Title of the Protocol: Assessment of Ultrasonographic Carotid Artery Corrected Flow Time and Internal Jugular Vein Collapsibility Index in Prediction of Hypotension during Induction of General Anesthesia

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PROTOCOL OF A THESIS FOR PARTIAL FULLFILMENT OF M.D. DEGREE IN ANESTHESIA

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Postgraduate Student: **Marina Adel George**
Degree: M.B.B.CH., M.Sc. Ain Shams University.

DIRECTOR: Prof. Dr. Amir Ibrahim Salah
Academic Position: Professor.
Department: Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Co-DIRECTOR: Prof. Dr. Sherif Sayed Ali Sultan
Academic Position: Professor.
Department: Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Co-DIRECTOR: Dr. Aya Hisham Moussa Ahmad
Academic Position: Lecturer.
Department: Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

Co-DIRECTOR: Dr. Ahmed Taha Saeed Abdelwahab
Academic Position: Lecturer.
Department: Department of Anesthesia, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

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What is already known on this subject?

Post induction hypotension is closely related to postoperative complications. Patients are at high risk of hypotension due to preexisting hypovolemia and the vasodilatory effects of induction agents. Ultrasonographic measurement of the Carotid artery corrected flow time and internal jugular vein collapsibility index may predict post induction hypotension.

1. INTRODUCTION:

Hypotension during induction of general anesthesia, is quite common in clinical practice. If hypotension is severe or prolonged, it may cause organ hypoperfusion and ischemia. It may also increase the incidence of postoperative adverse outcomes such as myocardial injury, ischemic stroke, acute kidney injury, and even increases 1-year mortality ***(Wang et al., 2020; Chen et al., 2022).***

The preoperative identification of patients at risk of developing hypotension during induction could guide anesthetists to preoperative adjustment of the anesthetic management. This may include decreasing the doses of the induction agents, increasing the amount of pre-anesthetic fluid loading, and early administration of prophylactic vasopressors ***(Juri et al., 2017).***

Previously, central venous catheterization was ~~a~~ considered the gold standard for predicting intravascular volume status. However, its invasiveness and possible serious complications limited its wide use in routine anesthetic practice. Recently, ultrasonography for assessing volume status or predicting fluid responsiveness as well as post-induction hypotension has been widely applied in different clinical scenarios ***(Okamura et al., 2019; Maitra et al., 2020).***

Ultrasonographic-guided corrected flow time (FTc) refers to the left ventricular ejection time corrected by heart rate. It is known to be proportional to left ventricular preload and cardiac inotropy and inversely proportional to systemic vascular resistance ***(Kim et al., 2018; Deepak et al., 2020).*** Accordingly, it may have a role in prediction of occurrence of hypotension during induction of anesthesia.

Furthermore, ultrasonographic evaluation of the internal jugular vein (IJV) has been shown to be effective in the prediction of intravascular volume. The collapsibility index, is defined as the change in IJV diameter associated with the respiratory cycle. Previously, inferior vena cava collapsibility index was valid in prediction of hypotension during induction of anesthesia ***(Szabo et al., 2019)***.

2. OBJECTIVES:

The aim of this study is to investigate the reliability of preanesthetic ultrasound

measurements of the carotid artery FTc and the internal jugular vein collapsibility index in predicting hypotension during the induction of general anesthesia.

3. METHODOLOGY:
Patients and Methods:

- **Type of Study:** Observational Prospective Cohort Design.
- **Study Setting and ethical consideration:** The approval of the Scientific Research Ethics Committee of the Faculty of Medicine, Ain Shams University will be obtained before starting work on the study. This study will be conducted in operating theatres of Ain Shams University Hospitals. Informed written consents to participate will be obtained from the patients.
- **Study Period:** One year (October 2023-October 2024)
- **Study Population:** Adult patient undergoing elective surgeries.
- **Selection criteria for cases:**
- ***Inclusion Criteria:***

1- Patients of American Society of Anesthesiologists (ASA) physical status I to II of both genders.

2- Aged 18-65 years.

3- Elective surgeries under general anesthesia.

4- BMI less than 40.

Exclusion criteria:

Patients with

1- Renal diseases.

2- Hepatic diseases.

3- ASA scores of 3-4.

4- The presence of a left ventricular ejection fraction less than 50%.

5- Age under 18 years old.

6- Patient refusal.

7- Coronary heart disease.

8- Cardiac disease including cardiomyopathy and mild to severe valve disease.

9- Pulmonary hypertension.

10-Peripheral arterial disease.

11-Preoperative cervical vascular ultrasound abnormalities including plaque, stenosis and anatomical variation.

12- Any previous neck surgery or trauma.

✦ **Sample Size:** Total patients (70 patients)

Using PASS 11 program for sample size calculation; setting power at 80%, α error at 5%, regarding the results of previous relevant study which revealed that the incidence of postinduction hypotension after general anesthesia was 63.6% and setting sensitivity and specificity of carotid FTc for predicting postinduction hypotension after general anesthesia at 72.2% and 93.7% respectively ***(Wang et al., 2022),*** the estimated sample size is 63 patients undergoing general anesthesia.

Assuming that the dropout is of 10%, a sample size **at least 70 patients undergoing general anesthesia** will be needed.

Study interventions:

In all patients, the fasting times will be set as at least six hours for light meals, eight hours for heavy meals and two hours for clear fluids before surgery. No premedication will be advised to the patient before reaching the induction room. The patient in the induction room will be attached to a standard monitoring. A saline infusion (10 ml/kg/h) will be started. The data will be recorded before induction of anesthesia. These data will include:

1- Heart rate
2- The baseline systolic (SBP), diastolic (DBP) and mean arterial blood (MAP) pressures
3- Respiratory rate (RR)
4- Carotid artery FTc
5- IJV collapsibility index.

HR and BP will be recorded for 3 mins at 1-min intervals, and the mean values of HR and MAP will be recorded as the baseline value. The ultrasonographic examination will be performed by the most experienced member of the research team, under complete aseptic technique using a 4–12 MHz linear transducer and ultrasound device (Sonosite M-Turbo c Ultra sound device HFL-38 X) to measure the carotid artery FTc and IJV collapsibility index.

Finally, anesthesia induction will take place as follows: 0.04 mg/kg midazolam will be injected IV then after about 1 minute fentanyl 1 microgram/kg IV will be given. One minute later, Propofol 10 mg/ml will be administered, titrated at a speed of 20 - 40 mg propofol every 10 seconds, until unconsciousness occurs. Then, Atracurium 0.5 mg/kg will take place. Anesthesia will be maintained with 50:50 oxygen mixed with air,

isoflurane 1-1.5% and Atracurium maintenance 0.1 mg/kg. Then blood pressure and heart rate will be collected after induction but before surgical incision. The blood pressure and HR values will be measured for 3 mins at 1-min intervals, and the mean values of HR and MAP will be taken during this period. A MAP less than 55 mmHg or more than a 20% decrease compared to the baseline level will be defined as hypotension during anesthesia induction. The patients will be then classified into the hypotension or non-hypotension group, according to this definition. Ephedrine (5 mg increments) will be administered to the patient when the MAP dropped below 55 mmHg, and atropine (0.5 mg) will be given when the HR dropped below 50 per minute. Patient will be under the responsibility and monitoring of the anesthesiologist who is attending the surgery.

▪ **Data recording:**

Sonographic examinations:

○ **Carotid artery ultrasonography:**

Ultrasound measurements will be performed under a vascular setting with a 4–12 MHz linear transducer and ultrasound device (Sonosite M-Turbo c Ultra sound device HFL-38 X) Carotid artery FTc measurements will be performed by one trained examiner. The ultrasonic data extraction will be conducted by the researcher. The right common carotid artery FTc will be measured in patients with their heads tilted 30° to the left.

Pulse wave Doppler will be selected, and the sampling frame will be placed in the area where the carotid artery has its best color flow, with an angle of less than 60°, to obtain the blood flow spectrum. After that, using the caliper function of the machine, cycle time (CT) will be measured from the beginning of the systole to the beginning of the following systole, and systolic flow time (ST) will be measured from the beginning of the systolic upstroke to the dicrotic notch.

○ **IJV ultrasonography:**

A clear transverse view of the right IJV will be recorded for fifteen seconds, with a linear ultrasound probe placed horizontally to the right of the middle level of the thyroid cartilage with minimal pressure. Variations in the IJV diameter with respiration will be assessed using M-mode imaging. The following three values will be recorded:

1. Maximum (max) and minimum (min) IJV diameter values (at the end of the expiration and inspiration, respectively);
2. Collapsibility index (%) = [(max IJV diameter - min IJV diameter)/max IJV diameter] × 100;
3. Max IJV area.

The primary outcome: the predictive value of the carotid Ftc for prediction of hypotension.

The secondary outcome: the predictive value of internal jugular vein collapsibility index for prediction of hypotension and predictive value of pre-anesthesia heart rate, respiratory rate and mean blood pressure.

Data collection: vital data of the patients including heart rate, respiratory rate and mean blood pressure before induction. Carotid artery Ftc, IJV collapsibility index and mean blood pressure during induction will be recorded till the start of the surgical incision, then it will be collected by the use of a reliable software program.

- **Statistical package and Analysis:**

The collected data will be revised, coded and introduced to a PC using statistical package for social science (SPSS 15.0.1. for windows; SPSS Inc, Chicago, IL, 2001).

Data will be presented as mean and standard deviation (+- SD) for quantitative prometric data. Suitable analysis will be done according to the type of data obtained. P< 0.05 will be considered significant. Then by using the receiver operating characteristic (ROC) curve will show the cut of values of prediction for both the carotid FTC and the internal jugular vein collapsibility index.

4. REFERENCES:

Chen Y, Liu Z, Fang J, et al. Correlation of carotid corrected flow time and respirophasic variation in blood flow peak velocity with stroke volume variation in elderly patients under general anaesthesia BMC Anesthesiol. 2022; 22(1):246.

Deepak S, Bhavna G, Varshney P, et al. Role of carotid corrected flow time and peak velocity variation in predicting fluid responsiveness: a systematic review and meta-analysis. Korean J Anesthesiol 2023; 76(3):183-193.

Juri T, Suehiro K, Kuwata S, et al. Hydroxyethyl starch 130/0.4 versus crystalloid co-loading during general anesthesia induction: a randomized controlled trial. KJ Anesth 2017; 31: 878-884.

Kim DH, Shin S, Kim N, et al. Carotid ultrasound measurements for assessing fluid responsiveness in spontaneously breathing patients: corrected flow time and respirophasic variation in blood flow peak velocity. Br J Anaesth 2018; 121:541–549.

Maitra S, Baidya DK, Anand RK, et al. Carotid artery corrected flow time and respiratory variations of peak blood flow velocity for prediction of hypotension after induction of general anesthesia in adult patients undergoing elective surgery: a prospective observational study. J Ultrasound Med. 2020; 39(4): 721‑30.

Okamura K, Nomura T, Mizuno Y, et al. Pre-anesthetic ultrasonographic assessment of the internal jugular vein for prediction of hypotension during the

induction of general anesthesia. J Anesth 2019; 33: 612-619.

Szabó M, Bozó A, Darvas K, et al. Role of inferior vena cava collapsibility index in the prediction of hypotension associated with general anesthesia: an observational study. BMC Anesthesiol. 2019; 19(1):139.

Wang J, Li Y, Su H, et al. Carotid artery corrected flow time and respiratory variations of peak blood flow velocity for prediction of hypotension after induction of general anesthesia in elderly patients. BMC geriatrics. 2022; 22(1):1-9.