Journal of Ayurveda and Integrative Medicine 14 (2023) 100718

Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: http://elsevier.com/locate/jaim

Original Research Article

Combined effect of yoga and naturopathy in uncomplicated varicose vein disease – a prospective randomized controlled trial

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ARTICLE INFO

Article history:
Received 20 January 2022
Received in revised form
1 November 2022
Accepted 24 April 2023
Available online xxx

Keywords:
Yoga
Naturopathy
Uncomplicated varicose vein
hs-CRP
Homocysteine

ABSTRACT

Background: Though the treatment of uncomplicated varicose vein (UVV) might prevent late complications such as skin change or ulceration, but, there are limited studies available to justify this concept. Yoga and Naturopathy being a proficient tool in managing non communicable diseases including many cardiovascular diseases; no attempt was made to study its potential effect in Varicose Vein diseases.
Objective: The present study aims to study the combination of Yoga and Naturopathy in uncomplicated varicose vein patients.
Materials and methods: 50 UVV participants were prospectively recruited and randomly divided into two groups, Experimental and Active control groups. Both the groups practiced their respective interventions, and follow up was done after 1 and 3 months of active intervention. Finally study was completed with 46 participants (2 dropouts in each groups). The sample size was calculated based on the previous study, considering power as 0.8 and 'α' as 0.05, using 'G' power software. The variables such as Body weight, BMI, Systolic blood pressure (SBP), Diastolic blood pressure (DBP), Heart rate (HR), high-sensitivity C-reactive protein (hs-CRP), homocysteine (HCy) were recorded before and after the intervention, but Aberdeen Varicose Vein Questionnaire (AVVQ) and Visual analogue heaviness scale (VAHS) were recorded on 60 and 120 days of the follow up in addition to active intervention period.
Results: There was a significant decrease in hs-CRP ($p < 0.05$) in the experimental group as compared to the control group. Body weight, BMI, SBP, HR, hs-CRP, HCy ($p < 0.001$) and DBP ($p < 0.05$) significantly decreases following the Combined Yoga and Naturopathy (CYN) intervention for a month in the experimental group. Also, the AVVQ ($p < 0.01$) and VAHS ($p < 0.05$) decreases following active intervention and two consecutive follow up. No adverse event was noted during or after the trial.
Conclusion: The combined effect of Yoga and Naturopathy reduced blood pressure and inflammatory markers suggestive of potential of recovery in inflammation in the endothelial tissue of the microvascular system in UVV patients.
Trial Registry number: CTRI/2018/10/015895; Clinical Trials Registry- India; www.ctri.nic.in.

1. Introduction

Varicose veins (VV) are twisted and dilated enlarged veins and long been considered as a cosmetic problem. VV is generally benign and the exact cause of this condition is not known. It is not the source of difficulty but affects psychological well-being. However, varicosities are the cause of discomfort, pain, loss of working days, disability and adversely affect the health related quality of life (QoL) [1–3]. It is noticed on the lower extremities of the body, afflicting about 16 percent of men and 29 percent of women [1]. Gourgou, Dedieu, Sancho-Garnier reported that VV is a complication for the population of prolonged standing for their regular job for more than 4 h [4].

The treatment of VV has undergone radical changes with the introduction of percutaneous endovenous ablation techniques, endo-venous laser therapy [5], radiofrequency ablation [6], and

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Peer review under responsibility of Transdisciplinary University, Bangalore.

https://doi.org/10.1016/j.jaim.2023.100718

liquid or foam sclerotherapy [7]. Also, there are alternative therapies viz., lifestyle modifications, avoidance of prolonged standing and straining, exercise, wearing non-restrictive clothing, modification of cardiovascular risk factors, the elevation of the affected leg; weight loss; and phlebotonics to reduce the adverse condition of VV [8–10] but with the help of these approaches, venous disorders cannot be managed alone. Furthermore, non-invasive procedures like compression therapy was found to improve symptoms of chronic venous insufficiency by improving venous functions [11]. Also, non-pharmacological alternatives viz., exercise training targets improvement in calf muscle pump function, which might be a useful adjunct therapy for VV treatment, ulcer healing and other aspects of physical health [12]. Exercise training was prescribed in routine for cardiovascular diseases such as peripheral arterial disease [13] and coronary vascular diseases [14]. Molski et al. reported a reduction in disease progression and QoL improvement in patients with venous diseases who underwent manual lymphatic drainage (MLD) before elective venous lower limb surgery [15]. In a couple of studies, physiotherapy and lifestyle changes were recognized to strengthen the calf muscles and improve the ankle range of motion that activates the calf muscle pump, thereby improving the VV condition. Leg elevation was used for long and still recommended to patients to relieve venous stasis symptoms, reduce leg oedema, and promote ulcer healing in chronic venous disorder patients [16,17].

Yoga is a mind-body technique, evolved in ancient India and it has various practices viz., yoga postures, yogic breathing, cleansing techniques and meditation. In contrary, Naturopathy is a system of medicine that uses natural therapies to heal the body by itself. Yoga postures consist of low-intensity and slow movement practices, found to be safe and appropriate for the individuals with all levels of physical activities [18]. However, a yoga module reduced the vascular inflammation, symptoms of Chronic Venous Insufficiency (CVI) in the industry workers [19]. Yoga was studied for the management of hypertension in many randomized controlled trials. Yoga practices were shown to reduce psychological cardiovascular disease risk factors viz., stress and depression [20]. Following yoga training, Siu, et al. reported reduction in waist circumference and blood pressure (BP) in middle aged and older adults with metabolic syndromes [18]. Also, the therapy practices of yoga resulted in a reduction in systolic and diastolic BP [21]. In an attempt to study the efficacy of yoga in atrial fibrillation (AF), Lakkireddy, et al., found the usefulness of yoga intervention in 49 patients with paroxysmal AF [22].

In addition, effect of yoga was studied in wide range of cardiovascular outcome viz., the high frequency measure of heart rate variability, pulse wave velocity, low density & high density lipoproteins, triglycerides, C-reactive proteins attributed to its positive impact in Cardio-vascular disorders (CVD) [23–25]. However, one year of yoga training reduced proinflammatory adipokines and increased anti-inflammatory adipokine in adults with metabolic syndrome and high-normal blood pressure [26]. The yoga-based program was found to reduce the risk of CVD. In a ten-days yoga intervention trial, Sarvottam, et al. reported a reduction in BMI (Body Mass Index), systolic BP, and a significant decrease in specific inflammatory markers viz., IL-6, and increase in adiponectin [27]. An attempt by Manchanda et al., 2000, demonstrated the slow progression of atherosclerosis in patients with severe coronary artery disease through yoga [28].

Moreover, Naturopathy is a unique health care system in itself that connects old traditional healing practices with that of advanced scientific methods. Naturopathy utilises body's inherent and innate healing capacity to promote and preserve health and to cure various diseases. Naturopathy was practised since 19th century where natural modalities such as water, air, nutrition etc. was utilized to cure diseases [29]. Few studies indicates the effectiveness of Naturopathy and Yoga in anxiety and depression in COVID-19 individuals [30]; in metabolic syndrome [31]; dysmenorrhoea [32] etc. Naturopathy with Yoga is practised in nature cure hospitals and clinics since decades, but there are barely any evidences available to prove its efficacy in venous disorders. Since therapeutic practices of yoga and naturopathy are evidentially reported to be the proficient tools to deal with many non-communicable diseases, including the cardio-vascular conditions, the current study was designed to study the combined effect of yoga and naturopathy in uncomplicated varicose veins (UVV) patients.

Since therapeutic practices of yoga and naturopathy are evidentially reported to be the proficient tools to deal with many non-communicable diseases, including the cardio-vascular conditions, the current study was designed to study the combined effect of yoga and naturopathy in uncomplicated varicose veins (UVV) patients.

2. Methods

2.1. Study participants

Participants were recruited from Balvantray Mehta Aarogya Bhavan, a Naturopathy and Yoga hospital, Gujarat, West India. Out of 150 participants screened, 75 were diagnosed with VV, out of which 50 met the inclusion criteria. The criteria considered to include the patients in this study were with age ranging from 30 to 75 years, C2 and C3 clinical type as per the CEAP classification system, subjects with great saphenous vein (GSV) insufficiency and those who were willing fully gave their consent to become the part of this trial. The exclusion criteria were patients with recent VV surgery, pregnancy, appearance of venous ulcers, vasculopathy, arterial disease, deep vein thrombosis, bleeding, varicose eczema, lipodermatosclerosis, thrombophlebitis, chronic lower limb ischemia, skin infections, lymphangitis, renal failure, malignancy, chronic obstructive lung disease, heart failure, any neurological and psychiatric illness, dementia, those who were receiving folate and vitamin B_{12} supplementations, as the supplements might interfere with homocysteine (HCy) readings [33], and the subjects who were using elastic stockings as a therapy. Further, the details of the characteristics of the patients are given in Table 1. The Institution Ethical Committee approved the project, and informed consent was obtained from the participants after explaining the research trial.

2.2. Study design

Fifty participants were prospectively recruited and randomly divided into two groups' viz., experimental and active control groups using a computerized random number table. This sample size of 46 was calculated based on the previous study [28], considering the power of the study as 0.8 and 'α' as 0.05, using 'G' power software. In the experimental group, there were 19 females and 4 males whereas, in the control group, 21 females and 2 males. There were 2 dropouts from each group and the reasons for dropping the trial is illustrated in Fig. 1. The study was a two arm parallel group's prospective randomized controlled trial.

2.3. Intervention

The experimental group received the combination of yoga and naturopathy (CYN) interventions, and the control group received passive exercises (PE) involving stretching of Neck, shoulder, elbow, wrist, fingers, hip, knees, ankles, and hamstring muscles for five days in a week for one month. The techniques administered for CYN group as part of Yoga were *Shuddhi Kriya* (Yogic cleansing

Table 1
Demographic data and characteristics of the UVV(Uncomplicated varicose vein) participants.

Sl. No.	Patient details	Experimental	Control
1.	Total participants	23	23
2.	Men	4	2
3.	Women	19	21
4	Age (Mean ± SD)	55.17 ± 13.34	55.17 ± 9.63
5.	Participants with category C2 of CEAP classification	15	14
6.	Participants with category C3 of CEAP classification	8	9
7.	Participants having no comorbidities	9	8
8.	Obesity	14	13
9.	Diabetes	2	1
10.	Hypertension	5	5
11.	Hypothyroidism	3	4
12.	Osteoarthritis	5	2
13.	Rheumatoid Arthritis	0	1
14.	Gout	0	2
15.	Insomnia	1	0
16.	Medication history-		
	a. Calcium channel blockers	1	2
	b.ACE inhibitors	1	0
	c.Angiotensin receptor blockers	2	2
	d.ACE inhibitors	0	1
	e.NSAIDs		
	i. Aspirin	7	6
	ii. Diclofenac	3	2
	iii. Ibuprofen	3	2
	iv. Piroxicam	1	2
	f. Antidiabetic agents		
	i. Biguanides	2	1
	ii. Insulin	0	1
	g. Hypothyroid medicines	3	4

techniques), *Sukshma Vyayma* (Subtle joint loosening), *Asanas* (yogic postures), *Pranayma* (voluntarily regulated breathing practices), Deep relaxation techniques (DRT), *Om Dhyana* (Meditation), and as part of Naturopathy full body massage, Massage to lower limbs, mud applications, and enema were administered very meticulously. The details about the above mentioned practices and the duration are given in Table 2. A trained therapists administered the CYN intervention to the experimental group for 60–90 min every day for five days a week. The standard protocol of CYN had been used for few decades, exclusively for VV pateints. Immediately after 30 days of the completion of the main trial in the host institution, the participants were advised to carry a tape, having the video of all the techniques with guided instructions for their practice at home. In case of the control group, the PE and lower limb stretching practices were administered by the trained therapists during their stay in the hospital. In addition, they were also given a tape for their regular practice at home like the experimental group. As the care takers of the respective patients were well verse with the techniques, following the active interventions, both the groups were also advised to continue their interventions with the help of their care taker at home as per the guided instruction given in the tape and regular follow-up was done from time to time over the phone. The practices for both groups are detailed in Table 2. No harm or untoward effect of protocol was noted during the trial or during laboratory investigation.

2.4. Assessments

Anthropometric measurements viz., weight (kg.), height (cm.) and body mass index (BMI) were assessed before and after the intervention. Weight was measured to the nearest 0.1 kg in light clothing using a Digital Weight Scale (Model No. WS2019; Narang Medical Ltd., New Delhi, India). Height was measured to the nearest 0.1 cm without shoes using non-elastic tape. BMI was calculated as weight (kg) divided by height squared (m^2) [34]. Likewise, pre and post-assessments of BP readings were carried out in the right arm in the sitting position using a validated Omron-automatic BP monitor (Model No. HEM-7203-AP; Omron Healthcare Co. Ltd., Kyoto, Japan). Also, AVVQ (Aberdeen Varicose Vein Questionnaire) and VAHS (Visual Analogue Heaviness Scale) were recorded before and 30 days after the respective interventions. AVVQ consists of a scoring grid as well as 13 questions which were used to assess health-related QoL of varicose vein individuals based on the severity of symptoms whereas VAHS is a ten-point scale with the starting point '0' indicating 'not heavy' and '10' for; very heavy'. The respondents were asked to mark a point on the scale that he/she experiences at that particular point in time. In addition, follow-up data of AVVQ and VAHS was recorded after one and three months of intervention in addition to pre and post-assessment.

Blood samples were collected from the legs, above knee from the tortuous and dilated varicose tributaries of the great saphenous vein using standard venepuncture. Samples were centrifuged at $1500 \times g$ for 20 min and the separated serum was stored frozen at −40 °C until assayed. Serum hs-CRP (highly sensitive C-reactive protein) was assessed using a commercially available Immulyte 2000 xpi analyzer by Siemens, Germany, using CLIA (Chemiluminescence immunoassay) and serum homocysteine was assessed on Architect 1000 SR by Abbott, U.S. using CMIA (Chemiluminescent microparticle immunoassay).

2.5. Data analysis

Data were analyzed using SPSS 10.0 version. The within-group comparison was made in both experimental and control groups, using students' paired 't' test, whereas an independent 't' test was done to make a comparison between the groups. Further, Analysis of Variance (ANOVA) to compare the scores recorded for both the groups at a regular intervals viz., Day '0', Day '30', Day '60' and Day '120'.

3. Results

The current research compared data from 46 subjects with venous disorders. Both male and female participants were included in the trial, and there were 23 subjects each in the experimental and control group.

3.1. Between group comparison

Comparison between the groups, determined by independent 't'-test, revealed a statistical change in the variables viz., Wt., BMI, SBP (Systolic Blood Pressure), DBP (Diastolic Blood Pressure), and HCy. There was a significant reduction in HCy ($p < 0.05$) in the experimental group, compared to the control group. No statistical change was observed in the control group.

3.2. Within group comparison

Likewise comparison within the group, ascertained by paired 't' test reported a significant reduction in scores of the variables viz., Body weight ($p < 0.001$), BMI ($p < 0.001$), Systolic BP ($p < 0.001$), Distolic BP ($p < 0.05$), HR (Heart Rate) ($p < 0.001$), hsCRP ($p < 0.001$) and HCy ($p < 0.001$).

Within-group, the comparison revealed a significant decrease in the scores of diastolic BP and HR ($p < 0.05$), whereas, hsCRP and HCy significantly increased ($p < 0.01$). No significant change was observed in the remaining variables viz., Body weight and Systolic BP.

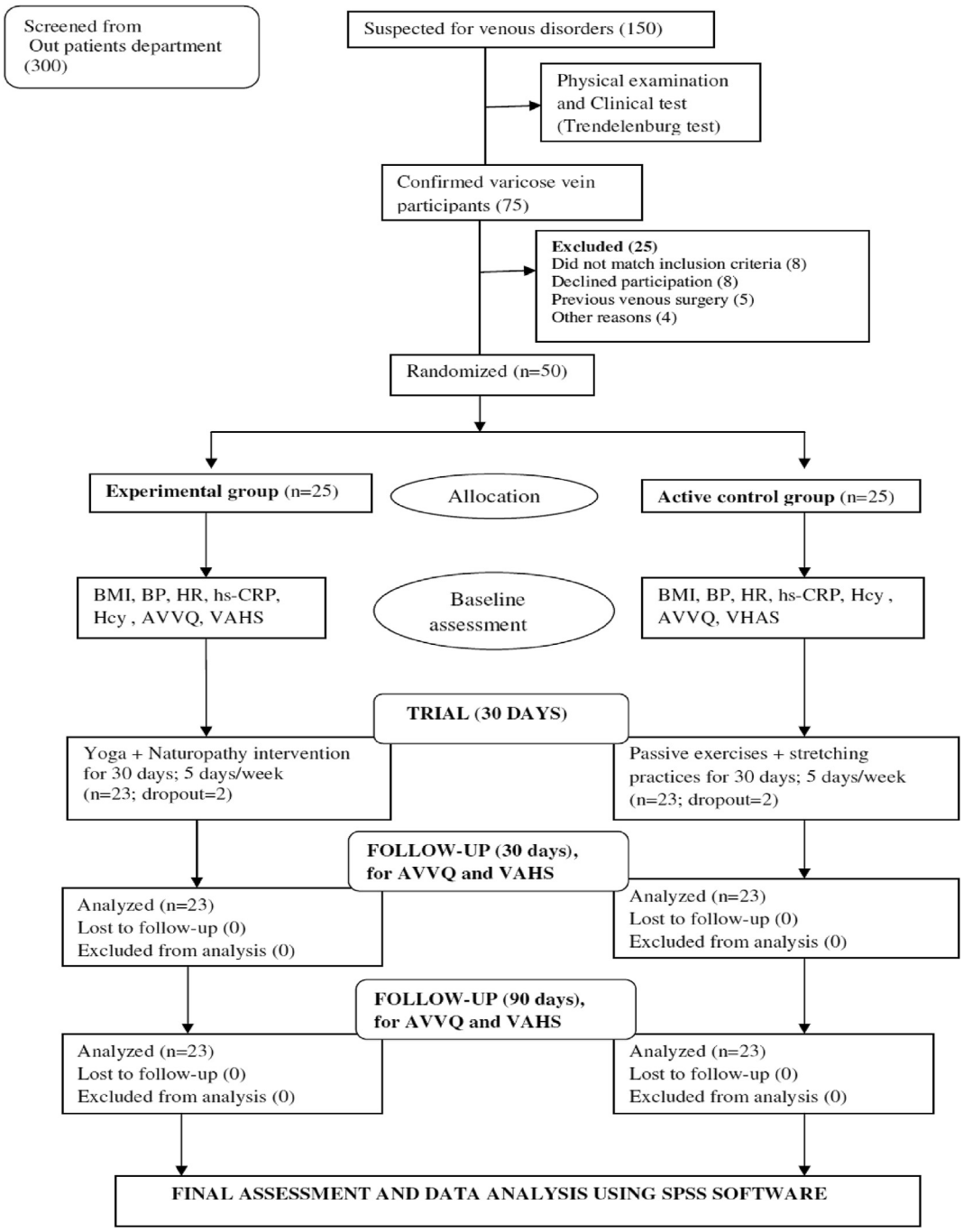

Fig. 1. CONSORT flow chart for study participants.

The Mean ± SD scores of all the variables and level of significance are depicted in Table 3. Also, the changes of means and S.D. of hs-CRP and HCy is shown in Fig. 2.

3.3. ANOVA for AVVQ and VAHS

Since AVVQ and VAHS were recorded at regular intervals of time, hence the scores of these two variables were compared before, one month, two months, and four months after the intervention using ANOVA. It was observed that after one month of active intervention and one and three months after the follow-up, the CYN intervention yielded the desirable results. It was noticed that both the AVVQ and VAHS reduced statistically at ($p < 0.01$) and ($p < 0.05$) respectively following the active intervention and follow up. The Mean ± SD scores and level of significance are detailed in Table 4.

5. Discussion

The present study investigated the efficacy of a month-long active intervention of CYN and a follow-up of one and three months in uncomplicated VV participants. The hs-CRP was reduced in the experimental group compared to the control group. Also, body weight, BMI, Systolic BP, Diastolic BP, HR, and

Table 2
The detail of practices introduced for both Experimental and Active control groups.

Groups	List of the practices	Frequency	Duration
EXPERIMENTAL GROUP	**YOGA PRACTICES**		
	1. SuddhiKriyas(yogic cleansing techniques)	**Once a week**	**15–20 min**
	VamanDhauti (yogic vomiting), Jal Neti(nasal cleansing)		
	2. Sukshma vyayama(subtle joint loosening practices)	**5 days a week**	**12–15 min.**
	Angulishaktivikasika (Finger loosening exercises), Manibandhashaktivikasika (wrist loosening exercises), Kaponishaktivikasika (elbow loosening exercises), Skandha chakra (shoulder rotation), Padangulinaman (toes stretch), Gulf naman (ankle stretch), Gulf Chakra (ankle rotations), Gulf goornan (ankle rotations), Janu chakra (knee crank), Janunaman (knee bending), Baddhkonasana asana (full butterfly pose)		
	3. Asanas (yogic postures)	**5 days a week**	**15 min.**
	Tadasana (palm tree pose), Utthanpadasana (Raised leg pose), Chakra padasana (leg rotation), Setubandhasana (Bridge pose), ViparitaKarni (Inverted Pose), Sarvangasana (shoulder stand pose), Pada sanchalanasana (cycling), Salabhasana (Locust Pose), Dhanurasana (bow pose), Paschimottanasana (Forward Stretch)		
	4. Pranayama(voluntarily regulated breathing techniques)	**5 days a week**	**15 min.**
	Vibhagiya Pranayama (Sectional Breathing), Kapalbhati (frontal brain cleansing), Nadisuddhi (Alternate nostril breathing)		
	5. Deep relaxation technique	**Thrice a week**	**20 min.**
	6. OM Dhyana(OM meditation)	**Twice a week**	**10 min.**
	Total duration	**60–90 min/day**	
	NATUROPATHY PRACTICES		
	Neem Water Enema (Colon cleansing), Centripetal Massage to Lower Limbs/Full body Massage, Mud application to Lower Limbs/Full body mud application, Lapet on lower limbs (leg pack)	**5 days/week**	
	Total duration	**60–90 min/day**	
CONTROL GROUP	**1. Passive Exercises**	**5 days a week**	**30–45 min.**
	A.Neck exercises- Head turns, Head tilts, Chin to chest		5–7 min.
	B.Shoulder and Elbow exercises- Shoulder movements- up and down, side to side, Elbow bends		5–7 min.
	C. Arm and wrist exercises- Wrist bends, Wrist rotations, Palm up and down		5–7 min.
	D. Hand and finger exercises- Finger bends, Finger spreads, Finger to thumb touches, Finger rotations		5–7 min.
	E.Hip and Knee exercises- Hip and knee bends, Leg movements-side to side, Leg rotation-in and out		5–7 min.
	F.Ankle and foot exercises- Ankle bends, Ankle rotation, Ankle movement -side to side, Toe bends, Toe spreads		5–7 min.
	2. Passive Stretchings	**5 days a week**	**30–45 min.**
	Calf stretchings & Hamstring stretchings		15–20 min each
	Total duration		**60–90 min/day**

Table 3
Table showing the Mean ± SD scores of the variables recorded before and 30 days after the Experimental and Control interventions.

Parameters	Experimental group, Mean ± SD		Control group, Mean ± SD	
	Pre	Post	Pre	Post
Systolic BP (mm/Hg)	129.57 ± 10.65	122.87 ± 7.62***	127.04 ± 9.04	124.78 ± 13.14
Diastolic BP(mm/Hg)	83.48 ± 5.20	79.22 ± 3.12***	84.78 ± 11.52	81.30 ± 4.99*
HR (bpm)	75.48 ± 5.66	73.13 ± 3.57***	76.78 ± 6.37	75.91 ± 5.80*
Body mass (kg)	69.54 ± 19.15	66.27 ± 17.22***	66.16 ± 14.38	65.70 ± 14.18
BMI (kg/m^2)	27.85 ± 6.35	26.23 ± 6.16***	26.42 ± 5.15	26.24 ± 5.11
hs-CRP (mg/L)	5.41 ± 4.84	2.57 ± 2.88***	3.59 ± 3.50	5.17 ± 4.23**
Homocysteine (μM)	18.40 ± 9.34	13.10 ± 4.40***$^{\alpha}$	15.84 ± 12.71	18.98 ± 4.52**

*p < 0.05, **p < 0.01 and ***p < 0.001, comparing the mean scores within the groups using paired t' test and $^{\alpha}$p < 0.05, between the groups, using independent t' test.

HCy decreased, following the CYN protocol regime for a month in the experimental group. However, the variables such as AVVQ and VAHS, that were recorded throughout, decreased significantly in both active interventions and after two consecutive follow-up.

Research studies in uncomplicated VV following the regime of conservative and conventional treatment protocols were barely sufficient, and therefore we highlighted a couple of studies in which interventions were introduced. Previously, it was argued that uncomplicated varicose veins might not manifest complications such as skin change or ulceration. However, there are no studies in the literature to justify this concept. In the current study, we recorded higher scores of hs-CRP and HCy, suggestive of the possibility of inflammation in the endothelial tissues of the varicose veins. It is implicated that shear stress plays a vital role in maintaining the structure and function of the blood vessels. It was generally believed that laminar shear stress promotes the release of some factors that suppress inflammation and the reduction of free radicals. In contrast, low shear stress, stasis of the veins and turbulent flow of blood promote inflammatory and thrombotic mediators [35]. Therefore, stasis in the veins results in inflammation and deterioration of the venous wall.

Few studies have investigated the systemic inflammation in varicose patients and inflammatory markers in the VV is rare. Still, the research by Poredos et al., 2015 reported an increase in some of the inflammatory markers including hs-CRP and indicators of endothelial dysfunction in VV blood [36]. Our study also reported an increase in the scores of hs-CRP in most the patients before the intervention regime. Our findings support the fact that there could be inflammation and endothelial dysfunctions due to the chronic damage of the blood vessels, which were not noticed in the patients recruited for our research trial.

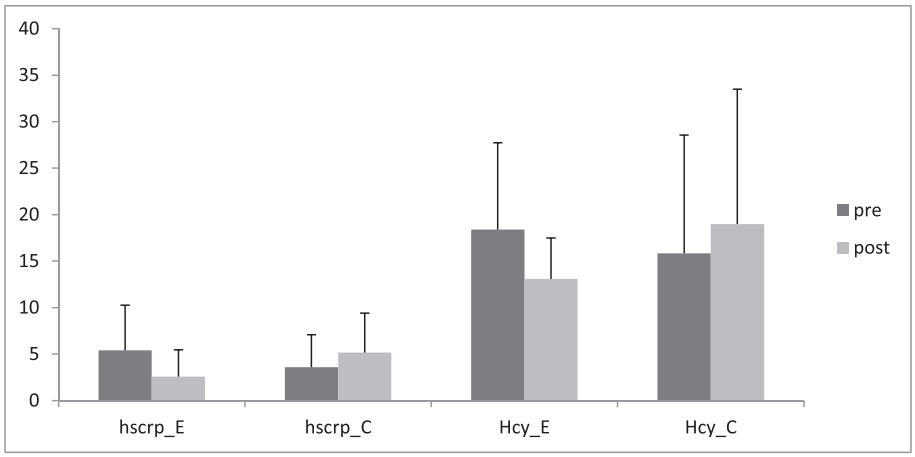

Fig. 2. Figure comparing Mean and S.D. of hs-CRP and Homocysteine (Hcy) in experimental and control group. *$p < 0.05$, comparing the mean scores of hs-CRP and Hcy between the groups. E = Experimental; C= Control.

Table 4
Table showing the mean ± SD scores of experimental and control groups following the interventions at various stages.

Groups	Baseline	30 days after	60 days after	120 days after	*p* value*
AVVQ scores					
Experimental	31.79 ± 11.24	16.30 ± 4.64**	12.13 ± 3.58**	9.16 ± 1.71**	$p <$ **0.01**
Control	30.79 ± 12.95	29.34 ± 12.17**	20.70 ± 9.65**	14.52 ± 6.75**	$p <$ **0.01**
VAHS scores					
Experimental	5.37 ± 1.57	4.64 ± 1.48*	4.00 ± 1.32*	3.23 ± 1.30*	$p <$ **0.05**
Control	5.08 ± 1.62	4.99 ± 1.64*	4.56 ± 1.56*	4.26 ± 1.58*	$p <$ **0.05**

*p < 0.05, **p < 0.01, comparing the mean scores at various stages of interventions, using Analysis of Variance. AVVQ = Aberdeen Varicose Vein Questionnaire; VAHS=Visual Analogue Heaviness Scale.

One of the essential vasoactive substances produced by the endothelial tissue of the blood vessels is nitric oxide (NO). This modulates vascular tone, inhibits the interaction between blood cells and the wall of the blood vessels. Endothelial tissue damage caused by chemical, metabolic and mechanical factors contributes to the disease manifestation characterized by inflammation, vasoconstriction, excessive thrombus formation and adhesion of leukocytes to the wall of the blood vessels [37]. Therefore endothelial dysfunction is not only the cause of VV but the pathogenesis of atherosclerosis and thrombotic complications.

In the current trial, there was a noticeable rise of HCy in all uncomplicated VV patients, and a reduction in HCy was observed following one month of CYN. On the other hand, there was no change in HCy in the control group following the intervention in the control group. The HCy was indicated to be promoting endothelial dysfunction, inflammation and leakage of the vascular wall. It was believed to be playing an essential role in helping the chronic venous disorder complications [38–40]. The HCy has also been identified as a potential risk factor for cardiovascular diseases. Raised circulating level of HCy has been associated with endothelial injury, platelet activation and thrombosis. However, superficial thrombosis has been found due to the results of the pathogenesis of primary chronic vascular disorder [41]. The HCy may increase the interaction of leukocytes with the endothelium and possibly implicate chronic vascular disorder's pathogenesis [42].

To explain in favor of the beneficial effects of yoga, exercise plays an important role. It might be one of the well accepted strategies for the management of VV complications. In an age-matched controlled trial, 25 min of treadmill exercise improved the microvascular endothelial function in post-surgical VV patients [43]. Moreover, a trial investigated the risk reduction in microcirculatory and cardiorespiratory functions in healthy sedentary participants. It was noticed that eight weeks of exercise and Mediterranean diet (MD) intervention improved the endothelial-dependent microvascular function and cardiopulmonary fitness in the MD group in particular [44]. Also, in a prospective controlled trial, patients with venous leg ulceration practiced supervised calf muscle exercise which improved their venous ejected venous volume, ejection fraction, residual venous volume, remaining venous fraction, calf muscular endurance and plantar flexion compared to the control group, suggestive of improvement in the ejecting ability and hemodynamics of the limbs with venous ulceration [45]. Moreover, a twelve-week home-based progressive resistance exercise program based on air plethysmography appeared to increase the ejection fraction of calf muscle pump in venous leg ulcer patients (VLU) [46]. Further, a 12 weeks randomized controlled trial investigated the efficacy of exercise intervention compared to the care group. Participants following the exercise regime improved their calf muscle pump efficiency and range of ankle motion in venous leg ulcers [47]. Furthermore, in a randomized controlled trial, the twelve weeks of exercise practices improved functional ability, quality of life and self-management scores of VLU [48]. In addition, in a randomized controlled trial, the exercise group having the patients with venous ulcers reported improving the status of lower limb microvascular reactivity following the lower limb aerobic and resistance exercise for 12 weeks [49].

In addition to reducing hsCRP and HCy, the CYN group markedly reduced the Body weight, BMI and BP. The practice protocol introduced in CYN consists of yoga practices to improve the range of motion in the joints and Naturopathic modalities of treatment, including massage to enhance the venous return and mobility of the blood from the veins. It has been already implicated that yoga based lifestyle intervention has a positive impact on cardiovascular risk factors such as β-endorphins and interleukins (IL-6 and IL-23)

[26], mainly by reducing stress and inflammation [50,51]. Also, it has already been implicated that those who practice yoga regularly will have a higher level of leptin and adiponectin, and adiponectin has been reported to be one of the key players of alleviating the inflammation in the endothelial tissue [52–54]. The practices administered in the trial are found to be useful in improving the range of motion in the joints and the efficiency of the calf muscle pump. Also, the reverse massage introduced during Naturopathy treatment was aimed at facilitating the venous return and healing the tense muscle and damaged blood vessels. Therefore, we can anticipate that yoga and naturopathy practices would have managed the inflammation at the microvascular level.

In the current research trial, we could not manage to have more participants, although there were efforts made to recruit more patients. Also, a couple of other markers viz., IL-6, IL-8, and MCP-1 should have been studied to get an idea about the said markers in the current study. Another limitation of this study was that the subjects would have been followed up with all the variables including AVVQ and VAHS, along with the variables that we studied before and after the active intervention.

6. Conclusion

The results suggest the combined effect of yoga and naturopathy reduced the blood pressure and inflammatory markers suggestive of possibility of recovery of inflammation in the endothelial tissue of the microvascular system in uncomplicated varicose vein patients.

Funding

This research did not receive any specific grant from the funding agencies in the public, commercial, or not-for-profit sectors.

Author contribution statement

Sweta Chauhan contributed in data collection, data analysis and drafting the manuscript; Sanjib Patra contributed in data analysis, drafting the manuscript, designing the analysis, Shailendra Pratap Singh contributed in writing the paper, collecting data and data analysis, and other contributions, Jitendra D Lakhani contributed in collecting the data and other contributions.

Declaration of competing interest

The Author(s) declare(s) that there is no conflict of interest.

Acknowledgements

The administration of Balvantray Mehta Aarogya Bhavan is gratefully acknowledged by the authors for allowing us to recruit participants for the research experiment in the aforementioned setting.

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