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Effect of ice application to head and spine on autonomic function in patients with hypertension: A randomized controlled trial protocol

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Abstract

Background: Hypertension is characterized by persistently elevated blood pressure in the systemic arteries. The global prevalence and incidence of hypertension are on the rise and need to explore various therapeutic interventions to manage this condition effectively. One such intervention is the application of ice application, particularly to the head and spine, which has been studied for its potential effects on blood pressure and heart rate variability.

Objective: To evaluate the effect of Ice application to the head and spine on autonomic function in patients with hypertension.

Methods: The proposed study is a randomized controlled trial comparing ice application to the head and spine with the control group. A total of 60 participants will be randomly divided into a study group (n=30) and a control group (n=30). The intervention group will undergo ice application to the head and spine. Participants in the control group will be advised to rest in the prone position for 20 minutes.

Outcome measurements: Heart rate, heart rate variability, and blood pressure will be assessed immediately before and after the intervention.

Conclusion: The results will confirm the effect of Ice application to the head and spine on autonomic function in patients with hypertension

Keywords: Hydrotherapy; Hypertension; Pupillary light reflex; Ice application; Heart rate variability

1. Introduction

Hypertension is the persistent chronically elevated blood pressure in the systemic arteries (1). Worldwide, the prevalence of hypertension is on the rise due to aging populations and increased risk factors (2). The global prevalence of hypertension among adults aged 30–79 remained stable from 1990 to 2019, but the number of cases doubled to 626

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million women and 652 million men in 2019 (3). The pharmacological management of hypertension involves the use of angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), diuretics, calcium channel blockers (CCBs), and beta-blockers (BBs). While these therapies are highly effective in controlling hypertension, they may also cause side effects such as hypotension, dizziness, headaches, and vomiting (4,5). The integrated approach in hypertension management, hydrotherapy is a part of naturopathy medicine and plays a crucial role in reducing pressure in the arteries (6). Hydrotherapy is a clinical application of water in external or internal with various forms (liquid, gas, solid) and various modes (duration, pressure, and location) (7). Existing research suggests that applying ice application to the head and spine enhances autonomic nervous system (ANS) regulation, indicating vagal dominance and improved blood pressure regulation (8). Changes in ANS activity can be effectively monitored using heart rate variability (HRV) and pupillary light reflex (PLR) measured with a dynamic pupillometer (9). Both HRV and PLR are valuable tools for assessing sympathetic and parasympathetic activity in the ANS (10, 11). A combined analysis of these techniques offers a comprehensive evaluation of autonomic function. However, no randomized controlled study has been conducted to evaluate the immediate effects of ice application on blood pressure and pupillary light reflex in hypertensive patients.

1.1. Aim

To evaluate the effect of Ice application on the head and spine on autonomic function in patients with hypertension

1.2. Objectives

- Primary objectives: To evaluate the effect of Ice application on the head and spine on autonomic function by assessing the heart rate variability and pupillary light reflex in patients with hypertension.
- Secondary objectives: To evaluate the effect of Ice application on the head and spine on blood pressure in patients with hypertension.

1.3. Study design

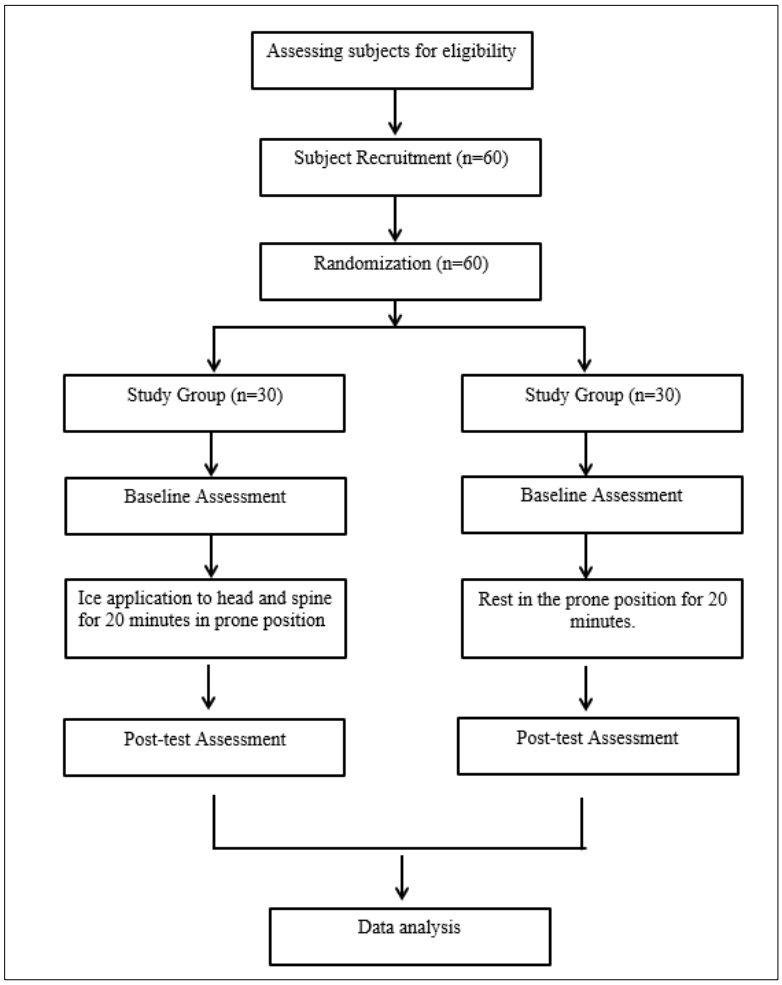

Figure 1 Trail profile

A randomized control study design will be adopted. Subjects will be randomly allocated to the study and control groups. Institutional ethical committee (IEC) approval has been taken, vide letter number (RES/IEC-GYNMC/2022/154). This study was prospectively registered at the clinical trial registry India (CTRI) (CTRI registration no: CTRI/2023/08/056774). The study group will receive an Ice application to the head and spine for 20 minutes in a Prone position whereas the control group will be allowed to rest in a prone position with closed eyes and will be restrained from using mobile phones and talking for 20 minutes. Heart rate variability and pupillary light reflex will be assessed before and immediately after the intervention for both the study and control group (Figure 1).

Figure 2 Ice bag

2. Materials and Methods

2.1. Study setting

The study will be conducted at Government Yoga and Naturopathy Medical College and Hospital, Chennai – 600106, Tamilnadu, India.

2.2. Inclusion criteria

- Age between 30 to 65 years.
- Both male and female patients.
- Primary hypertensive patients are those who are willing to participate in the study.
- Patients with < 160mmHg systolic blood pressure and< 100mmHg diastolic blood pressure.
- Primary hypertensive patients under one or two classes of anti-hypertensive medications with (or without regular medications) and also newly diagnosed hypertensive patients.

2.3. Exclusion criteria

- Open wounds, burns, and scalds on the head, cervical and spinal areas.
- Women during menstruation, pregnancy, and lactation.
- Patients with secondary hypertension
- Patients who are not willing to participate in the study
- Patients with complications of hypertension (cardiac diseases, stroke diseases).

3. Intervention

3.1. Study group

30 hypertensive patients will undergo only one session of ice application to the head and spine for 20 minutes in the prone position. Ice (1°C–2°C) filled in a rubber bag (ice bag). Then, an ice bag will be placed on each participant's head (4–6 seconds each on the crown, back, right, and left sides) and spine (4–6 seconds in the cervical, 8–12 seconds in the thoracic, and 4–6 seconds each in the lumbar and sacral regions) by continuous displacements. The same procedure will be repeated for 20 mins (12).

3.2. Control group

The patient will not receive any kind of treatment. The patient will be advised to rest in the prone position for 20 minutes.

3.3. Assessment

3.3.1. Primary outcome

Pupillary light reflex (PLR): The PLR will be recorded using dynamic pupillometry for 10s. A video will be initially recorded in total darkness for pupil dilation, followed by a flash of white light for 2s for pupil constriction. The video recording will be done using Debut software. The recorded video with the PLR will be split into multiple images using video splitter software (Video to jpeg converter Ver.5.0.101.201) with 30 fps. Later, these images will be subjected to image analysis software (ImageJver.1.43u National Institute of Health, USA) (10).

Heart rate and heart rate variability will be assessed before and after intervention by using 16 16-channel polygraphs (BIOPAC SYSTEM MP160). The Ag/Agclpregelled electrodes will be placed according to the standard limb lead II configuration for recording the electrocardiogram. Data will be acquired at the sampling rate of 2000 (8)

3.3.2. Secondary outcomes

Assessment of systolic blood pressure and diastolic blood pressure will be measured before and after the intervention session by using a non-invasive arm-type automatic blood pressure monitor.

3.3.3. Participant timeline

The participant timeline is shown in Figure 3.

3.3.4. Sample size

60 participants will be recruited and randomized into two groups

3.3.5. Sampling technique

The participants will be recruited from Government Yoga and Naturopathy Medical College and Hospital by using a convenient sampling technique.

3.3.6. Randomization

Participants are randomly divided (1:1) into two groups using simple random methods with the use of computerized randomization. Allocation concealment will be done by using a sequentially opaque sealed envelope technique. Randomization will be done by a research consultant who will not participate either in the data collection or intervention trial.

3.3.7. Blinding

Participants will be blinded and investigators will not be blinded in this study.

3.3.8. Data collection

Data collection will be performed after getting approval from the Institutional Ethical Committee (IEC) and after registration by the Clinical Trials Registry - India (CTRI). Study protocol will be explained to the subjects and a signed

consent will be obtained from each subject. Primary outcome variable (Heart rate and heart rate variability) and Secondary outcome (blood pressure) will be collected by the primary investigator.

3.3.9. Data management

All the data will be entered into a Microsoft Excel sheet and kept confidentially under the custody of the research department.

3.4. Statistical methods

Data will be entered in Microsoft Excel, 2011 and analysis will be done using Statistical Package for the Social Science Software (SPSS), Version 16.0. Kolmogorov Smirnov test will be done to check the normal distribution of the data. Based on the data distribution, within-group analysis will be done using paired-samples t-test or Wilcoxon signed rank test and between-group analysis will be done using independent samples t-test or Mann Whitney U test. P value <0.05 will be considered significant.

3.4.1. Data monitoring

Data monitoring in the proposed study will be carried out by the primary investigator, and the quality control of the entire project will be monitored by the Head of the Department and research guide to identify problems in the project implementation process promptly and to implement the corresponding countermeasures. The researchers will be handling the control bias by examining and supervising the acquired data.

4. Discussion

This is the first-ever study to investigate the effect of an ice-cold compress on the neck and spine on the pupillary dynamometer. A previous pilot study was conducted on the effect of ice application to the head and spine on autonomic function in healthy volunteers, the result suggests that the impact of cold application stimulates lateral branches of the vagus nerve in the neck and induces parasympathetic dominance (8). Previous research has shown that cold stimulation in the neck region can lead to a reduction in heart rate and discomfort during vascular access, as well as systolic and diastolic hypertension (9). Hypertension is a prevalent condition globally, affecting a significant portion of the population (3). The current study explores how ice application to the neck and spine can potentially reduce systolic and diastolic blood pressure, and promote pupillary constriction.

5. Conclusion

The positive findings of the current study highlight its potential to regulate hypertension, offering a cost-effective treatment that can help reduce the global burden of the condition.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare that there is no conflict of interest.

Statement of ethical approval

The study will be carried out after getting approval from the Institutional Ethics Committee (REF/2023/07/) and clearance will be obtained from Government Yoga and Naturopathy Medical College and Hospital, Chennai before recruitment of the first subject.

Statement of informed consent

Study protocol will be explained to the subjects and a signed consent will be obtained from each subject.

Harms

The subject may feel chillness in the head and spine.

Auditing

Auditing will be done promptly.

Protocol amendments

In case of any changes, it will be informed to the department and IEC.

Confidentiality

Govt. Yoga & Naturopathy Medical College and Hospital will protect the confidentiality of your records to the extent provided by Law.

You understand that the study sponsor and the Institution have the right to review your records.

Access to data

The data will be available in the department, it can be accessed by request with a valid reason.

Protocol availability

The protocol is freely available.

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