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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.

Acknowledgements We extend our heartfelt gratitude to Chief Liling Xu of the Scientific Research Department, along with Dr Jingwen Yue and Ms Yinyin Shen, for their invaluable assistance throughout this research. Our thanks also go out to our colleagues in the Department of Anaesthesiology for their support and collaboration.

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.

Provenance and peer review Not commissioned; externally peer reviewed.

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上海市同仁医院

SHANGHAI TONG REN HOSPITAL **V2.0** 2023.09.28

知情同意书

受试者须知页

方案名称：被动抬腿体位对肥胖患者右颈内静脉横截面积的影响

主要研究者：裴东亮 申办方:上海市同仁医院

尊敬的受试者：

您正在被邀请参加一项名为“被动抬腿体位对肥胖患者右颈内静脉横截面积的影响”的研究。在签署知情同意书前,请仔细阅读以下信息:请仔细阅读本知情同意书并慎重做出是否参加本项研究的决定。参加这项研究完全是您自主的选择。作为受试者，您必须在加入临床研究前给出您的书面同意书。当您的研究医生或者研究人员和您讨论知情同意书的时候，您可以让他/她给您详细解释知情同意书的各项内容。您可以在做出参与此项研究的决定之前，和您的家人及朋友进行充分讨论。您有权拒绝参加本研究，也可随时退出研究；您不会因此而受到处罚，也不会失去您应有的权利。若您正在参加别的研究，请告知您的研究医生或者研究人员。本研究的背景、目的、研究过程及其他重要信息如下：

一、研究背景

右颈内静脉穿刺置管是临床中常用的操作，对于肥胖的外科患者来说，静脉通路是一个重要问题，尤其重大手术需要中心静脉导管,其准确且迅速完成右颈内静脉穿刺置管对手术的顺利进行至关重要。但目前大多数评估此类操作对 IJV CSA 影响的研究都是在非肥胖患者中进行的。但在肥胖患者中的的有效性和安全性仍在争论中。

二、研究目的

观察 PLR 对肥胖患者右颈内静脉 CSA 的影响,为肥胖患者右颈内静脉穿刺置管提供依据。

三、研究过程

1. 40 人会在本院参与本研究。

2. **研究步骤**

a.研究人员获取麻醉医生在常规手术前麻醉访视和手术后访视评估材料（非常简短）

b. 进入手术室后，工作人员会抬起您的双腿，大概持续 2 分钟，然后超声测量右颈内静脉。放下双腿后再次测量。

3. **这项研究会持续多久？**

大概持续 4～5 分钟。本研究不会增加您的手术或麻醉风险，也不会增加医疗费用和住院天数。

4. 研究中收集的信息和生物标本

您的所有研究记录将被匿名化,个人信息将被严格保密。研究结果仅以统计学方式呈现。

四、风险与受益

本研究不会增加您的手术或麻醉风险,也不会增加血液检测项目。参与研究也不会影响您的待遇。您的参与有助于提高右颈内静脉穿刺置管的技术发展和提高。

五、研究结果的使用和个人信息的保密

在您和其他受试者的理解和协助下，通过本项目研究的结果可能会在医学杂志上发表，但是我们会按照法律的要求为您的研究记录保密。研究受试者的个人信息将受到严格保密，除非应相关法律要求，您的个人信息不会被泄露。必要时，政府管理部门和医院伦理委员会及其它相关研究人员可以按规定查阅您的资料。

七、关于研究费用及相关补偿

1. 研究所用的药物及相关检查费用

本研究不会干预您的诊疗过程。参加本研究不会额外增加您的医疗开支和医疗风险，也不会增加您的住院天数、康复周期等。

2. 参加研究的补偿

参与本研究不会给您带来额外的花费，因此没有额外的补偿。

3. 发生损伤后的补偿/赔偿

参加研究不会增加麻醉手术风险，因此也不涉及赔偿。

八、受试者的权利和相关注意事项

1. 您的权利

参加研究的整个过程您都是自愿的；如果您决定不参加本研究，不会影响您应该得到的其他治疗。如果您决定参加，会要求您在这份书面知情同意书上签字。您有权在试验的任何阶段随时退出试验而不会遭到歧视或受到不公平的待遇，您相应的医疗待遇与权益不受影响。

2. 注意事项

作为受试者，您需要提供有关自身病史和当前身体状况的真实情况；告诉研究医生自己最近是否将参加其他研究，或目前正参加其他研究。

九、获知信息的相关联系方式

如果在研究过程中有任何重要的新信息可能影响您继续参加研究的意愿时，您的医生将会及时通知您。您可以在任何时间提出有关本项研究的任何问题，包括您自己的研究数据或项目完成后本研究的发现，并得到相应的解答，请通过电话 18017337069 与裴东亮医生联系。如果不能解决您的问题，请联系上海同仁医院伦理审查委员会，电话：02152039999-76213

受试者签字页

知情同意声明：

我已被告知此项研究的目的、背景、过程、风险及获益等情况。我有足够的时间和机会进行提问，问题的答复我很满意。

我也被告知，当我有问题、想反映困难、顾虑、对研究的建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。

我已经阅读这份知情同意书，并且同意参加本研究。

我知道我可以选择不参加此项研究，或在研究期间的任何时候无需任何理由退出本研究。

我已知道如果我的状况更差了，或者我出现严重的不良事件，或者我的研究医生觉得继续参加研究不符合我的最佳利益，他/她会决定让我退出研究。无需征得我的同意，资助方或者监管机构也可能在研究期间终止研究。如果发生该情况，医生将及时通知我，研究医生也会与我讨论我的其他选择。

受试者签名： 日期：

法定代理人签字: 日期：

研究者签名： 日期：

（注：如果受试者无行为能力/限制行为能力时，则需法定代理人签名和签署日期）