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Effect of passive leg raising on the cross-sectional area of the right internal jugular vein in patients with obesity: a randomised controlled trial protocol

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ABSTRACT

Background Venous access in patients with obesity presents significant challenges. The success of central venous catheterisation largely depends on the cross-sectional area (CSA) of the internal jugular vein (IJV). While techniques like the Trendelenburg position have been traditionally used to increase IJV CSA, recent studies suggest its ineffectiveness in patients with obesity. Conversely, the potential of the effect of passive leg raising (PLR) has not been thoroughly investigated in this group of patients.

Methods This protocol outlines a planned randomised controlled trial to evaluate the effect of PLR on the CSA of the IJV in patients with obesity slated for central venous catheterisation. The protocol involves dividing 40 participants into two groups: one undergoing PLR and another serving as a control group without positional change. The protocol specifies measuring the CSA of the IJV via ultrasound as the primary outcome. Secondary outcomes will include the success rates of right IJV cannulation. The proposed statistical approach includes the use of t-tests to compare the changes in CSA between the two groups, with a significance threshold set at $p<0.05$.

Ethics approval This study has been approved by the Institutional Review Board of Shanghai Tongren Hospital. All the participants will provide informed consent prior to enrolment in the study. Regarding the dissemination of research findings, we plan to share the results through academic conferences and peer-reviewed publications. Additionally, we will communicate our findings to the public and professional communities, including patient advocacy groups.

Trial registration number ChiCTR: ChiCTR2400080513.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study uses a randomised crossover design to compare the intervention effects among the participants.
⇒ Dividing the study into two separately randomised parts enhances the credibility of the results.
⇒ As a single-centre study, the generalisability may be limited.

INTRODUCTION

Venous access represents a critical challenge in patients with obesity undergoing surgery, particularly for major surgeries requiring central venous catheterisation.[1 2] The right internal jugular vein (IJV) is the most commonly used vessel for deep venous catheter placement. However, IJV cannulation can lead to serious complications, including arterial puncture, arteriovenous fistula, cardiac tamponade and even death.[3 4] The placement of central venous catheters can be particularly difficult in patients with obesity due to the obscured neck landmarks; furthermore, a high body mass index (BMI) is one of the most significant risk factors for complications during IJV cannulation in the surgical period.[5 6] The success rate of central venous cannulation correlates with the venous cross-sectional area (CSA).[7–10] Techniques such as positive end-expiratory pressure, the Trendelenburg position, passive leg raising (PLR): a technique to elevate the patient's legs to increase the venous return, and the Valsalva manoeuvre have been shown to increase the CSA of the IJV in anaesthetised patients.[11–15] However, most studies evaluating the impact of these manoeuvres on IJV CSA have been conducted in patients with non-obesity.[16 17] The effectiveness and safety of these techniques in patients with obesity remain debated, especially since studies like those by Ozkan *et al* have not found the Trendelenburg position to increase the CSA of the IJV in patients with obesity.[18 19] PLR, involving elevating the patient's legs to a certain angle for a duration, can rapidly assess the volume status of patients with heart failure[20] and increase the CSA of the IJV, offering a simple and commonly used method for adjusting the position for IJV cannulation.[11] PLR has a lesser impact on cardiac output compared with the Trendelenburg position.[21] However,

there is a lack of research on the effectiveness of PLR in patients with obesity. This research aims to observe the impact of PLR on the right IJV CSA and the success rate of IJV cannulation.

METHODS AND ANALYSIS

Primary objective

To assess the effectiveness of PLR position in increasing the CSA of the IJV in patients with obesity scheduled for elective surgery.

Secondary objective

To compare the success rates of right IJV cannulation in patients with obesity across different positions.

Trial design

Step 1: randomised crossover intervention trial

On entering the operating room, the patients undergo right IJV imaging in two different body positions, in the order detailed in a white sealed envelope—S0: horizontal supine position; PLR40: PLR position (legs elevated on a special pillow, with an angle of 40°±2° between the legs and the horizontal plane). After maintaining each position for at least 1 min, the patient assumes a horizontal supine position without a pillow, with the head rotated 20° to the left. Ultrasound images of the right IJV are obtained at the end of expiration and stored in the ultrasound machine. An ultrasound device equipped with a linear (7.5 MHz) probe is used to obtain a transverse ultrasound image of the IJV at the level of the cricoid cartilage. The right IJV appears in the centre of the ultrasound image. The pressure exerted by the probe is kept as low as possible to avoid compressing the IJV. The probe is placed perpendicular to the skin during measurements. All the procedures are performed by an experienced anaesthesiologist proficient in ultrasound-guided IJV puncture. After the completion of the first and second steps for each patient, the stored ultrasound images will be analysed by another anaesthesiologist who will measure the CSA of the right IJV using the machine's built-in software. This anaesthesiologist will be blinded to the patient's position during the image acquisition.

Step 2: randomised controlled trial for evaluating success rate of IJV catheterisation

Following the completion of step 1, the patients resume the horizontal supine position and wait for at least 5 min before being re-randomised according to a computer-generated sequence, with the group allocation placed in a yellow-sealed envelope. 40 patients are divided into two groups (20 in the S0 group and 20 in the PLR40 group). The IJV catheterisation procedure is performed by the same anaesthesiologist who acquired the ultrasound images in step 1. This anaesthesiologist uses the short-axis out-of-plane technique under ultrasound guidance for both ultrasound imaging and right IJV puncture. Successful cannulation is defined as a successful puncture on the first attempt. Failure is defined as more than two attempts or if the puncture occurs in the internal carotid artery. The pulse rate is continuously monitored throughout the study, recording any abnormalities (pulse rate >130 beats per minute or <45 beats per minute). The study is immediately terminated if the patient experiences severe discomfort, chest tightness or shortness of breath.

Inclusion criteria

BMI>30 kg/m^2; patients scheduled for elective surgery; American Society of Anesthesiologists (ASA) classification II; patient's informed consent obtained.

Exclusion criteria

History of neck surgery, such as thyroid surgery; severe cardiovascular disease; end-stage renal disease; severe infection or sepsis; significant coagulopathy; inability to perform PLR.

Withdrawal criteria

Onset of discomfort or intolerance during the trial; decision to withdraw from the trial by the participant.

Data handling for withdrawn participants

Complete clinical data will be retained for the participants who withdraw from the trial, documenting the reason for withdrawal and completing a conclusion form. Reasons for withdrawal are categorised into six types: adverse events (including drug adverse reactions and allergic reactions), lack of efficacy (deterioration of condition or occurrence of complications), violation of the trial protocol (including poor compliance), loss to follow-up (including the participant's own decision to leave the trial), termination by the sponsor or other reasons.

Blinding (masking)

Due to the nature of the interventions (different body positions), it is not possible to blind the patients or the anaesthesiologist performing the procedures. However, the following measures will be taken to minimise the potential bias:

- The stored ultrasound images will be analysed by a different anaesthesiologist who will measure the CSA of the right IJV. This anaesthesiologist will be blinded to the patient's position during image acquisition.
- The statistician conducting the data analysis will be blinded to the group allocation.

Although complete blinding is not achievable due to the necessity of different body positions, these measures aim to minimise the potential bias and enhance the objectivity of the study results.

Sample size

Sample size calculations were performed using the PASS software. The primary observational indicator is the change in the CSA of the IJV in S0 and PLR40 positions, designated as the main variable for calculating the sample size. Reference literature[22] reports that the average CSA of the jugular vein in the supine position is approximately

1.4 cm^2, with an SD of about 0.5 cm^2. It is hypothesised that the PLR position can increase the CSA by 20%, leading to an average CSA of about 1.68 cm^2 in the PLR40 position.

For calculating the sample size for a paired t-test, a two-sided test is used with α=0.05 and a power of 1-β=0.9, resulting in a required sample size of n=32. Taking into account a dropout rate of 20%, the total sample size is determined to be 40 participants.

Randomisation

For the sample size of 40 patients, 10 patients per cluster are determined.

The random number generation function of SPSS statistical software is used to record eight sets, each with 10 random numbers, for a total of 80 random numbers generated using different seeds.

The random numbers are placed into opaque envelopes for safekeeping. White envelopes are used in the first step; yellow envelopes are used in the second step.

Patients with obesity who meet the inclusion criteria open the white envelopes in sequence during the first step to undergo measurement of the CSA of the right IJV as directed by the contents of the envelope. Subsequently, they are allocated to either the S0 group or PLR40 group for the right IJV puncture based on the group number found within the envelope.

Details such as the length of clusters, seed numbers and the SPSS program used during the randomisation process are all saved in a record of the randomisation process to ensure that the random number generation is reproducible. After qualifying through screening, the participants are assigned a random number, with researchers sequentially opening the envelopes and meticulously recording the identity of the person who opened each envelope and the time it was opened.

Eligibility criteria

This study will be conducted in operating rooms capable of performing ultrasound-guided IJV punctures and have established protocols for managing patients with obesity.

The study's inclusion and exclusion criteria for the participants are clearly defined, focusing on BMI, elective surgery status, ASA II classification and informed consent agreement.

Data management and statistical analysis

Data will be meticulously collected using the paper case report forms and subsequently entered into a database for comprehensive analysis. All the analyses will be conducted using SPSS V.25.0 software, ensuring the data remain anonymised to uphold participant confidentiality. The primary outcome, involving changes in the CSA of the right IJV, will be assessed through paired t-tests. Additionally, the success rates of IJV cannulation will be compared using the χ^2 test or Fisher's exact test, as deemed appropriate for the data distribution.

On the completion of the trial, all the data will be made publicly available as supplementary materials to the published paper, allowing for transparency and the opportunity for further research by the scientific community.

Outcomes

Baseline characteristics

Patients' age, gender, preoperative haemodynamics, fasting time, haemoglobin, weight, height and ASA classification will be analysed and compared between the two groups.

Primary outcome

The primary outcome is the CSA of the right IJV measured by ultrasound at different body positions (supine and PLR at 40°).

Secondary outcome

The secondary outcome is the success rates of right IJV cannulation in each group. Successful cannulation is defined as a successful puncture on the first attempt, while failure is defined as more than two attempts or puncture of the internal carotid artery.

Safety outcomes

Pulse rate will be continuously monitored throughout the study, and any abnormalities (>130 beats per minute or <45 beats per minute) will be recorded. The study will be immediately terminated if the patient experiences severe discomfort, chest tightness or shortness of breath.

ETHICS AND DISSEMINATION

This study adheres to the ethical guidelines with approval from the Institutional Review Board of Shanghai Tongren Hospital and informed consent obtained from all the participants. The study is registered with the Chinese Clinical Trial Registry, registration number ChiCTR2400080513.

A model informed consent form is provided as online supplemental file 1. This form includes detailed information about the study purpose, procedures, potential risks and benefits, confidentiality and voluntary participation. All the participants will be required to sign this form prior to enrolment.

The research findings will be disseminated through peer-reviewed publications, oral and poster presentations at scientific conferences, facilitating communication of the study results to the clinicians and the general public.

The hospital's research department ensures study compliance with protocols, ethical guidelines and regulatory requirements through rigorous oversight of the clinical research team. Responsibilities include study oversight, regulatory compliance, quality assurance, ethical guidance, and providing training and support, ensuring study integrity, transparency and ethical conduct.

Any significant protocol modifications will be formally amended and approved by the IRB prior to implementation, maintaining transparency and integrity throughout the study.

Patient and public involvement

Patients were not involved in the design and conception of this study.

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Contributors DP contributed to the study's design, data analysis, manuscript drafting and critical revision. He approved the final manuscript and is accountable for the work's accuracy and integrity. SW secured funding, managed the project, supervised the research, reviewed the manuscript critically, approved the publication and oversaw the work's accuracy and integrity. CS was involved in data curation and analysis, helped draft and critically review the manuscript, approved the final version and ensured the work's integrity. In the preparation of this manuscript, I have used AI language models for the tasks of English translation and language polishing. Specifically, I used Claude, an AI assistant created by Anthropic, to translate portions of the manuscript from Chinese to English, as well as to refine the language and phrasing in the English version. The AI was used as an assistive tool to improve the clarity and quality of the English writing, while the core content and scientific substance were developed by the author team. The AI did not participate in the study design, data analysis or interpretation of results.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design and conception of this study. However, we plan to disseminate the study findings to patient groups and the general public.

Patient consent for publication Not applicable.

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