

Impact of Yoga Therapy on D-dimer Level in Asymptomatic Varicose Vein Disease – a Randomized Controlled Trial

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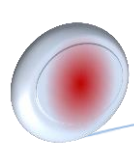
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Abstract

Background: Varicose veins (VV) affect a significant portion of the population, particularly middle-aged men, causing discomfort and potential complications. Elevated D-dimer levels may indicate thrombotic risk in VV patients. Yoga therapy (YT) has emerged as a complementary approach for managing vascular disorders, but its impact on biomarkers like D-dimer remains unclear, especially in middle-aged men with VV.

Material and Methods: This randomized controlled trial recruited 80 middle-aged men diagnosed with VV. Participants were equally and randomly assigned to a yoga therapy group (YTG) or a control group (CG). The YTG received tailored YT sessions three days a week for 12 weeks, focusing on specific asanas, pranayama techniques, and meditation. The CG continued with their usual activities. Outcome assessments included Systolic blood pressure (SBP), Diastolic blood



pressure, Heart rate (HR), high-sensitivity C-reactive protein (hs-CRP), and D-dimer levels. Assessments were conducted before and after the intervention period for both groups.

Results: Following the yoga intervention in varicose vein patients, significant improvements were observed compared to the CG. SBP decreased from 140 mmHg to 128 mmHg in the YTG, whereas in the CG, it decreased from 142 mmHg to 138 mmHg. Similarly, DBP decreased from 90 mmHg to 85 mmHg in the YTG, while in the CG, it decreased from 92 mmHg to 90 mmHg. Heart rate also showed improvement in both groups, with a decrease from 80 bpm to 70 bpm in the YTG and from 82 bpm to 78 bpm in the CG. Furthermore, levels of hs-CRP decreased from 3.5 mg/L to 2.8 mg/L following the intervention in the YTG, whereas in the CG, there was a slight increase from 3.6 mg/L to 3.7 mg/L. Moreover, D-dimer levels, indicative of thrombotic risk, decreased from 1.6 mg/L to 1.4 mg/L after the YT, whereas in the CG, they remained relatively stable at 1.7 mg/L before and after the intervention.

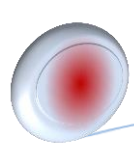
Conclusion: This study highlights the potential of YT as a non-invasive intervention for managing VV and reducing thrombotic risk in middle-aged men. Further research is warranted to validate these findings and explore the mechanisms underlying the observed effects of yoga on biomarkers like D-dimer.

Keywords: Varicose veins, D-dimer, Yoga therapy, Middle-aged men, Randomized controlled trial.

Introduction

Varicose veins (VV) are a common vascular condition, characterized by enlarged, twisted veins, affecting a significant portion of the population, especially among middle-aged men (1). This is due to damaged or weakened valves within the veins, leading to abnormal blood flow and pooling (Piazza, 2014). While VV are often considered a cosmetic concern, they can cause discomfort and pain, and in severe cases, lead to complications such as inflammation (thrombophlebitis) and ulceration of the veins (Gawas et al., 2022; Piazza, 2014). The D-dimer test is one of the valuable tools for assessing the risk of vascular clotting in various clinical conditions, including venous insufficiency (Wauthier et al., 2023).

D-dimer is a degradation product of fibrin into fragments during blood clots breakdown (Moorthy et al., 2022). Elevated levels of fibrin fragments in the blood denote the process of Coagulation and fibrin degradation (Haapaniemi & Tatlisumak, 2009). In VV condition, D-dimer levels may signal thrombus-associated complications, although challenging due to underlying venous insufficiency (Cornuz et al., 2002). Yoga therapy (YT), an ancient practice involving physical asanas (Sengupta, 2012; Sergii et al., 2021), breathing exercises (Maheshkumar et al., 2022), meditation (Pramanik et al., 2023; Rajagopalan et al., 2022), and mindfulness techniques (Wankhar et al., 2024), has gained recognition as a complementary



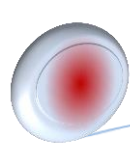
approach to managing various medical conditions, including vascular disorders like VV (Venugopal et al., 2022). Yoga interventions for VV often focus on improving circulation, alleviating venous congestion, and reinforcing the venous system through specific asanas and pranayama techniques (Das et al., 2023). However the growing interest in YT for VV, limited research has investigated its effects on biomarkers such as D-dimer in middle-aged men with enlarged veins. Middle-aged men are especially vulnerable to VV due to factors such as senescent modifications in venous function, long durations of sedentary or upright work, and hormonal influences (Whiteley, 2022). Understanding the impact of YT on D-dimer levels in this demographic is essential for interpreting its potential role in reducing thrombotic risk and strengthening overall vascular health. This study aims to investigate the effects of a tailored yoga intervention on D-dimer levels among middle-aged men diagnosed with varicose veins, enlightening the therapeutic potential of yoga in the management of venous disorders and thrombotic complications.

Methodology

Study Participants

Participants were recruited from nearby corporate sectors, schools and colleges through open flyers, Chennai, India. Out of 104 participants screened, 24 were diagnosed with VV, out of

which 80 met the inclusion criteria (See Figure.1). The inclusion criteria for this study encompass individuals who are willing to participate and demonstrate the capacity to provide informed consent by signing the written consent form. Participants must have been diagnosed with VV as per the CEAP classification (Clinical, Etiological, Anatomical and Pathophysiological), displaying symptoms of skin with VV visible (Lurie et al., 2020). The study specifically targets middle-aged men falling within a defined age range and diagnosed with varicose veins. D-dimer levels are required to fall within the range of 0.49 mg/L to 1.8 mg/L. Additionally, prospective participants should not have a history of practicing yoga or engaging in other regular exercise routines. A thorough physical examination by qualified healthcare professionals determined suitability for participation. The exclusion criteria included individuals with active clinical surgery or other major clinically significant disorders or diseases. Additionally, those with any tumors, blood clotting disorders, or patients on prolonged anti-coagulant drugs were excluded. Individuals suffering from high blood pressure were also not eligible to participate. Furthermore, participants who did not provide consent by signing the consent form were excluded from the study. These criteria were established to ensure the safety of participants and the validity of



study results. The trial has been reviewed and approved by the Institutional Ethics Committee (IEC) of Meenakshi Academy of Higher Education and Research (Deemed to be University) in the committee meeting held on 20th February 2022. The Institutional Ethics Committee clearance certificate reference number is MMCH/RI/PhD/01/JAN/23. The trial

has been registered in the Clinical Trials Registry-India (CTRI). The registration number for the trial is CTRI/2023/05/052928. The Institutional Ethics Committee approved these exclusion criteria to protect the well-being of participants and uphold ethical standards in research.

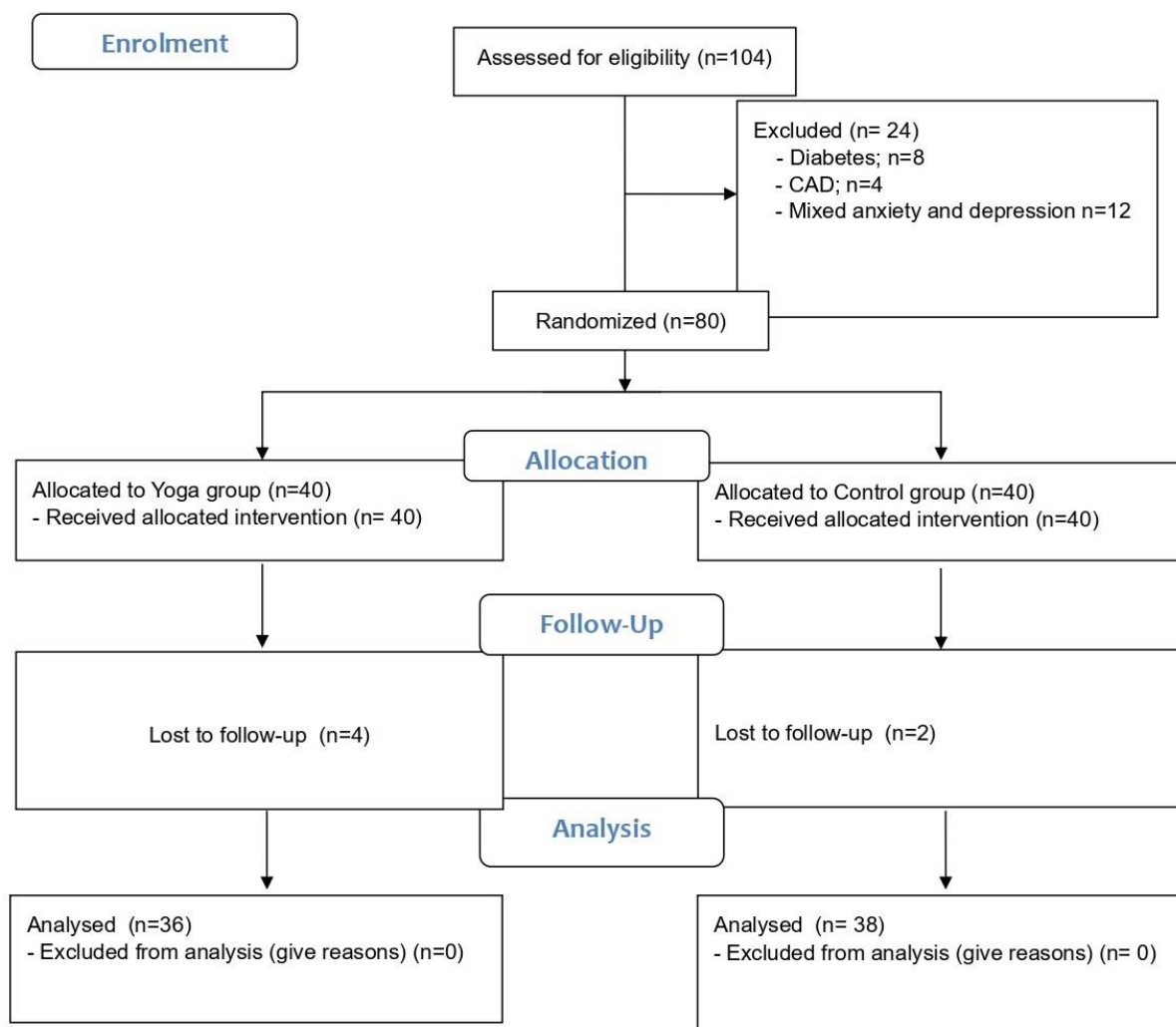
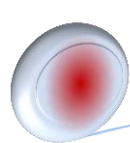


Figure 1. CONSORT statement



Study design and randomization

This single-center, randomized, single-blinded, controlled clinical trial was conducted from January 1, 2023, to December 31, 2023. All participants provided written informed consent before participation. The study adhered to the Consolidated Standards of Reporting Trials reporting guideline and the Standards for Reporting Interventions in Clinical Trials of Yoga interventions (Ward et al., 2022). The randomization sequence was generated and participants were randomized using the sealed envelope method.

Intervention details

The participants in the YTG received yoga sessions for 3 months, three days per week with each session lasting for 60 minutes, a total 12 weeks of duration (Table.1). The participants in the study were instructed to practice various yoga poses and breathing techniques based on existing research findings, including Utthanpadasana (Raised leg pose), Chakra padasana (leg rotation), Setubandhasana (Bridge pose), ViparitaKarni (Inverted Pose), Sarvangasana (shoulder stand pose), Padasanchalanasana (cycling), Salabhasana (Locust Pose), Dhanurasana (bow pose), and Paschimottanasana (Forward Stretch). Additionally, they were taught Pranayama, which involves voluntarily regulated breathing techniques such as Kapalbhata (frontal brain cleansing) and

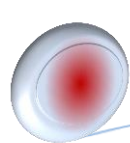
Nadisuddhona pranayama (Alternate nostril breathing). Participants were also encouraged to practice at home, with weekly check-ins to track progress and address any concerns. The control group (CG) did not receive any YT and continued active rest with their usual activities. Outcome assessments were conducted to measure the effects of these practices on the participants' well-being.

Outcome Assessment

Heart rate and blood pressure measurements were obtained in the supine position using a calibrated digital blood pressure monitoring device (Omron Hem 7130L) placed over the brachial artery. Each participant underwent three recording trials with a five-minute interval between each trial, and the average of these recordings was calculated and included in the analysis (A et al., 2018). Serum CRP and D-Dimer levels were measured by automatic biochemical analyzer, which serves as a prothrombotic biomarker and a sensitive measure for assessing varicose conditions. Assessments will be taken before and after the intervention to determine the effectiveness of YT in improving both physical and mental health outcomes.

Statistical analysis

The data, presented as mean with standard deviation (SD), and normality also tested using the Kolmogorov-Smirnov test. A p-value greater than



0.05 indicated a normal Gaussian distribution. For all the outcomes, both paired and unpaired t-tests were

conducted using R statistical software version 3.1.1.

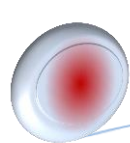
Table: 1 The details of Yoga Therapy Intervention Protocol for Varicose Veins: A 12-Week Program

YOGA	LIST OF PRACTICES	FREQUENCY	DURATION
Sukshma vyayama (subtle joint loosening practices)	Finger loosening exercises, wrist loosening exercises, elbow loosening exercises shoulder rotation, toe stretch, ankle stretch, ankle rotations, ankle rotations, knee crank, knee bending, full butterfly pose	3 times each practice	15 minutes, three days per week, 12 weeks
Asana(Yogic postures)	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)	5 times each asana	25 minutes, three days per week, 12 weeks
Pranayama(voluntarily regulated breathing techniques)	Kapalbhati (frontal brain cleansing), Nadisuddhi (Alternate nostril breathing)	20 rounds each pranayama	10 minutes, three days per week, 12 weeks
Meditation	“AUM” Chanting	10 times	10 minutes, three days per week, 12 weeks

Results of the study

The baseline demographic and clinical characteristics of participants in the study were comparable between the CG and YTG (See Table:2) . The mean age of participants in the CG was 49.20

years (SD=13.70), while in the YTG it was 47.58 years (SD=18.45). Similarly, the mean BMI in the CG was 26.45 kg/m² (SD=6.50), and in the YG it was 24.87 kg/m² (SD=5.30). Additionally, the distribution of gender, marital



status, and education level showed no significant differences between the two groups.

Table 2. Baseline demographical and clinical Characteristics of participants in this study

Characteristic	Control Group N(%) / Mean (SD) [95% CI]	Yoga Treatment Group N(%) / Mean (SD) [95% CI]
Age (yrs)	49.20 (13.70) [44.03 -53.16]	47.58 (18.45) [41.93 -59.23]
BMI (kg/m²)	26.45 (6.50) [21.55- 31.25]	24.87 (5.30) 20.41-30.22]
Gender		
Male	28 (70%)	24 (60%)
Female	12 (30%)	16 (40%)
Marital status		
Married	23 (57%)	29 (72.5%)
Unmarried	14 (35%)	10 (25%)
Divorced	3 (8%)	1 (2.5%)
Education level		
Degree or above	18(45%)	15 (37.5%)
Secondary level	16(40%)	10 (25%)
Primary level	6(1.5%)	5 (12.5%)

This suggests that both groups were well-matched at baseline, enhancing the comparability of their outcomes during the study period. Table 3 compares blood pressure and serum inflammatory markers before and after intervention in the YG and CG. The YG showed significant

reductions in heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), high-sensitivity C-reactive protein (hs-CRP), and D-dimer levels after 6 months (**p < 0.01). Conversely, the CG exhibited minimal changes in these parameters.

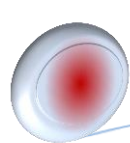


Table 3. Blood pressure and serum inflammatory markers before and after intervention

Variables	Yoga Treatment Group (n=36)			Control group (n=38)		
	Before	6 months after	Δ value	Before	6 months after	Δ value
HR (bpm)	80.28±9.26	70.73±7.19**	-9.55±3.40	82.12±9.05	78.08±9.65	1.06±0.48 ⁺
SBP (mmHg)	140.85±12.80	120.50±16.05**	19.03±5.34	142.19±8.94	138.52±7.53	2.21±0.50 ⁺⁺
DBP (mmHg)	80.93±10.04	70.06±11.83**	8.03±1.90	82.75±10.71	78.22±10.32	3.02±0.72 ⁺⁺
hs-CRP (mg/L)	3.52±1.50	2.85±1.93**	1.13±0.34	3.62±1.27	3.76±1.03	0.79±0.20 ⁺
D-dimer (mg/L)	1.6±1.06	1.42±1.02**	0.31±0.05	1.72±0.58	1.70±0.96	-0.02±0.02 ⁺

Data are represented in the mean ± SD (standard deviation). Δ (Delta), changes between before and 6-months after treatment.

*p<0.05, **P<0.01, ***p<0.001 compared with before and 6 months after.

⁺p<0.05, ⁺⁺P<0.01, ⁺⁺⁺p<0.001 compared with yoga and control group.

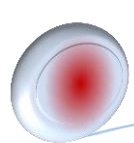
Discussion

This study aimed to investigate the impact of YT on biomarkers, specifically D-dimer levels, in middle-aged men with varicose veins. The results of this study showed a significant decrease in D-dimer levels following YT in middle-aged men with VV. This study is one of the first to investigate the impact of YT on biomarkers in patients with varicose veins, and its findings contribute to the growing body of research on the use of YT for managing vascular disorders. A previous study explored the combined impact of Yoga and Naturopathy on uncomplicated varicose vein (UVV) patients and showed reductions in hs-CRP, body weight, BMI, blood pressure, and symptoms were observed

in the experimental group after 3 months of intervention. These findings suggest promising potential for Yoga and Naturopathy in alleviating inflammation and improving vascular health in UVV patients (Chauhan et al., 2023).

Another randomized, parallel-group, active-controlled experimental study was to assess the impact of yogic therapy on the 6-minute walk test in middle-aged men with varicose veins. Post-intervention, the experimental group exhibited a significant increase in 6-minute walk test distance compared to the control (p < 0.05), supporting the hypothesis that YT benefits VVpatients in maintaining proper walking patterns (Badri and Subbulakshmi., 2019). A study on





chronic venous insufficiency (CVI) among industry workers exposed to prolonged standing with yoga interventions showed significant reductions in plasma homocysteine levels and improvements in CVI symptoms after 12 weeks, affirming its safety and efficacy for CVI management (Yamuna et al., 2024).

Exercise and Yogic techniques offer a safe and cost-effective treatment option for varicose veins, without adverse effects. Lower limb exercises strengthen calf muscles, improve ankle mobility, and enhance venous return, reducing venous hypertension and improving valvular function. This leads to decreased endothelial damage, inflammation, and free radical formation, ultimately improving venous condition. Given the complementary nature of exercise and Yoga, the positive effects of exercise support the effectiveness of Yoga in managing varicose vein conditions (Gawas et al., 2022; Mahajan, 2021).

A recent review provided an overview of available treatment options, including conventional and nonconventional approaches like Ayurveda, exercise, and Yoga, highlighting the importance of alternative therapies in VV management. Despite numerous studies, evidence supporting Yoga's efficacy in treating VV remained scarce, underscoring the need for urgent research to validate its

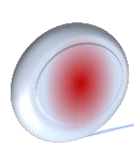
effectiveness (Chauhan & Patra, 2021). This study provides evidence for the potential benefits of YT in managing VV and reducing thrombotic risk in middle-aged men. The study's sample size was relatively small, and the results may not be generalizable to other populations or to women with varicose veins. Further research is needed to confirm the long-term effects of YT on biomarkers in patients with VV and to determine the optimal yoga intervention for this population.

Conclusion

In conclusion, the findings of this study suggest that YT may be a beneficial adjunct to conventional treatment for middle-aged men with varicose veins, as it resulted in significant improvements in blood pressure, heart rate, and biomarkers such as hs-CRP and D-dimer levels. Further research is needed to explore the long-term effects of YT on VV and to investigate its potential benefits in other patient populations. Additionally, the mechanisms underlying the effects of YT on biomarkers and vascular health need to be further elucidated.

Authors Contributions

Conceptualization, K.B, V.S; methodology, K.B, V.S; software, M.E, H.G, K.G; check, J.T, K.M, M.P and K.G; formal analysis, M.E, H.G, K.G; investigation, K.B, V.S; resources, K.M, M.E, H.G, K.G; data curation, K.B, V.S; writing - rough preparation, M.E, H.G, K.G; writing - review and



editing, M.E, H.G, K.G; visualization, M.E, H.G, K.G; supervision, V.S; project administration, K.B, V.S; receiving funding, K.G and K.M All authors have read and agreed with the published version of the manuscript.

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Conflicts of interest

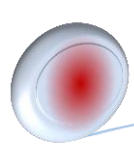
The authors declare no competing interests.

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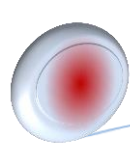
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