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Correlation between postprandial hypotension and post-induction hypotension in the elderly: a protocol for a prospective cohort study

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ABSTRACT

Introduction Post-induction hypotension (PIH) is particularly common in elderly patients undergoing general anaesthesia and is associated with severe postoperative complications. Autonomic nervous system (ANS) dysfunction is a potential risk factor for significant haemodynamic fluctuations during general anaesthesia in elderly patients. Tools to identify ANS are currently lacking in perioperative clinical practice. Postprandial hypotension (PPH) is closely linked to ANS dysfunction and is also common among elderly individuals. Therefore, this study aims to explore the relationship between PPH and PIH in elderly patients undergoing non-cardiac surgery. By examining this correlation, we hope to better understand the factors contributing to PIH and explore the potential role of PPH in predicting PIH.

Methods and analysis This is a prospective observational cohort study. 120 elderly Chinese patients aged ≥65 years and scheduled to undergo non-cardiac surgery under general anaesthesia at Peking Union Medical College Hospital (PUMCH) will be included. PPH assessments will include baseline pre-prandial records and blood pressure measurements immediately after meal completion, followed by every 5 min for 120 min. To evaluate PIH, blood pressure will be monitored from the patients' entry into the operating room until 20 min after anaesthesia induction or the initiation of surgery. PIH is defined as systolic blood pressure of <90 mmHg or main arterial pressure <65 mmHg or a decrease of more than 30% from baseline within 20 min after general anaesthesia induction or before surgical incision. Baseline assessment will include regular preoperative assessment, symptoms and medical history related to baroreflex dysfunction, and preoperative volume status will be assessed by passive leg raising test. Follow-up will be conducted at 1, 3, 7 and 30 days and 6 months postoperatively. The primary outcome is PIH. Secondary outcomes include early intraoperative hypotension, postoperative complications graded by Clavien–Dindo classification, 30-day postoperative mortality and 12-item WHO Disability Assessment Schedule 2.0 (12-item WHODAS 2.0) score 6 months postoperatively.

Ethics and dissemination This study has been registered in the ClinicalTrials.gov system of the National Institutes of Health (registration number NCT05575661). The Ethics Committee of PUMCH has also granted ethical approval (approval number I-22PJ008). The study results will be disseminated through publication in peer-reviewed journals focused on anaesthesiology and geriatric medicine, as well as presentations at relevant scientific conferences.

Trial registration number NCT05575661.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study is a prospective cohort study to investigate the correlation between the incidence of postprandial hypotension (PPH) and post-induction hypotension (PIH) among elderly patients undergoing non-cardiac surgery.
⇒ Assessment of volume status via passive leg raising enables stratified analysis of hypovolemic patients, thereby mitigating the confounding influence of hypovolemia on PIH.
⇒ Recording caloric intake at the time of PPH assessment allows for adjustment of dietary influences on haemodynamic measurements, thus minimising dietary intake as a confounding variable.
⇒ Detailed documentation of preoperative assessments like frailty status, autonomic nervous system-related history and antihypertensive medication strengthens the internal validity and generalisability of the findings.
⇒ The study's limited sample size may affect the generalisability of the findings.

INTRODUCTION

Intraoperative hypotension is a well-known risk factor for serious postoperative complications such as myocardial injury, arrhythmias, acute kidney injury and increased mortality.[1–3] Approximately 70% of intraoperative hypotension events occur after anaesthesia induction but before surgical incision, known as post-induction hypotension (PIH).[4] Previous studies have identified several risk factors of PIH, including advanced age, baseline blood pressure levels, preoperative blood volume status, type and dosage of anaesthetic drugs, an American Society of Anesthesiologists (ASA) functional classification greater

than III and long-term use of ACEI/ARB (angiotensin-converting enzyme inhibitors/angiotensin II receptor blockers).[5 6] However, most are non-modifiable and the pathophysiological mechanisms underlying this phenomenon remain unclear. Moreover, with the ageing population, major surgeries among elderly adults are becoming more prevalent.[7] These patients often have multiple comorbidities and higher ASA classifications, leading to a higher incidence of PIH and consequently more adverse postoperative outcomes.[5 6]

It is traditionally believed that PIH is related to hypovolemia before induction.[8] However, fluid optimisation, according to the stroke volume (SV) response to passive leg raise before surgery, has been demonstrated to have no significant impact on haemodynamic instability.[9] Turner *et al* also found that infusing 20 mL per kilogram of crystalloid for venous preloading does not prevent PIH after anaesthesia induction with propofol and fentanyl.[10] These study results suggest that there is an influence of factors other than hypovolaemia on the occurrence of PIH.

Blood pressure is influenced by preload, myocardial contractility and peripheral vascular resistance (PVR). While fluid optimisation before induction has been shown not to significantly impact haemodynamic instability, myocardial contractility and PVR, which are regulated by the cardiovascular autonomic nervous system (ANS), experience dynamic changes after the administration of anaesthetic agents. Several existing studies have explored the relationship between preoperative ANS function and hypotension during general anaesthesia,[11–15] noticing that patients with ANS dysfunction, whether they present autonomic neuropathy or not,[16] experience more significant blood pressure fluctuations during general anaesthesia, owing to impaired ability of haemodynamic self-regulation.[11 12 14 15] These findings suggest that patients with ANS dysfunction are inherently more susceptible to PIH due to compromised haemodynamic compensatory mechanisms.

As the ageing process progresses, the function of the ANS also declines, resulting in reduced capabilities in various physiological aspects. One common condition in the elderly is postprandial hypotension (PPH), a manifestation of impaired blood pressure regulation.[17] PPH is defined as a drop in systolic blood pressure (SBP) of more than 20 mmHg within 2 hours after a meal, a postprandial SBP of ≤90 mmHg when pre-meal SBP is ≥100 mmHg or the presence of symptoms such as fainting.[17 18] PPH is influenced by factors such as age, hypertension, diabetes, Parkinson's disease, medications and lifestyle.[17 19] The incidence of PPH can reach 25–67% and is associated with an increased risk of adverse outcomes like falls, syncope, cardiovascular disease and mortality.[20] Possible mechanisms of PPH are visceral blood flow increase after a meal intake and a committing decrease in blood pressure. Under normal physiological conditions, eating stimulates sympathetic nervous system activity to maintain blood pressure stability.[21] However, changes related to ageing and disease can weaken sympathetic nervous system activation. Additionally, age-related vascular stiffening reduces older individuals' ability to respond to sympathetic nervous system activity,[22] thereby contributing to the occurrence of PPH.[23]

Theoretically, PPH reflects abnormal or at least suboptimal ANS regulation, which may also contribute to the development of PIH in patients undergoing general anaesthesia. However, no studies have yet explored the relationship between PPH and PIH. This prospective cohort study aims to examine this correlation among elderly patients undergoing non-cardiac surgery. Through this, we hope to better understand the factors contributing to PIH and explore the potential role of PPH as a predictor of PIH, while laying the groundwork for future studies focused on developing effective interventions for managing PIH. Prior to the main study, we conducted a pilot study to refine study procedures and to better estimate the incidence of both the primary outcome and the exposure of interest.

METHODS AND ANALYSIS

Study design and setting

This is a prospective, single-centre cohort study aimed at exploring the correlation between the occurrence of preoperative PPH and the occurrence of PIH. Our study will be conducted at Peking Union Medical College Hospital (PUMCH) and has obtained approval from the Research Ethics Committee of PUMCH (approval no: I-22PJ008). It has also been registered on ClinicalTrials.gov (Registration No: NCT05575661).

Study population

Inclusion criteria

- Patients aged at least 65 years.
- Patients with an American Society of Anesthesiologists (ASA) physical status class of I–III.
- Patients scheduled to undergo elective non-cardiac surgery under general anaesthesia, with an anticipated surgical duration of over 1 hour.
- Patients with intra-tracheal intubation following intravenous general anaesthesia induction and maintenance.

Exclusion criteria

- Patients with vascular diseases such as aortic aneurysm, aortic dissection, symptomatic atherosclerotic obliterans, Buerger's disease and Raynaud's syndrome, as these conditions may impair the accuracy of blood pressure measurement or be detrimental in long-term blood pressure measurement.
- Patients with secondary hypertension, including renal hypertension and endocrine hypertension.
- Patients with chronic kidney disease requiring dietary restrictions or dialysis.
- Patients with Parkinson's disease or other conditions causing tremors.

- Patients with problems related to oral food ingestion or those requiring enteral nutrition.
- Patients with difficulties in measuring the upper extremities or communication problems that would interfere with study procedures.
- Patients unable to remain in the supine position for at least 2 hours after lunch during PPH assessment in the ward.

Protocol

Acquisition of baseline data

Comprehensive baseline data will be collected on patient admission and prior to surgery to establish a detailed clinical profile for each participant. Baseline assessment will include demographic information, detailed medical history, current medication use, laboratory and diagnostic test results, physical examination findings and frailty status. Frailty, characterised by reduced physiological reserves and diminished stress tolerance,[24] has been recognised as a potential risk factor for PIH.[25] Previous studies have shown that frail individuals have a higher prevalence of autonomic dysfunction,[26] which may contribute to PPH. Given its potential impact on autonomic regulation and vascular responsiveness,[27] frailty will be evaluated using two validated tools (the FRAIL Scale and the Fried Frailty Phenotype)[28 29] and will be considered as a potential confounding variable in the multivariable regression analysis to assess whether it influences the correlation between PPH and PIH.

Medication data, including drug type, dosage and administration frequency, will be obtained via structured face-to-face interviews and cross-validated against the hospital's electronic prescribing system. Particular attention will be given to agents known to affect autonomic function, including anticholinergic drugs, sympathomimetics, para-sympathomimetics, corticosteroids and adrenergic receptor blockers. Medical history will be collected with an emphasis on identifying conditions that may affect cardiovascular ANS function. This includes prior diagnoses or symptoms such as resting tachycardia, exercise-induced tachycardia, orthostatic tachycardia or arrhythmias, orthostatic hypotension and abnormal skin colour changes with temperature variations. All preoperative assessments, including preoperative volume status and PPH assessments, will be conducted by the same trained researcher, while intraoperative data collection and postoperative follow-up will be handled by a separate assessor to ensure consistency and reduce observer bias.

PPH measurement

PPH will be assessed 1–3 days before surgery using a blood pressure monitoring device (Mindray-ePM 10M, China) in the ward after admission to hospital. Measurements will be taken between 10:30 AM and 1:30 PM to minimise the interference of circadian rhythms on blood pressure.[30] Patients will be instructed to take their antihypertensive medications as usual on the morning of the measurement day. Before consuming a meal, participants will rest in a supine position for 15 min to achieve a relatively stable state. Blood pressure will then be measured four times, at 5 min intervals, and the average of these measurements will be taken as the baseline blood pressure for PPH and PIH. Patients will then consume the provided meal. Within 2 hours after finishing the meal, blood pressure will be measured every 5 min. During the blood pressure measurement before and after meals, the patient should remain in a supine position. All blood pressure measurements will be conducted in a quiet hospital room at a temperature of 25±1°C. Meals will be provided by the hospital nutrition department and will include approximately 250 grams of rice, steamed buns or noodles along with common Chinese side dishes. The specific macronutrient composition (protein, fat and carbohydrates), total caloric content and meal temperature will be recorded.

Assessment of preoperative volume status

On the day of surgery, approximately 30 min before anaesthesia, a preoperative volume status assessment will be conducted (table 1). While the patient is in the preoperative waiting area, cardiac output (CO) and SV status will be continuously measured using the LiDCO rapid (Masimo Corporation, USA). A passive leg-raising test will be performed, and the change in stroke volume (ΔSV) will be recorded. A ΔSV of ≥12% will indicate a hypovolaemic state.[31] This variable will be included as a covariate in the multiple logistic regression analysis.

Anaesthesia management and intraoperative data collection

All enrolled patients will be monitored continuously with non-invasive blood pressure (NIBP), four-lead ECG and pulse oximetry (SpO_2) after being transferred to the operating room (OR). A peripheral intravenous access will be established with Lactated Ringer's solution initiated at a rate of 2 mL/kg/h as the maintenance fluid. NIBP will be measured at intervals of 2 min during the post-induction period and at 3 min intervals during the surgical period. SBP, diastolic blood pressure, mean arterial pressure (MAP), SpO_2, heart rate (HR), bispectral index (BIS) and minimum alveolar concentration will be documented every 2 min for 20 min following induction of anaesthesia or until surgical incision, and every 3 min for a period of 30 min following surgical incision. Standard intravenous anaesthesia induction protocol, established by the Department of Anesthesiology at PUMCH, will be used for all subjects, which includes fentanyl (1–3 µg/kg), propofol (1.5–2.5 mg/kg) or etomidate (0.1–0.3 mg/kg) and rocuronium (0.6–0.9 mg/kg). The choice of anaesthetic agents (propofol or etomidate) used during the induction and maintenance phases will not be strictly restricted and will be selected by experienced anaesthesiologists independent of this study.

Following intravenous anaesthesia induction, all subjects will receive endotracheal intubation and will be mechanically ventilated with the goal of maintaining normocapnia and normoxia. During the anaesthesia process, there is no restriction on the use of vasoactive

Table 1 Timeline and schedule for enrolment, allocation and assessments

	Study period						
	Enrolment	Surgery	Postoperation				Close-out
Timepoint	Pre-D1-3	D0	POD1	POD3	POD7	POD30	POD180
Enrolment:							
Eligibility screen	X						
Informed consent	X						
Allocation	X						
Assessments:							
Baseline data	X						
Frailty status	X					X	
PPH assessment	X						
Preoperative volume status		X					
PIH assessment		X					
eIOH assessment		X					
Postoperative follow-up							
Postoperative complications			X	X	X	X	
POD-30 mortality						X	
12-item WHODAS 2.0 score							X

12-item WHODAS 2.0, 12-item WHO Disability Assessment Schedule 2.0.[32]
eIOH, early intraoperative hypotension; PIH, post-induction hypotension; POD, postoperative day; PPH, postprandial hypotension.

medications. If a patient's blood pressure falls below safety standards, they may be treated with 6 mg of ephedrine or 10 µg bolus of phenylephrine. The administration of anaesthetic agents and vasoactive medications will be recorded to enable adjustment for potential confounding factors during data analysis.

Post-operative follow-up

Follow-ups will be conducted on postoperative days 1, 3, 7, 30 and 180, with recovery status and postoperative complications documented using the Clavien–Dindo classification system and the 12-item WHODAS 2.0 score.[32 33]

Outcome measures

Primary outcome

The primary outcome of this study is PIH, defined as a SBPof <90 mmHg, MAP of <65 mmHg, or a decrease of more than 30% from baseline within 20 min after anaesthesia induction or before surgical incision. To exclude interference from elevated blood pressure due to patient anxiety on entering the OR, the diagnosis of PIH will use the same baseline as PPH.

Given the lack of a universally accepted definition of PIH, previous studies have employed various criteria, including absolute thresholds for SBP of <90 mmHg[6] and MAP of <65 mmHg,[4] relative decreases from baseline,[34] combinations of these parameters or even the need for vasopressor administration as a surrogate marker of hypotension.[6 35] As a result, reported PIH incidence has ranged from 18.1% to 53%. To enhance comparability and clinical applicability, we adopted a composite definition incorporating both absolute thresholds and relative changes, consistent with existing literature.

Secondary Outcomes

The secondary outcome measures of this study are:

1. Early intraoperative hypotension (eIOH), defined as hypotension occurring within the first 30 min after the start of surgery, characterised by a SBP of <90 mmHg, MAP of <65 mmHg or a decrease of more than 30% from baseline.
2. Postoperative complications graded using the Clavien–Dindo classification system. Postoperative complications will be defined based on the European Perioperative Clinical Outcome definitions and classified according to the Clavien–Dindo system.[33]
3. 12-item WHODAS 2.0 score 6 months after surgery.
4. Mortality within 30 days after surgery

Sample size calculation

The primary outcome of this study is the incidence of PIH. According to previous studies, the incidence of PPH can reach 25–67% depending on different criteria with different populations. The estimated incidence of PPH in patients aged over 65 years in geriatric departments is approximately 50%.[18 23 36] Given the limited existing literature investigating the association between PPH and PIH, a pilot study was conducted involving 30 participants. In this pilot, the overall incidence of PIH is 67.7%, with incidence rates of 86.7% in patients with PPH and 46.7% in those without PPH. Sample size estimation was performed using PASS version 21.0 software, based on a

comparison of two independent proportions. A two-sided significance level (α) of 0.05 and a power (1-β) of 0.90 were assumed. The calculation indicated that a minimum of 24 patients per group (48 in total) would be required to detect a statistically significant difference between the two groups.

Furthermore, a multivariable logistic regression analysis will be conducted to control for potential confounding variables. Assuming the inclusion of another six independent variables in the model and applying the rule of thumb requiring at least 10 events per variable,[37 38] a total of 105 participants would be necessary (105≈7X10/0.667). After accounting for an anticipated dropout rate of 10%, the total sample size required is estimated to be 117 participants. For practical considerations, a total of 120 participants will be recruited, with 60 patients in each group. Additionally, an online supplemental table S1 has been included to present type II error probabilities (β errors) under various assumed PPH prevalence rates and effect size.

Statistical analyses

All statistical analyses will be conducted using SPSS software (version 27.0). Baseline characteristics, including age, sex, body mass index, ASA physical status and preoperative auxiliary examination results will be summarised using descriptive statistics. Continuous variables will be presented as mean±SD or median with IQR, depending on data distribution. Categorical variables will be expressed as frequencies and percentages. A two-sided p value of <0.05 will be considered statistically significant.

For comparisons between patients with and without PPH, X^2 tests will be used for the PIH as well as secondary outcomes including eIOH and 30-day postoperative mortality. X^2 statistics and corresponding p values will be reported. The severity of postoperative complications, graded using the Clavien–Dindo classification, will be compared using Spearman's rank correlation test. For the 12-item WHODAS 2.0 scores at 6 months postoperatively, independent samples t-tests will be performed, with t values and p-values reported.

Univariable logistic regression will be conducted to assess the effect of PPH on the risk of PIH, with the strength of association expressed as ORs and 95% CIs. A multivariable logistic regression model will then be constructed to adjust for potential confounders, with particular attention given to the following variables: age, ASA classification, long-term use of ACEI/ARB medications, frailty status, pre-induction SBP, preoperative volume status and the type of anaesthetic induction agents. Covariate selection will be based on clinical relevance.

As an exploratory analysis, an ordinal logistic regression model will be used to examine the relationship between PPH and the severity of postoperative complications, as classified by the Clavien–Dindo system. Additionally, simple linear regression will be employed to evaluate the impact of PPH on long-term quality of life, as measured by the WHODAS 2.0 score at 6 months postoperatively. All regression analyses will adjust for the same set of confounders as in the primary outcome analysis to ensure the robustness of the results.

Ethics and dissemination

This study has received approval from the Research Ethics Committee of PUMCH on 10 June 2022, with approval number I-22PJ008. Prior to enrolling patients into the study, researchers will provide comprehensive explanations to patients regarding the research objectives and procedures. Patients will be informed of their right to refuse participation or withdraw from the study at any time. Informed consent will be obtained from patients, and they will be asked to sign a written informed consent form before participating in the study. This study has been registered in the ClinicalTrials.gov database of the National Institutes of Health with registration number NCT05575661. The findings of this study will be published in peer-reviewed journals focused on anaesthesiology and geriatric medicine, as well as presentations at similar scientific conferences.

DISCUSSION

With diminished physiological reserves and impaired autonomic regulation, elderly individuals are more prone to intraoperative haemodynamic instability, including PIH.[5] CO, arterial blood pressure and volume distribution are regulated by the ANS. However, the induction of anesthesia disrupts this balance, leading to intravascular volume redistribution and potential instability.[39] PPH occurs due to an inadequate sympathetic response to the physiological post-meal blood pressure drop, failing to sufficiently increase PVR, heart rate and CO.[20] Given that aging is associated with ANS dysfunction, it is reasonable to hypothesise that patients with PPH have an increased susceptibility to PIH.

To our knowledge, this is the first prospective study to investigate the correlation between PPH and PIH. Variability in anaesthetic agents used during induction is inevitable due to clinical considerations. However, this potential confounding factor will be controlled through appropriate statistical methods. Additionally, to exclude potential bias caused by preoperative volume status, which is often overlooked in previous studies, a passive-leg raising test will be conducted on all subjects, enhancing the study's methodological rigor. The findings of this study may carry important implications for both clinical decision-making and healthcare resource allocation. On an individual level, identifying an association between PPH and PIH could facilitate personalised risk assessments and targeted interventions, potentially reducing PIH incidence, improving recovery and enhancing postoperative quality of life (assessed by the 12-item WHODAS 2.0 score). From a healthcare system perspective, analysis of follow-up data in this study may offer preliminary insights into better PIH management, contributing to shorter hospital stays, lower readmission

rates, optimised resources utilisation and reduced overall healthcare costs.

Despite being a single-centre study, our hospital is a large, Grade A tertiary institution that serves a diverse patient population from across the country. As such, the findings are likely to be generalised to similar tertiary hospitals in China. Nonetheless, the study's single-centre design and relatively limited sample size may affect external validity, warranting future validation in multi-centre studies.

In summary, despite certain limitations, this study has the potential to provide novel evidence of an association between PPH and PIH, paving the way for future research to elucidate the underlying mechanism of PIH and develop effective interventions for its management.

Contributors LX was responsible for study conception. TL, HZ, LX, LC and QC formulated the study methodology and design and are responsible for obtaining ethical approval. Statistical expertise appropriate for the proposed study methodology was provided by TL and LC. TL and HZ are responsible for participant recruitment and data collection. All authors contributed towards the refinement of the study protocol and approve the final manuscript. LX is the guarantor of this work and accepts full responsibility for the conduct of the study, the integrity of the data and the accuracy of the data analysis.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

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