APPENDICES

Effect of Yoga on Endothelial Function, Vascular Compliance and Sympathetic Tone in Elderly Subjects with Increased Pulse Pressure: A Randomized Clinical Study
APPENDIX-1
SAMPLE WRITTEN INFORMED CONSENT FORM

BLDEU's SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL AND RESEARCH CENTRE BIJAPUR
DEPARTMENT OF PHYSIOLOGY

CONSENT FORM

Title of the Project

Effect of Yoga on endothelial function, vascular compliance and sympathetic tone in elderly subjects with increased pulse pressure: A Randomized clinical study

Principal investigator's name: Satish G Patil

1. PURPOSE OF RESEARCH: I have been informed that this study will assess the effect of Yoga on vascular function in elderly subjects with hypertension. This study will be also useful to understand the benefits of mechanism of Yoga on hypertension.

2. PROCEDURE: I understand that, the procedure of the study will involve recording of various physiological and biochemical parameters. The procedure will not interfere with any of my physiological parameters and they are non invasive.

3. RISK AND DISCOMFORTS: I understand determination of above mentioned tests will not cause any discomfort to me and do not involve any risk to my health.

4. BENEFITS: I understand that my participation in the study may have a direct benefit to me and also to the field of cardiovascular research.

5. CONFIDENTIALITY: I understand that medical information produced by this study will become part of institutional records and will be subject to the confidentiality and privacy regulation of the said institute. Information of a sensitive personal nature will not be a part of medical record, but will be stored in investigators research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secured location.

If the data are used for publication in the medical literature and for teaching purposes no names will be used and other identities such as photographs, audio and video tapes
will be used only with my special written permission. I understand I may see the photographs and the video tapes and have the audio tapes before giving this permission.

6. REQUEST FOR MORE INFORMATION: I understand that I may ask more questions about the study at any time. Concerned researcher is available to answer my questions or concerns. I understand that I will be informed of any significant new findings discovered during the course of this study which might influence my continued participation. If during the study or later, I wish to discuss my participation in all concerns regarding this study with a person not directly involved, I am aware that the social worker of the Institute is available to talk with me. A copy of this consent form will be given to me to keep for careful re-reading.

7. REFUSAL OR WITHDRAWAL OF PARTICIPATION: I understand that my participation is voluntary and may refuse to participate or may withdraw my consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital. I also understand that researcher may terminate my participation in this study at any time after she/he has explained the reasons for doing so and had helped arrange for my continued care by my physician or physical therapist if this is appropriate.

8. INJURY STATEMENT: I understand that in unlikely event of injury to me resulting directly from my participation in this study, if such injury were reported promptly, then medical treatment will be available to me, but no further compensation would be provided. I understand that by my agreement to participate in this study I am not waiving any of my legal rights.

I have explained to ____________________________ (Patient/Relevant guardian) the purpose of the research, procedures required and the possible risk and benefits to the best of my ability.

Investigator        Date
I confirm that ____________________________ (Name of the Principal Investigator) has explained to me the purpose of research, the study procedure that I will undergo, and the possible risk and discomforts as well as benefits that I may experience. Alternative to my participation in the study have also been to give my consent from. Therefore I agree to give consent to participate as a subject and this research project.

Participant                      Date:

Witness to signature             Date:

## APPENDIX-II

### AWARDS

a. **Young Research Award** (2013) for best scientific poster communication at 9\textsuperscript{th} European Congress Geriatric Medicine Society held in Venice, Italy from 2-4\textsuperscript{th} October 2013.

b. **Travel fellowship award** (2013) from Centre for International Co-operation in Science (CICS), Chennai, to present research findings of PhD Thesis at 9\textsuperscript{th} European Congress Geriatric Medicine Society held in Venice, Italy from 2-4\textsuperscript{th} October 2013.

c. **Foreign Travel Grant** (2013) from Council for Scientific and Industrial Research (CSIR) to present research findings of PhD Thesis at 9\textsuperscript{th} European Congress Geriatric Medicine Society held in Venice, Italy from 2-4\textsuperscript{th} October 2013.

d. **INSPIRE Research Fellowship award** from Department of Science & Technology (DST), New Delhi (2011) to pursue full-time PhD in BLDE University, Bijapur, Karnataka


Effect of Yoga on Oxidative Stress in Elderly with Grade-I Hypertension: A Randomized Controlled Study

ABSTRACT

Background and Objectives: Hypertension, especially in elderly is a strong risk factor for cardiovascular mortality and morbidity. Oxidative stress has been implicated as one of the underlying cause of hypertension. Yoga has been found to control hypertension in the elderly, but the underlying benefits of mechanism in relation to oxidative stress regulation remains unclear. The purpose of the study was to investigate the effect of yoga on oxidative stress in elderly with Grade-I hypertension.

Methods: An open parallel-arm randomised controlled study was conducted at BLDE University’s Shri B.M.Patil Medical College, Hospital and Research Centre, India on elderly male individuals with Grade-I hypertension (n=57, age 60-80 years). Study (Yoga) group was assigned for yoga intervention and control group for walking for one hour in the morning for six days in a week for three months under the supervision of yoga instructor and physical training instructor respectively. Serum malondialdehyde (MDA) as an indicator of oxidative stress and antioxidants such as serum superoxide dismutase (SOD), reduced glutathione (GSH) and vitamin C levels were estimated.

Results: Yoga practice for three months has significantly reduced serum MDA level (p<0.001), and enhanced antioxidants level such as SOD activity (p=0.007), serum GSH (p=0.002) and vitamin C (p=0.002). In the control group, we observed a significant increase in serum MDA level (p=0.04) and reduction in serum vitamin C level (p=0.015) with no significant difference in the SOD activity and GSH level.

Conclusion: These findings suggest that yoga is an effective means to reduce oxidative stress and to improve antioxidant defense in elderly hypertensive individuals.

Keywords: Antioxidants, Brisk-walk, Elderly, Hypertension, Oxidative stress, Yoga

Introduction

Ageing is an established cardiovascular (CV) risk factor. Hypertension is becoming an important medical and public health problem all over the world and is found to be one of the common disorders of ageing [1]. According to World Health Organization (WHO), the most common cause of preventable death in developed countries is hypertension, which is significantly increasing in developing countries [2]. There are diverse mechanisms and age-related factors involved in the development of hypertension in older individuals. Oxidative stress has been implicated as one of the underlying cause of hypertension [3-6]. An increase in the production of reactive oxygen species (ROS) such as superoxide radicals (O$_2^-$), hydrogen peroxide (H$_2$O$_2$), hydroxyl radical (\(^{•}\)OH), and singlet oxygen causes oxidative stress. Although, ROS are generated in multiple compartments and by multiple enzymes within the cell, but the majority of ROS are produced within the mitochondria during ATP production by oxidative phosphorylation contributing to aging and age-related disorders. If ROS are not removed or neutralized, it can target various cellular constituents like lipid membranes, proteins, DNA and RNA. Our body has evolved complex antioxidant defense mechanism to prevent the deleterious effects of ROS. An imbalance between ROS and antioxidants results in oxidative stress [7]. Oxidative stress contributes to inactivation of nitric oxide, a potent vasodilator, resulting in its decreased bioavailability and endothelial dysfunction [8,9]. Endothelial dysfunction associated with decreased nitric oxide production results in impaired vasodilation and increased blood pressure (BP) [10].

Physical activity and exercise have many beneficial effects for maintaining health, preventing age-related chronic diseases and improving quality of life of older adults [11-13]. However, the optimal amount of exercise for achieving health benefits in the individuals is still unknown. On the other hand, exercise when performed strenuously or even moderately by elderly individuals, is associated with increased production of ROS and oxidative stress [14]. Yoga is another life-style modality, which has well-established health benefits. Yoga has been found to control hypertension in the...
60 to 80 years, in BLDE University’s Sri B.M.Patil Medical College, Hospital and Research Centre, India. Subjects with systolic blood pressure (SBP) from 140-159 mmHg and diastolic blood pressure (DBP) from 90-99 mmHg were categorised as Grade-I hypertension as per 2007 guidelines of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC) [16]. Subjects on any medications and subjects with CV risk factors such as diabetes mellitus, hypercholesterolemia and high triglyceride level were excluded from the study. The study was approved by the institutional ethical committee of BLDE University’s Sri B.M.Patil Medical College, Hospital and Research Centre as per the guidelines (2006) of Indian Council of Medical Research and informed written consent was obtained for participation in the study. The declaration of Helsinki has been followed during the entire study. The study has been reported as per CONSORT declaration [17].

**Study protocol**

Screening of elderly individuals attending geriatric clinic above 60yrs for Grade-I hypertension was done and were selected after thorough examination as per our inclusion and exclusion criteria. As BP is more variable in older people, the diagnosis of hypertension was made by taking nine BP readings on three separate visits [18]. Brachial BP was measured three times with an interval of one minute on a visit for three consecutive days in a sitting posture using mercury sphygmomanometer (Diamond, Industrial Electronic and Allied Products, India) [19]. Selected subjects were randomly divided into yoga group (n=30) and control group (n=30) by using random number table.

The yoga group was assigned for yoga practice under the supervision of yoga instructor for six days in a week for one hour daily in the morning from 06:00 to 07:00 hours for three months. The integrated yoga module for intervention includes: Opening prayer (1min); Sukshma Vyayama or loosening practices (5min); Breathing practices like Hands in and out breathing, Ankle stretch breathing, Straight leg raising breathing, Lumbar stretch breathing (5 min); Asanas or maintaining postures such as Padhastasana, Ardha Chakrasana, Shashankasana, Ardha Ustrasana, Bhujangasana, Ardha Salabasana and Trikonasana (15min); Pranayama or breathing exercises such as Anuloma Viloma Pranayama and Brahmari Pranayama (5min); Cyclic meditation, a yoga based guided relaxation technique [20]; Devotional session (5min); and Closing prayer (1min). The protocol for control group includes flexibility or stretching practices for 15 -20 min followed by application of relaxation and meditation techniques for 5min.

Before three months of intervention in the morning between 08:00 to 11:00 hours after supine rest for 10min. On the day of investigation, no intervention was given to the participants. Person’s handling data analysis were kept blinded.

The recordings were made twice, one at baseline and another after three months of intervention in the morning between 08:00 to 11:00 hours after supine rest for 10min. On the day of investigation, no intervention was given to the participants. Person’s handling data analysis were kept blinded.

The participant flow during the study is shown in [Table/Fig-1]. Two participants from the yoga group and one participant from the control group attended the respective training in the morning.

### Methods

#### Study design

This open parallel-group randomised controlled study was conducted on elderly male subjects with Grade-I hypertension (n=57) between elderly [15], but the underlying benefits of mechanism in relation to oxidative stress regulation remains unclear. The aim of the present study was to determine the effect of yoga on oxidative stress in elderly with Grade-I hypertension.

#### Study design

This open parallel-group randomised controlled study was conducted on elderly male subjects with Grade-I hypertension (n=57) between 60-80 years old, with mild to moderate hypertension (diastolic blood pressure (DBP) 90-99 mmHg and systolic blood pressure (SBP) 140-159 mmHg) in a private hospital in India. The study was approved by the institutional ethical committee of BLDE University’s Sri B.M.Patil Medical College, Hospital and Research Centre as per the guidelines (2006) of Indian Council of Medical Research and informed written consent was obtained for participation in the study. The declaration of Helsinki has been followed during the entire study. The study has been reported as per CONSORT declaration [17].

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The yoga group was assigned for yoga practice under the supervision of yoga instructor for six days in a week for one hour daily in the morning from 06:00 to 07:00 hours for three months. The integrated yoga module for intervention includes: Opening prayer (1min); Sukhsha Vyayama or loosening practices (5min); Breathing practices like Hands in and out breathing, Ankle stretch breathing, Straight leg raising breathing, Lumbar stretch breathing (5 min); Asanas or maintaining postures such as Padhastasana, Ardha Chakrasana, Shashankasana, Ardha Ustrasana, Bhujangasana, Ardha Salabasana and Trikonasana (15min); Pranayama or breathing exercises such as Anuloma Viloma Pranayama and Brahmari Pranayama (5min); Cyclic meditation, a yoga based guided relaxation technique [20]; Devotional session (5min); and Closing prayer (1min). The protocol for control group includes flexibility or stretching practices for 15-20 min followed by walking for 35-40 min and rest for 5min for six days in a week, for one hour in the morning between 06:00 to 7.00 hours for three months under the supervision of an authorised instructor.

The recordings were made twice, one at baseline and another after three months of intervention in the morning between 08:00 to 11:00 hours after supine rest for 10min. On the day of investigation, no intervention was given to the participants. Person’s handling data analysis were kept blinded.

The participant flow during the study is shown in [Table/Fig-1]. Two participants from the yoga group and one participant from the control group attended the respective training in the morning.
regularly but did not appear for the post-interventional investigation due to domestic reasons. Hence, they were not included in the final analysis.

**Assessment of oxidative stress and antioxidant status**

The blood sample was collected through venous puncture in the morning with overnight fasting for estimation of biochemical parameters. Serum malondialdehyde (MDA), a marker of oxidative stress was estimated by Kei Satoh method [21]. Antioxidants such as reduced glutathione (GSH) was estimated by Beutler E et al., method [22]; Serum vitamin C by 2,4-dinitrophenylhydrazine method [23,24]; and superoxide dismutase (SOD) activity was measured by Marklund and Marklund method [25].

**Estimation of blood glucose and lipid profile**

Commercial kits from Erba-Mannheim were used for estimation of fasting blood glucose (Trinder’s method), serum triglyceride (GPO-PAP method), serum cholesterol (CHOD-PAP method) and HDL cholesterol (phosphotungstic acid method).

**Statistical Analysis**

The obtained data was expressed as mean and standard deviation. Paired t-test for normally distributed data and Wilcoxon signed rank test for non-normally distributed data was applied for determination of statistical significance. Statistical significance was established at p< 0.05. SPSS software version 20 was used for data analysis.

**Results**

[Table/Fig-2] shows the baseline characteristics of yoga and control group participants. There was no significant difference in the characteristics of participants between two groups suggesting an equal distribution. The baseline values of fasting blood glucose, serum triglyceride, total cholesterol and HDL cholesterol were within the normal range in all the participants.

Yoga practice for three months has significantly reduced serum MDA level (p<0.001) in elderly participants, where as in the control group, it was significantly elevated (p=0.04) [Table/Fig-3].

A significant enhancement in antioxidant capacity has been observed in yoga participants. Superoxide dismutase (SOD) activity and GSH level were significantly increased (p=0.007 and p=0.002 respectively) in yoga participants where as no such change was noticed in the control group [Table/Fig-4,5]. We have also noticed a significant increase in serum vitamin C level (p=0.002) in yoga group, while it was significantly decreased in the control group (p=0.015) following intervention [Table/Fig-6].

[Table/Fig-7] shows a significant reduction in SBP (p<0.001), PP (p<0.001) and MAP (p<0.001) in participants of yoga group, where as in the control group no such changes were noticed.

**Discussion**

Reactive oxygen species induced oxidative stress, damages the membrane polyunsaturated fatty acids resulting in generation of MDA. Elevation in serum MDA level in hypertensive subjects has been demonstrated [26]. In the present investigation, we observed a significant reduction in serum MDA level, an indicator of oxidative stress by 20.54% in yoga practitioners, which is nearly similar to the findings of Hegde et al., (20%) and Gordon et al., (19.9%) in type 2 diabetic subjects [27,28]. Conversely, we found an increase in the serum MDA in the control group. These results in control group are consistent with results reported by other studies [29,30]. In another study, Gordon et al., found reduction in oxidant level following moderate-intensity exercise for six months in individuals with type 2 diabetes [28]. According to Park J et al., mild exercise such as low-volume walking programme (30-60 minute walking session twice in a week) induce more beneficial changes in the oxidative stress in older adults than moderate-intensity exercise [31]. It may be noted in the yoga module of the present study that, we have incorporated 45min for slow-breathing practices, relaxation technique and meditation, while for asanas (maintaining postures) 15min was given. It is widely accepted that increased oxygen consumption during exercise results in excess generation of ROS. Whereas, yoga based relaxation technique and meditation was found to be associated with decreased oxygen consumption [32]. Hence, we presume that low consumption of oxygen during yoga practice probably reduced serum MDA level in the yoga practitioners of the present study. To the best of our knowledge, this is the first study reporting on effect of yoga on oxidative stress and antioxidant defense in elderly hypertensives.

Growing evidence indicates a strong association between oxidative stress and BP [26]. Reactive oxygen species influences cardiovascular structure and function by modulating cell growth and inflammatory responses via reduction-oxidation-dependent signaling pathways. Increased vascular oxidative stress damage the endothelium, reduces nitric oxide production by inhibiting e-NOS pathways and impairs endothelium-dependent vasodilation with resultant enhanced vascular tone and thus hypertension [5,6,8]. Further, oxidative stress causes thickening of the vascular media by promoting smooth muscle cell proliferation and hypertrophy with collagen deposition resulting in narrowing of vascular lumen [6,8]. These evidences indicate that oxidative stress may play an important role in the development of hypertension. In the present study, yoga has been found effective in reducing BP and oxidative stress in elderly individuals.

A decrease in the activity of antioxidants such as SOD, catalase, glutathione, vitamins C and E may also contribute to oxidative stress [3]. Antioxidants such as SOD, catalase and glutathione act as a primary line of defense against the toxic effects of ROS. Superoxide radicals are detoxified by SOD to produce hydrogen peroxide (H$_2$O$_2$) which is further converted to water by catalase and glutathione peroxidase (GSPx). Glutathione peroxidase requires GSH as a coenzyme to convert H$_2$O$_2$ to water [33]. A negative correlation between antioxidants (such as SOD, GSH and vitamin C) and hypertension has already been reported [26]. In our study, evaluation of antioxidant status demonstrated significant increase in SOD activity by 31.35%, GSH level by 20.45% and vitamin C by 9.89% in yoga practitioners [Table/Fig-4,6]. Yoga induced enhancement in endogenous antioxidants like SOD and GSH may be due to increase in their upregulation [34] and decreased rate of utilization due to lowering of oxidative stress. Similarly, an increased level of serum vitamin C, an exogenous antioxidant, in yoga practitioners may also be due to lowering rate of utilization. This yoga induced achievement in antioxidant capacity may help to cope with deleterious effects of oxidative stress and prevents further damage to cardiovascular cells. Superoxide radicals combine with nitric oxide to form peroxynitrite leading to nitrosative stress. Yoga induced elevated SOD level may also prevent formation of peroxynitrite and thus reduces possibility of nitrosative stress.

Regular exercise has been shown to improve both exogenous and endogenous antioxidant status in animal and human studies [28, 35]. However, we could not find any significant improvement in the antioxidant status of control group participants [Table/Fig-4,6]. Our results are in accordance with findings of Rosado-Perez et al., study [29]. Some studies have reported beneficial effects of moderate-intensity exercise on antioxidant system in elderly [28,36]. A significant decrease in serum vitamin C level by 10.84% was noticed in the subjects of control group [Table/Fig-6]. Reduction in vitamin C level might be due to its excessive utilization for detoxification of high levels of ROS generated in the control group subjects.

**Conclusion**

The findings of the study suggest that yoga can be used as an effective life-style modality to reduce oxidative stress and to enhance antioxidant defense in elderly with hypertension. Further, it
is essential to develop effective physical activity strategies to reduce oxidative stress in elderly with hypertension.

Acknowledgement
We express our sincere thanks to Department of Science and Technology, Government of India and BLDE University for financial assistance. We are also thankful to all elderly volunteers for participation in the study.

References
Comparison of the effects of yoga and lifestyle modification on grade-I hypertension in elderly males: A preliminary study

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Abstract

Background and Aim: Aging along with hypertension is a major risk factor for cardiovascular (CV) morbidity and mortality. It is noticed that systolic hypertension in elderly is often associated with increased CV risks and is resistant to pharmacological treatment. Hence, we aimed to assess the difference between practice of yoga and lifestyle modifications (LSM) in elderly grade-I hypertensive males.

Methods: A randomized control study was conducted on age and body mass index (BMI)-matched elderly male subjects (n = 42) between 60–80 years with grade-I hypertension. They were equally divided into yoga group (n = 21) and LSM group (n = 21). Their fasting blood glucose and lipid profile were recorded before the intervention period, and both the groups were matched for these biochemical parameters. The yoga group was assigned for practice of a yoga module and the LSM group (n = 21) was assigned for stretching exercises and brisk walk, for 6 days in a week, for 1 h in the morning for 6 weeks. Their CV parameters including heart rate and blood pressure (BP) were recorded before and after the intervention period.

Results: We found a significant decrease in systolic BP (P < 0.001), pulse pressure (P < 0.001), mean arterial pressure (P < 0.001), and rate pressure product (P < 0.001) in elderly hypertensives following yoga therapy for 6 weeks, whereas no statistically significant change was noticed in the LSM group practicing stretching exercise and brisk walk for the same duration.

Conclusion: Yoga intervention for 6 weeks could be an effective non-pharmacological means for better management than the LSM for control of BP in elderly subjects having grade-I hypertension.

Key words: Elderly, grade-I hypertension, lifestyle modification, males, yoga

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INTRODUCTION

Increased age is an established cardiovascular (CV) risk factor. Aging along with hypertension is a major risk factor for CV morbidity and mortality. The prevalence of hypertension in elderly ranges from 60 to 80%, and it is estimated that two of three individuals over 75 years of age suffer from hypertension. A change in the patterns of hypertension with age has been observed. In elderly, systolic blood pressure (SBP) increases without much change in diastolic blood pressure (DBP), which is categorized as isolated systolic hypertension (ISH). Systolic hypertension may lead to stroke, myocardial infarction, dementia, renal failure, and death. These clinical complications affect the quality and longevity of life in elderly. According to World Health Organization, the most common cause of preventable death in developed countries is hypertension, which is significantly increasing in developing countries.

Reduction of systolic hypertension in elderly subjects could reduce clinical complications, extend lifespan, and improve
quality of life.[5] However, the elderly individuals suffering from ISH are often resistant to pharmacological treatment and attempts to reduce the SBP aggressively also lowers DBP to a greater extent that compromises coronary blood flow.[6] Among the non-pharmacological approaches, yoga has emerged as the most effective therapy to control hypertension and improve CV function.[7-10] Though practice of lifestyle modification (LSM) such as morning walk and stretching exercises is known to reduce blood pressure (BP), its impact in elderly patients may not be effective as many of them invariably suffer from osteoarthritic joint diseases that prevent them from fruitful participation in such LSM program. Yoga is an ancient system of spiritual practice having a psychosomatic discipline comprising physical and mental techniques, that help to achieve a harmony between the mind and body. However, no study has been conducted till date to compare the benefits of yoga with LSM practice in elderly mild hypertensives. Therefore, the present study was conducted to assess the difference in the effects of practice of yoga and LSM in elderly grade-I hypertensive males.

**MATERIALS AND METHODS**

**Participants and study design**

It is a randomized control study conducted on elderly male subjects between 60 to 80 years with grade-I hypertension. Subjects with SBP from 140 to 159 mmHg and DBP from 90 to 99 mmHg were included for the study. Subjects on any medications, suffering from diabetes mellitus or CV diseases, hypercholesterolemia, and high triglyceride level were excluded from the study. The task force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC) in its 2007 guidelines, classified hypertension/ISH into three categories: Grade-I (SBP/DBP: 140−159/90−99 mmHg), grade-II (SBP/DBP: 160−179/100−109 mmHg), and grade-III (SBP ≥ 180 or DBP ≥ 100 mmHg).[11] In the same guidelines, they recommended for lifestyle changes intervention for few months for grade-I hypertension without any CV risk factors, before drug therapy. The present study was approved by the institutional ethical committee as per the guidelines (2006) of Indian Council of Medical Research. We followed the declaration of Helsinki and the study was reported as per the recommendations of the CONSORT group.[12] Informed written consent was obtained for participation in the study.

**Randomization and intervention**

Subjects were randomly divided into yoga group (n = 21) and LSM group (n = 21) by using random number table. However, it was ensured that subjects of both the groups matched for age, body mass index (BMI), fasting blood glucose, and lipid profile [Table 1]. The yoga group was assigned to yoga practice by an authorized yoga instructor for 6 days in a week for 1 h daily in the morning from 06:00 to 07:00 h for 6 weeks. The integrated yoga module for intervention includes: Opening prayer (1 min); Sukshma Vyayama or loosening practices (5 min); breathing practices like hands in and out breathing, ankle stretch breathing, straight leg raising breathing, lumbar stretch breathing (5 min); asanas or maintaining postures such as Padhastasana, Ardhamukhasana, Shashankasana, Ardha Ustrasana, Bhujangasana, Ardha Salabasana, and Trikonasana (15 min); Pranayama or breathing exercises such as Anuloma-Viloma Pranayama and Brahmari Pranayama (5 min); cyclic meditation, a yoga-based guided relaxation technique;[13] devotional session (5 min); and closing prayer (1 min). The protocol for the LSM group consisted of flexibility or stretching practices for 20 min followed by brisk walk for 35 min and rest for 5 min for 6 days in a week, for 1 h in the morning between 06:00-07:00 h for 6 weeks under the supervision of an authorized instructor.

**Table 1: Baseline characteristics of participants in both yoga and LSM groups**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Yoga (n=21)</th>
<th>LSM (n=21)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>69.42±5.32</td>
<td>69.52±5.59</td>
<td>0.959</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>24.18±3.39</td>
<td>24.64±2.67</td>
<td>0.676</td>
</tr>
<tr>
<td>HR (bpm)</td>
<td>70.33±8.30</td>
<td>72.09±8.82</td>
<td>0.509</td>
</tr>
<tr>
<td>Systolic BP (mmHg)</td>
<td>147.23±5.62</td>
<td>147.00±5.82</td>
<td>0.894</td>
</tr>
<tr>
<td>Diastolic BP (mmHg)</td>
<td>74.95±3.8</td>
<td>75.52±5.43</td>
<td>0.695</td>
</tr>
<tr>
<td>Pulse pressure (mmHg)</td>
<td>72.28±6.03</td>
<td>71.47±6.09</td>
<td>0.668</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>98.8±3.53</td>
<td>98.8±4.94</td>
<td>1.000</td>
</tr>
<tr>
<td>Fasting blood glucose (mg/dl)</td>
<td>95.09±10.79</td>
<td>91.52±12.51</td>
<td>0.328</td>
</tr>
<tr>
<td>Serum triglyceride (mg/dl)</td>
<td>97.85±27.14</td>
<td>105.76±23.29</td>
<td>0.317</td>
</tr>
<tr>
<td>Total cholesterol (mg/dl)</td>
<td>149.19±24.98</td>
<td>152.33±21.84</td>
<td>0.667</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dl)</td>
<td>46.6±4.37</td>
<td>46.61±4.63</td>
<td>0.973</td>
</tr>
</tbody>
</table>

Values are expressed in mean±SD. Statistical analysis was done by student’s unpaired ‘t’ test. P<0.05 was considered statistically significant.

LSM: Lifestyle modification, HR: Heart rate, BMI: Body mass index, MAP: Mean arterial pressure, HDL: High-density lipoprotein, BP: Blood pressure, SD: Standard deviation

Measurement of heart rate and BP

Heart rate (HR) was derived from RR interval of electrocardiogram (ECG) recordings (Physiopac, Medicaid systems, India). Brachial BP recordings were made twice, one at baseline and another after 6 weeks of intervention in the morning between 08:00-11:00 h after supine rest for 10 min. BP was measured thrice with an interval of 1 min for 3 consecutive days using mercury sphygmomanometer (Diamond, Industrial electronic, and allied products, India) and the average of nine measurements was considered.[6,14] Rate pressure product (RPP), a determinant of myocardial oxygen consumption and work load was calculated using the formula, RPP = (BHR × SBP) × 10⁻².[15] Pulse pressure (PP) was calculated as the difference between SBP and DBP.
Mean arterial pressure (MAP) was obtained by adding one-third of the PP and DBP. No intervention has been given on the day of investigation to both the yoga and LSM group. Persons handling data analysis were kept blinded.

 Statistical analysis

The obtained data were expressed in mean and standard deviation. To determine the statistical significance, paired ‘t’ test and Wilcoxon signed rank test for normally and non-normally distributed data were applied respectively, using software Statistical Package for Social Sciences (SPSS) version 20 (SPSS Software Inc, Chicago, IL, USA). Statistical significance was established at $ P < 0.05 $.

 RESULTS

The baseline characteristics of the participants were shown in Table 1. As there was no significant difference in age, BMI, and BP parameters between the yoga and LSM groups, it implies that samples were equally distributed. Table 1 also shows that DBP was within the normal range where as SBP was high indicating ISH in both the groups. Fasting blood glucose, serum triglyceride, total cholesterol, and high-density lipoprotein (HDL) cholesterol levels of the participants were summarized in Table 1.

Yoga practice for 6 weeks has significantly lowered HR ($ P < 0.01 $), SBP ($ P < 0.001 $), PP ($ P < 0.001 $), and MAP ($ P < 0.001 $) in elderly individuals, whereas no significant change was noticed in the LSM group subjects practicing brisk walk and stretching exercise. There was no significant difference in DBP of both yoga and LSM groups following intervention [Table 2]. The results further revealed reductions in SBP by 2.72% and in PP by 6.53% following yoga practice for 6 weeks. RPP was significantly reduced in yoga group when compared with the LSM group [Figure 1].

 DISCUSSION

There are diverse etiologies and mechanisms involved in the development of hypertension in elderly. The major age-related physiological changes attributed for the development of hypertension in elderly are vascular stiffness, endothelial dysfunction, and sympathetic overactivity.$ ^{[10]} $ Two major age-related structural changes that take place in elastic arteries are stiffness and dilatation. These changes result in decline in expansion of aorta (due to stiffness) during ventricular systole leading to elevation in SBP (ISH), and failure in recoiling (due to decreased elasticity) of the arterial wall results in decrease in DBP, thus causing widening of PP. The PP is a good indicator and independent predictor of arterial stiffness.$ ^{[16]} $ RPP is an established marker of CV risks, especially in hypertensives.$ ^{[15]} $ In the present study, there was a significant decrease in SBP and PP [Table 1], though there was no significant change in DBP following 6 week practice of yoga therapy in yoga group. Thus, reduction in PP implies improvement in vascular compliance in these subjects. Further, decreased RPP in these subjects [Figure 1] indicates decreased myocardial work stress and reduced CV risk. These findings suggest that practice of yoga for six weeks could be beneficial in reducing the SBP (arterial stiffness) and CV risks in elderly mild hypertensives. However, changes in BP parameters were not significant in LSM group, indicating that 6 week practice of LSM was not effective in these mild

### Table 2: HR and BP changes in yoga and LSM group

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Yoga group</th>
<th>LSM group</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR (bpm)</td>
<td>Before: 70.33±8.30, After: 66.8±5.95</td>
<td>Before: 72.09±8.82, After: 72.5±9.16</td>
</tr>
<tr>
<td>SBP (mmHg)</td>
<td>Before: 147.23±5.62, After: 143.09±5.67</td>
<td>Before: 147.0±5.82, After: 146.28±5.14</td>
</tr>
<tr>
<td>DBP (mmHg)</td>
<td>Before: 74.95±3.53, After: 75.33±3.54</td>
<td>Before: 75.52±5.43, After: 75.09±5.43</td>
</tr>
<tr>
<td>PP (mmHg)</td>
<td>Before: 72.28±6.03, After: 67.76±5.11</td>
<td>Before: 71.47±6.09, After: 71.19±5.16</td>
</tr>
<tr>
<td>MAP (mmHg)</td>
<td>Before: 98.8±3.53, After: 97.61±3.12</td>
<td>Before: 98.80±4.94, After: 98.28±4.07</td>
</tr>
</tbody>
</table>

Values are expressed in mean±SD; *$ P < 0.05 $, **$ P < 0.01 $, ***$ P < 0.001 $. Statistical analysis was done by student’s paired ‘t’ test. $ P < 0.05 $ was considered statistically significant. LSM: Lifestyle modification, HR: Heart rate, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, PP: Pulse pressure, MAP: Mean arterial pressure, SD: Standard deviation.

![Figure 1: Change in RPP (mmHg/min) in yoga and LSM group following intervention Asterisk (*) indicates $ P < 0.001 $. RPP = Rate pressure product, LSM = Lifestyle modification.](http://www.jcep.org)
hypertensive elderly patients. The decrease in MAP and PP was secondary to the decrease in SBP. The present study is the first of its kind comparing the effects of yoga with LSM in elderly hypertensive patients. Another novelty of the present study is assessment of RPP, the indicator of myocardial work load and stress, which was significantly less in yoga practice group, compared with the LSM practice group. Also, there was significant reduction in basal HR following practice of yoga therapy in yoga group subjects, indicating further reduction in CV risk in these subjects, as decrease in resting HR per se has been reported to reduce CV risk.

The yoga module advocated in the present study included slow pranayamic breathing as a major component of yoga practice. It was reported in previous studies that practice of slow and regular breathing lowers BP and maintains sympathovagal balance through stabilization of CV reflex control system. As slow and paced breathing was part of the yoga module in the present study, we presume that the reduction in BP in yoga group might be through the improvement in respiratory and CV reflex control systems. Evidences suggest that yoga reduces sympathetic activity and stabilizes the sympathovagal balance by optimizing the autonomic function. In the present study, the practice of relaxation technique such as meditation in addition to pranayama might have contributed to the sympathovagal balance and reduction of BP, as recently a study by Pal et al. has reported improvement in autonomic balance and CV function following practice of such relaxation therapy. Therefore, studies should be conducted to assess if reduction in BP in elderly hypertensives could be due to improvement in sympathovagal balance. Age-related endothelial dysfunction results in a decreased bioavailability of nitric oxide, a potent vasodilator, with resultant enhanced vascular tone leading to hypertension. A study conducted by Sivasankaran et al. has demonstrated that the yoga practice enhances endothelial-dependent vasodilation in elderly subjects with coronary artery disease. The findings of this preliminary study has not only demonstrated reduction in BP in elderly group-I hypertensives but also the reduction in CV risks in this elderly population that is at higher risk of CV diseases. Therefore, future studies should address the biochemical mechanisms, especially the level of endothelial inflammatory markers in reduction in CV risks in these highly vulnerable subjects.

The difference in the effect of yoga therapy and LSM (mainly brisk morning walk and stretching exercises) could be due to the fact that the elderly people usually suffer from osteoarthritis and do not exercise or walk effectively. Nevertheless, they adapt to yoga practice (breathing, asana, pranayama, and meditation) effectively because of their attitude towards a yoga life, which is usually observed in old age. Present study is the first of its kind to assess the difference between practice of yoga and LSM in elderly group-I hypertensive males. The novelty of the study was that we had two groups of apparently healthy subjects matched for age, BMI, blood glucose, and lipid profile, which is difficult to get in elderly population. However, this study is a preliminary one that suggests further clinical research in establishing the efficacy of yoga therapy in the management of mild hypertension in elderly population.

**Limitations of the study**

In the present study, the major limitation was small sample size, which was mainly due to less availability of elderly male grade-I hypertensives not on any medications and not suffering from diabetes mellitus, CV diseases, and hypercholesterolemia. It is difficult to get a larger sample size of elderly subjects aged between 60-80 years with grade-I hypertension without having diabetes and CV risks. Another limitation was that we could not do correlation and regression analysis for establishing the relationship between BP status and RPP (CV risk) due to the less sample size. The CV risks in males are equal to females after menopause. But, in the present study, we did not include females. Therefore, future studies in larger sample size should address the effect of gender on benefits of yoga, in treatment of group-I hypertension in elderly population.

**CONCLUSION**

In the present study, yoga practice for 6 weeks in elderly grade-I hypertensive subjects not only reduced BP but also the CV risks compared with the subjects practicing LSM. As elderly people cannot effectively perform regular physical exercises and may not be able to tolerate chronic antihypertensive medication, the yoga therapy could be a non-pharmacological alternative for management of hypertension, at least during its early phase. Yet, as the sample size was less in the present study, the results of this study cannot be directly extrapolated to application in general population. Therefore, future studies are warranted to address the effect of such yoga therapy in a larger sample size in both male and female elderly hypertensives.

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**REFERENCES**

2. Radhakrishnan S, Balamurugan S. Prevalence of diabetes...


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