Study group	Mean±SD		
		Day 0 (baseline)	Day 14 (visit 1)	Day 28 (visit 2)
Difference of HR at start and end of exercise	TC 300	24.5±3.5	21±4.9	19.17±4.5*
	TC 150	30.83±5.4	27.17±3.5	25.16±3.4*
	Placebo	30.5±1.3	31±2.1	30.33±1.6
Difference of SBP at start and end of exercise	TC 300	18±2.9	14±1.9*	14.33±0.6*
	TC 150	20.66±2.3	19±2.4	16.67±1.4*
	Placebo	19±1.1	18.7±1.2	17±1.9
Difference of DBP at start and end of exercise	TC 300	14.33±2.1	11.33±0.9	9.66±1.1*
	TC 150	15.66±1.3	13.33±1.8*	9.67±1.2*
	Placebo	18.67±1.4	15.67±2.9	17±1.9

Data: Mean±SD on *post hoc* Tukey test, \*P<0.05 compared to baseline visit. HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, TC: *Tinospora cordifolia* aqueous extract, SD: Standard deviation

hepatoprotective, and antineoplastic.<sup>[19,20]</sup> Its mechanism of action by stimulation of neuroendocrine-immune axis is very useful for this effects.

In this study, *T. cordifolia* aqueous extract when administered in a dose of 150 mg to healthy volunteers demonstrated a significant increase in – (i) maximum speed from baseline speed of 45.58 km/h to 47.68 km/h by day 28, (ii) hand grip strength that is muscle power from baseline 40.312 kg to 41.133 kg by day 28, and (iii) maximum oxygen consumption that is VO<sub>2</sub> max increased from baseline 35.075 mL/kg/min to 35.620 mL/kg/min by day 28. Similarly, when a dose of 300 mg of *T. cordifolia* aqueous extract was administered orally to healthy volunteers, by day 28, a significant increase was noticed in variables such as (i) distance travelled from baseline 3.21 km to 3.44 km, and (ii) VO<sub>2</sub> max from baseline 34.06 mL/kg/min to 35.50 mL/kg/min. Thus, *T. cordifolia* demonstrated a significant increase in variables used to assess the physical performance of healthy volunteers in the presence of physical stress.

*T. cordifolia* aqueous extract (150 mg/day and 300 mg/day) were compared with placebo, no significant increase in the physical performance parameters was noted except for the variable maximum speed in healthy volunteers. It is observed that *T. cordifolia* 150 mg and 300 mg aqueous extract when administered daily to healthy volunteers for 4 weeks has shown improvement (increasing trend) in distance, and max speed, VO<sub>2</sub> max and muscle power in the presence of physical stress,

although compared with placebo group no statistical difference was detected.

Literature search in databases such as PubMed and Google Scholar revealed no evidence of any clinical study, in which the effect of *T. cordifolia* has been studied on the sympathetic nervous system in the presence of physical stress.

However, preclinical data search has shown the significant anti-stress effect of *T. cordifolia* in animal studies.<sup>[21,22]</sup> The effect α-D-glucan, obtained from *T. cordifolia* was assessed on the hemodynamic, respiratory, hematological, and immune response in Sprague–Dawley rats. In this study, rats were anesthetized with pentobarbital, tracheotomized and femoral artery and vein were cannulated. The mean arterial BP and HR was recorded for 6 h after administration of α-D-glucan in a dose of 0.5 mg/kg and 10 mg/kg. Mean arterial BP was stable (baseline = 83.8 mmHg, at 6 h = 85 mmHg) throughout the 6 h period after administration of the drug in all the groups. The effect of α-D-glucan on HR showed mild tachycardia as evident from baseline was 259 bpm and at 6 h was 305. In this study, α-D-glucan obtained from *T. cordifolia* showed an insignificant change in mean BP and mild tachycardia, which was recorded at resting level without any stress.<sup>[23]</sup>

However, this study found decrease in both BP and HR on day 28 after administration of *T. cordifolia* aqueous extract in healthy volunteer when exposed to the constant physical stress of fixed workload exercise and cold pressor test.



## Limitations

It was an open-label, pilot study including a small number of volunteers and the biochemical parameters of stress such as blood cortisol level was not measured.

## Future recommendations

To produce more concrete and promising results, there is a need to conduct similar kind of studies in a large number of healthy adult population by proper sample size calculation and with proper blinding and randomization procedure for a long duration of 3–6 months.

## Conclusion

*Tinospora cordifolia* possess anti-stress/adaptogenic property. It may be used to improve the physical performance during day-to-day stressful lifestyle. In Ayurvedic literature, this herb is mentioned as an adaptogen (antistress activity). Study findings of improvement in physical performance and suppressing the over-activation of the sympathetic nervous system goes according to their classical Ayurvedic properties of *T. cordifolia* as mentioned in the standard Ayurvedic literature. *T. cordifolia* has mainly down-regulated the over activity of sympathetic nervous system as compared to placebo. *T. cordifolia* can be taken daily as a prophylactic agent to prevent the long-term chemical changes in the body and related adverse consequences on the heart and other body system due to chronic activation of the sympathetic nervous system.

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## Conflicts of interest

There are no conflicts of interest.

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## हिन्दी सारांश

# गुडूची का निरोगी सहभागीयों पर शारीरिक तनाव प्रेरित भौतिक तथा हृदयसंवहनीय प्रभाव

भारत ए. सालवे, राखी के. त्रिपाठी, अनुप यु. पेटारे, अश्विनीकुमार ए. राऊत, निर्मला एन. रेगे

आयुर्वेद चिकित्सा पद्धति में गुडूची (टीनोस्पोरा कार्डिफोलिया) का प्रयोग उसके रसायन, दीपन, ज्वरनाशन, त्रिदोष शामक गुणधर्मों के कारण औषधोपचार में इस्तेमाल किया जाता है। यह शरीर के रोग प्रतिरोधक प्रणाली को प्रभावित करती है। शरीर पर होनेवाले तनाव, अति स्निग्धता इस कारण औषधि उपचार में भी प्रयोग किया जाता है। इस अध्ययन में निरोगी सहभागीयों के शरीर पर गुडूची का प्रयोग कसरत करते समय होनेवाले तनाव के विरुद्ध किया गया है। इस अध्ययन का मुख्य प्रयोजन गुडूची का शरीर पर होनेवाले तनाव विरोधी गुणों को दर्शाना है, द्वितीय उद्देश्य - शारीरिक तनाव में मासपेशियों की ताकत (बाहुबल), ऑक्सीजन लेने की अधिकतम क्षमता, अनुकंपी तांत्रिकांत्र की गतिविधि (कूटभेषज), इन पैमानों की तुलना प्लेसीबो दिए जानेवाले सहभागी समूह और गुडूची औषधि लेनेवाले सहभागी समूह के बीच की गयी। कुल ३० सहभागीयों को तीन समूह में विभाजित किया गया। हर एक समूह में दस सहभागी को नियुक्त किया गया। टीसी १५० समूह और टीसी ३०० समूह जिनमें सहभागीयों को गुडूची जलीयसत्व के १५० मिग्रा और ३०० मिग्रा का एक कैप्सूल हर सप्ताह लगातार २८ दिन के लिए खिलाया गया। इन पैमानों का मूल्यांकन सिर्फ तीन दिन किया गया। पहला आधारभूत भेट, १४ दिन और २८ दिन, शरीर में तनाव पैदा करने हेतु स्वस्थ सहभागीयों को यंत्र द्वारा कसरत करने को कहा गया। इन मशीन के नाम जिसपर कसरत किया गया:- साइकल अर्गोमीटर, जमार हैंड डायनमो मीटर, कोल्ड प्रेसर टेस्ट। भौतिक तनाव १. अधिकतम तय की हुई दूरी और तेजी/गति, २. ऑक्सीजन लेने की क्षमता, ३. हथेली से कसके पकड़ने की ताकत इन मापदण्डों में नाँपा गया। हर टेस्ट में हृदयगति और रक्तचाप का मापन किया गया। औसत अधिकतम गति में अट्टाइसवे दिन प्लासीबो समूह की तुलना में टीसी १५० समूह में महत्वपूर्ण बढोत्री देखी गई। चौदहवे और अट्टाइसवे दिन टीसी १५० समूह में रक्तचाप और हृदयगति में महत्वपूर्ण कमी देखने को मिली, प्लेसीबो समूह की तुलना में देखें तो १४ और २८ दिन रक्त दबाव में कमी हुई है जबकि हृदय में कमी सिर्फ २८ दिन को ही देखा गया है। कोल्ड प्रेसर टेस्ट करने पर चौदहवे और अठारबिसवे दिन को, टीसी ३०० समूह ने हृदयगति में प्लेसीबो सहभागी समूह के तुलना में अधिकतम कमी देखने मिली। इस अध्ययन से पता चलता है कि गुडूची वनस्पति के ग्रहण करने से सहभागीयों के शारीरिक क्षमता में वृद्धि और अनुकंपी तांत्रिका की गतिविधि (हृदयगति और रक्तदबाव) में कमी देखी गई है, जो उसके तनाव विरोधी क्षमता को दर्शाता है।