Protocol of a Thesis for Partial Fulfillment of **M.D.** degree in Anesthesia

Title:

Preoperative Evaluation of IVC Collapsibility Index and Caval Aorta Index for Prediction of Hypotension after Induction of General Anesthesia in patients Undergoing Craniotomy Surgeries

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What is already known on this subject? AND
What does this study add?

Intraoperative hypotension has been the most frequent side effect after anesthesia, with an incidence of 15.3% to 33%. Hypotension can be severe (incidence 5.4%) and may cause systemic hypoperfusion and ischemic events. **(Jor, O., Maca J., Koutna J., et al.2018)**

The caval aorta index (IVC/Ao) compares the maximum diameter of the IVC with the abdominal aorta (Ao).

This study is to assess the accuracy, repeatability, and reproducibility of preoperative evaluation of IVC Collapsibility Index and Caval Aorta Index for prediction of hypotension after induction of general anesthesia.

1.INTRODUCTION

Post- anesthesia hypotension is of common occurrence, and it hampers tissue perfusion. The magnitude of hypotension is determined by the preoperative volume status, which varies depending on ASA physical status, preoperative comorbidities, preoperative medications, and fasting. **(Bajawa S, Jindal R , Kulsherestha A. 2013)**

Intraoperative hypotension may solely be responsible for unfavorable consequences during or after surgery, including myocardial infarction, stroke, acute kidney injury, extended hospital stay, and higher death rates after one year in both cardiac and non-cardiac operations. **(Monk TG , Saini V , Weldon BC , et al . 2005)**

General anesthesia causes significant alterations in hemodynamics, as both inhalational and intravenous anesthetics cause bradycardia, decrease in systemic vascular resistance and vasodilatation, and decrease in myocardial contractility, cardiac output and stroke volume, with the absence of surgical stimulus, making induction of anesthesia is the most crucial period at which hypotension occurs. There are non-modifiable factors for post general anesthesia hypotension as ASA III & IV, old age, and the inevitable use of propofol and fentanyl, however there are modifiable factors and preoperative intravascular volume is one of the most important of them. **(Kouz K , Hoppe P , Briesenick L , et al , 2020)**

There is no uniform definition for intra-operative hypotension. It even remains unknown whether intra-operative hypotension should be defined based on absolute arterial pressure thresholds or on relative thresholds considering a decrease from

baseline arterial pressure. Frequently used definitions include systolic arterial pressure below 80 mmHg, a decrease in systolic arterial pressure of more than 20% below baseline, and a combination of definitions consisting of an absolute SAP below 100 mmHg and/or 30% decrease below baseline**.(Saugel B , Reuter DA, Reese PC , 2017).**

Due to different definitions of hypotension and diverse patient populations, the effect of volume preload on prevention of hypotension is still controversial. Many recommendations to identified sonographic determination of inferior vena cava (IVC) collapsibility index (IVCCI) as non-invasive, and easy technique for evaluating volume status. Recent guidelines from the American Society of Echocardiography support the general use of IVCCI in assessing volume status**.(Dipti A , Soucy Z , Surana A, et al 2017)**

The etiology of intra-operative hypotension is multifactorial. Intra-operative hypotension can, among other factors, be caused by vasodilation (anaesthetic drugs, systemic inflammation), intravascular hypovolaemia (bleeding), low cardiac output (bradycardia or low stroke volume), high intra-thoracic pressure (mechanical ventilation), impairment of sympathetic nervous system or compromised baroreflex regulation. **(Kouz K , Hoppe P , Briesenick L , et al , 2020).**

With some individual variation, autoregulation of cerebral blood flow (CBF) typically occurs within a mean arterial pressure(MAP) range of 60 to 150 mmHg . Outside of this range, the brain is unable to compensate for changes in perfusion pressure, and thecerebral blood flow (CBF) increases or decreases passively with corresponding changes in pressure, resulting in the risk of ischemia at low pressures and edema or hemorrhage at high pressures. We aim for a MAP above the lower limit of autoregulation.**(Lassen NA.)**

2.AIM /OBJECTIVES

- **Primary aim**: Assessment of the accuracy, repeatability, and reproducibility of preoperative evaluation of IVC collapsibility index and Caval Aorta Index for prediction of hypotension after induction of general anesthesia.
- **Secondary aim:** to compare values of both IVCCI and Aorto-Caval Index in prediction of post general anesthesia induction hypotension.

3.METHODOLOGY:
Subjects and Methods

- **Type of Study:** Prospective cohort study.
- **Study Setting:** the study will be conducted at Ain-Shams University Hospitals.
- **Study Period:** the study will take place till reaching the target sample size.
- **Study Population:**

Selection criteria:

Inclusion Criteria:

- Patients aging 18-40 years.
- BMI < 40 kg/m².
- ASA I, II.
- Fasted according to the ASA guidelines: 2 hours for clear fluids, 6 hours after light meal, 8 hours after a full meal with high calorie or fat content.
- Scheduled for elective craniotomy surgeries before induction of general anesthesia.

- *Exclusion Criteria:*

  - Patients < 18 or >40 years.
  - BMI > 40 kg/m².
  - ASA III, IV.
  - Current or recent pregnancy (within 3 months).
  - Pre-existing cardiac disease or hypertension.
  - On medications affecting blood pressure (BBs, CCBs,..) .
  - Refusing to undergo the study.

- **Sample Size Calculation:**
  Using PASS 11 program for sample size calculation ; setting power at 80% , error at 5%, incidence of hypotension among patients undergoing general anesthesia at 78.43% **(Omar et al.,2023)**, and sensitivity and specificity of ultrasound guided Aorto-Caval index (IVC-AO) for prediction post general anesthesia hypotension at 77.5% and 63.6% , respectively, **(Omar et al.,2023)** , so a sample size of 32 patients undergoing craniotomy surgeries under general anesthesia will be needed.

  Assuming that a drop out is of 10% , a sample size of at least 36 patients undergoing craniotomy surgeries under general anesthesia will be needed.

- **Ethical Consideration**:

-Approval from the research Ethics committee of faculty of medicine ,Ain shams university is mandatory and will be obtained before start in this study.
-Obtaining an informed consent: Written signed and dated informed consent will be obtained from patients or legal guardian of each participant before being entered into the study.
-Patients can withdraw from the study at any time and still get the full medical service within the facility. patients can refuse to participate and still get the standard care.
-Patients, privacy and confidentiality with the right to know the research results are ensured.

- **Sample size**: 40 cases
- **Study Tools:** Ultrasound curvilinear array, low - frequency (2- 5 MHz)
- **Study Procedure**

Pre-operative: All patients will be subjected to:

1- Detailed medical history taking with special emphasis on:
- History of cardiac disease or anti-hypertensive medications.
- Demographic data (age, sex, weight, height, body mass index).

2- Thorough clinical examination including:
- General and local examination.
- American Society of Anesthesiologists (ASA) physical status classification.

3- Laboratory investigations:
- Complete blood picture (CBC).
- Prothrombin time (PT), INR and activated partial thromboplastin time (aPTT).

- Liver functions tests.
- Cardiac enzymes.
- Kidney function tests.

4- Electrocardiogram (ECG).

Intra-operative:

-On the day of surgery, pre-operative fasting for 8 hours will be confirmed.

- Upon arrival to the operating room, routine monitors in the form of pulse oximetry, electro-cardiogram and non-invasive blood pressure monitors will be applied. Intravenous line will be secured.
- central venous line and invasive arterial line will be applied.
- Systolic blood pressure, diastolic blood pressure, MAP, and HR at baseline will be recorded.
- After obtaining informed consent, the patient is placed in the supine position with the head of the bed elevated 30 degrees.

- The ultrasound transducer is placed in the right subcostal position to visualize the IVC.
- The maximum (expiratory) and minimum (inspiratory) IVC diameters are measured.
- The IVCCI is calculated using the following formula:

IVCCI = (maximum IVC diameter - minimum IVC diameter) / maximum IVC diameter * 100

- To the left of the IVC, the abdominal aorta is visualized 10 mm above the coeliac trunk.
- The aortic diameter is measured at maximum diameter during systole
- The IVC : Ao index will be derived by taking the ratio of the maximum IVC diameter during expiration and the maximal abdominal aortic diameter during systole.
- The IVC/Ao index is calculated using the following formula:

IVC/Ao index = IVC diameter / aortic diameter.

- The measurements are repeated three times and the average is calculated.**(Finnerty NM, Panchal AR , Boulger C, et al 2017)**

- The patients will be induced as per a standard protocol. They will be given midazolam 0.05–0.1 $mg.kg^{-1}$, and fentanyl 2–3 $\mu g.kg^{-1}$ before

induction. Patients will be induced with propofol 1–2 mg.kg $^{-1}$, till loss of response to verbal commands. They will then mask ventilated with 100% oxygen and isoflurane 1.0%–1.2%. Atracurium (0.5 mg.kg $^{-1}$) will be given for muscle relaxation. Three minutes after atracurium, patients will be intubated by performing a gentle and quick laryngoscopy lasting not more than 15 s. In males, 8 mm or 8.5 mm internal diameter endotracheal tube will be used. In females, 7 mm or 7.5 mm internal diameter endotracheal tube will be used.**(Chowdhury SR, Datta PK, Maitra S, et al ,2023)**

- Measurement tools - Mean arterial blood pressure will be measured in supine position in one of the upper limbs in the operating room at 1-minute intervals starting from the baseline preoperative reading until skin incision as follows: 1-minute post-induction reading, 2-minutes post-induction reading, pre-intubation reading & post-intubation readings until skin incision. Taking in consideration that the maximum time for recording the readings of the blood pressure is 15 minutes because if hypotension occurred after this time it is unlikely to be due to the effect of induction of anesthesia.
- Heart rate will be recorded at 1-minute intervals starting from the baseline pre-operative reading until skin incision as follows: 1-minute post-induction reading, 2-minutes post-induction reading, pre-intubation reading & post-intubation readings until skin incision. Any episode of hypotension (defined as mean arterial pressure < 80% of the baseline reading or or MAP less than 60 mmHg) will be managed by ephedrine 5 mg every 2 min to increase SBP to 80% of the baseline or MAP more than 70 mmHg. If the hypotensive episode persisted for 2 minutes, another bolus of norepinephrine will be administered.

- The strength of the association between different parameters and post-anesthesia hypotension was calculated. To find out the value of the optimal cut-off for the prediction of post-anesthesia hypotension.

- **Statistical Method:**

Data collection: Demographic, clinical data, investigations, imaging, ECG and echocardiographic data will be obtained and recorded in special registration form.

Statistical analysis:

Statistical data will be tabulated, and Statistical analysis is to be performed using the latest available version of SPSS.

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