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**Impact of Intra-operative use of peristaltic pneumatic
compression device on Haemodynamics vis-à-vis fluid
requirement during General Anaesthesia and Surgery:
A Randomized Prospective Study**

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Introduction

Induction of general anaesthesia is associated with cardiac depression and peripheral vasodilatation resulting in hypotension.⁽¹⁾ This hypotension can be corrected by giving intravenous fluid,⁽²⁾ or the vasoconstrictor. While optimum fluid balances in the perioperative period is of vital importance in overnight fasting patients to correct the fluid deficit, any fluid overload is not only counterproductive to the heart function but is associated with fluid retention in body and edema in postoperative period⁽²⁾⁽³⁾⁽⁴⁾⁽⁵⁾.

Peristaltic pneumatic compression device, a variant of intermittent sequential compression of legs, uses higher pressure and longer compression cycles to avoid venous stasis in immobilized patients. Sequential compression devices have sleeves with pockets of inflation, which works to squeeze on the appendage in a “milking action”.⁽⁹⁾ The most distal areas will inflate initially, and the subsequent pockets will follow in the same manner. The primary aim of the device is to squeeze blood from the underlying deep veins to proximal side. When the inflatable sleeves deflate, the veins will replenish with blood. The intermittent compressions of the sleeves will ensure the movement of venous blood.⁽⁹⁾

We hypothesize that the intermittent pneumatic compression of the lower extremity is associated with increased venous return and avoid pooling of blood in peripheral circulation and might help in maintenance of hemodynamic targets during anaesthesia and surgery⁽⁸⁾. The aim of present thesis is to compare hemodynamic status of patients during anesthesia by using intermittent pneumatic compression pump vis-à-vis intravenous fluid or vasoconstrictor requirement.

Review of literature.

Induction of general anaesthesia causes certain hemodynamic changes .There is a fall in mean blood pressure and decrease in heart rate with most of the intravenous anaesthetic agents (table 1).Volatile agents also produce dose dependent depression of left ventricular(LV) ,right ventricular and left atrial myocardial contractility, LV diastolic function, and LV-arterial coupling in normal heart. Volatile anaesthetics depress baroreceptor reflex control of arterial pressure to varying degrees.⁽¹⁾

To counter this, fluid is being administered to improve preload and to counteract hypotension induced by general anaesthetic agents but there are no standard recommendations regarding the amount of fluid to be given. Fluid overload may be deleterious causing poor outcome in post -operative period.⁽⁴⁾

In the low-risk patient undergoing low risk or ambulatory surgery, high-volume crystalloid infusions of the order of 20–30 ml kg⁻¹ (e.g. 2 litres over 30 min to the average adult) improves ambulatory anaesthesia outcomes such as pain, nausea, dizziness.On the other hand, high-risk patients undergoing major surgery seem to benefit from a ‘restrictive’ fluid regimen. This remains to be clearly defined, but a good working definition in a patient with normal renal function would be that intraoperative urine output is kept between 0.5 and 1.0 ml kg⁻¹hr⁻¹ .⁽²⁾

For patients who are undergoing mild to moderately invasive procedures a baseline crystalloid infusion of 1 to 2 mL/kg per hour with crystalloid boluses (20 to 40 mL/kg and for major surgical procedures, a fluid restricted or goal-directed fluid approach over a fixed volume regimen is recommended. The traditional practice of fixed volume fluid administration should be abandoned. Crystalloid (0.5 to 1 mL/kg per hour) is administered to replace sensible and insensible losses and colloid is used to replace plasma losses (blood).⁽⁶⁾

Restoring preload can be done by passive leg raising or trendelenburg positioning or by compression devices .the former two are not feasible in many situations. External compression of extremities acts similarly to the above mentioned maneuvers. Compression devices can be intermittent compression devices or graduated compression stockings. Intermittent compression devices can be single or multi chamber type/sequential compression device.

Compression with the single-chambered device produced a significant rise in venous blood flow velocity; however, this could not be maintained and the results indicate a higher average velocity was achieved with the sequential gradient device. The sequential gradient device also moved a greater volume of blood and achieved a higher average blood flow rate. The time between deflation of the sleeve and return of a phasic respiratory signal was greater after compression with the sequential gradient device.⁽⁷⁾

A significant effect of stockings may be to reduce pooling of blood in deep veins by mechanically preventing distension of the vessels. The major drawback with stockings is their fitting. Thigh-length stockings, in particular, appear to be difficult to apply and wear in some circumstances. The danger is that poorly fitted stockings, or those of an incorrect shape and size, could produce “tourniquets” at the proximal end, causing ischemia, and an increased risk of thrombosis.⁽⁹⁾

Peristaltic pneumatic Peristaltic Pneumatic Compression of the legs significantly reduces fluid demand and enhances stability during minor ear, nose, and throat surgery. Peristaltic pneumatic Compression has the potential to support fluid restriction regimens during surgery.⁽⁸⁾

Intermittent sequential pneumatic compression by the Lympha-press fully reverses the cardiac depression and head-up tilt position and overcompensates for the state of peripheral venous stasis induced by pressure pneumoperitoneum during laparoscopic surgery. ⁽¹⁰⁾

The application of sequential pneumatic compression to the lower limbs is associated with minor increases in mean arterial blood pressure, with moderate reduction of cardiac output and heart rate.⁽¹¹⁾

Diagnostic accuracy of passive leg raising for prediction of fluid responsiveness in adults by systematic review and meta-analysis of clinical studies. Passive leg raising-induced changes in cardiac output can reliably predict fluid responsiveness regardless of ventilation mode and cardiac rhythm. PLR-changes in Cardiac Output has a significantly higher predictive value than PLR-changes in arterial Pulse Pressure.⁽¹²⁾

Partial pressure of End Tidal Carbon dioxide (PETCO₂) is the partial pressure or maximal concentration of carbon dioxide (CO₂) at the end of an exhaled breath, which is expressed as a percentage of CO₂ or mmHg. PETCO₂ effectively tracked changes in Cardiac Output during the Passive Leg Raising maneuver and predicted fluid responsiveness in patients with acute circulatory failure with fixed minute ventilation, assuming a constant tissue CO₂ production.⁽¹³⁾

The volume status of patient can be assessed by noninvasive method of ultrasonography of abdomen to measure diameter of inferior vena cava and femoral vein blood flow velocity.

Changes in stroke volume, radial pulse pressure, and peak velocity of femoral artery flow induced by passive leg raising are accurate and interchangeable indices for predicting fluid responsiveness in non-intubated patients with severe sepsis or acute pancreatitis. The Delta velocity of femoral artery flow $\geq 8\%$ predicted fluid responsiveness with sensitivity of 86% and specificity of 80%.⁽¹⁴⁾

A significant reduction in common femoral venous flow occurs during laparoscopic cholecystectomy coincident with pneumoperitoneum and reverse Trendelenburg's position. Intermittent sequential pneumatic compression reversed that effect, returning peak systolic velocity to normal.⁽¹⁵⁾

Inferior Vena Cava (IVC) collapsibility index

In a patient requiring ventilator support, there is an inversion of the cyclic changes in IVC diameter, leading to increases in the inspiratory phase and decreases in the expiratory phase. The respiratory variations in IVC diameter in a mechanically ventilated patient are therefore only observed when right atrial pressure is normal, that is low. In a patient presenting with signs of circulatory insufficiency, this finding may indicate hypovolemia. Absence of respiratory variations in IVC diameter in a mechanically ventilated patient presenting with signs of circulatory insufficiency suggests that volume expansion will be ineffective in most of the cases.

The IVC distensibility index. It is expressed as the difference between the value of the maximum diameter and the minimum diameter, divided by the minimum of the two values.

IVC distensibility (evidence in vented patients only)⁽¹⁶⁾.

Barbier et al: distensibility index: $(D_{\max} - D_{\min}) / D_{\min} \times 100\%$. Threshold of 18% has 90% sensitivity and specificity for volume responsiveness.

Feissel et al: respiratory variation in IVC diameter: $(D_{\max} - D_{\min}) / ((D_{\max} + D_{\min}) / 2)$. Threshold of 12% predicted fluid responders with a Positive predictive Value of 93% and Negative Predictive Value of 92%

IVC diameter (evidence in all patients):

Meta-analysis of studies measuring IVC size in shock patients found all had IVC <15mm

Feissel et al found that 29 of 30 fluid non-responders had IVC >15mm, 2 of 16 fluid responders had IVC >25mm⁽¹⁶⁾.

HYPOTHESIS

We hypothesize that the peristaltic pneumatic compression of the lower extremity will be associated with increased venous return and avoid pooling of blood in peripheral circulation and avoids hypotension, thereby maintaining the hemodynamic stability. The aim of present thesis is to compare hemodynamic status of patients during anesthesia by using peristaltic pneumatic compression device vis-à-vis intravenous fluid or vasoconstrictor requirement.

Aims and objectives.

AIMS:

To study effect of Intermittent Pneumatic Compression devices on hemodynamic effects of induction of General Anesthesia and maintenance.

OBJECTIVES

Primary objectives

1. Compare the need of total fluid requirement between the study groups.
2. Compare vasoconstrictor requirement between the study groups.

Secondary objectives

1. Compare the fluid status of the patient by assessing inferior vena cava diameter and blood flow.
2. Compare haemodynamic complications.
3. Compare Postoperative recovery and morbidity.

STUDY DESIGN

A randomized prospective study will be conducted in department of Anaesthesiology, at the All India Institute of Medical Sciences, Rishikesh, over a period of 1-2 years. The informed written consent will be taken before enrolment by the patients. Randomization of the patient into two groups will be done by sealed envelope technique

SAMPLE SIZE

All the groups will receive fluid therapy according to an identical goal directed protocol. The primary endpoint is the difference in total volume of fluid administration. An *a priori* sample size analysis based on the assumption of normal distribution indicated that 30 patients per group would provide 80% power to detect a statistically significant difference of 500 versus 750 ml with a SD of 300 ml (Cohen's $d = 0.72$) at an α level of 0.05.

Material & Methods

Patient inclusion criteria:

The study would comprise of 3 groups of 30 patients each, of ASA grade I or II, of both genders, in the age group of 25 to 50 years, posted for surgeries under General Anaesthesia for anesthesia lasting 2-3 hours.

Patient exclusion criteria:

Patients expected to get major blood loss.

Burns patients.

Patients with significant cardiac diseases.

Patients with pulmonary diseases.

Patients with impaired renal function.

Study Groups:

Peristaltic Pneumatic Compression (PPC) devices would be placed in both the groups.

In Group 1 – The PPC shall be placed on operating table, next to patients calves during the procedure.

In Group 2 – The PPC shall be placed over calves and inflated during induction of General Anaesthesia and maintenance.

Upon arrival in the operating room, standard monitoring including electrocardiogram, Non-invasive arterial blood pressure (NIBP), heart rate (HR), pulse oximetry (SpO₂) were applied and venous access will be established.

Anaesthesia will be induced with intravenous fentanyl (1-2 µg/ kg), propofol (1-2mg/kg), and vecuronium (0.08-0.1 mg/kg). Neuromuscular monitoring (NMT) will be applied following induction of anaesthesia. Patient will be mask ventilated till train of four (TOF) ratio comes to 0. Direct laryngoscopy will be done and patient will be intubated with PVC endotracheal tube. Correct position of tube will be confirmed by auscultation. Anaesthesia will be maintained with oxygen (33%) with nitrous oxide (77%) and sevoflurane and top up of vecuronium (0.05 mg/kg) according to neuromuscular

function monitoring. Anaesthesia depth will be monitored with BIS monitoring and maintained between 40 to 50 levels on DRAGER PRIMUS INFINITY C700.

Randomization and Blinding Procedure

In the operating room, immediately before induction of anesthesia, patients were randomly allocated to groups by a sealed envelope procedure. An operation theatre staff assistant applies the compression device to the patient, allocated to PPC group. In other groups, the cuffs were placed next to patient's legs. The device will be covered with drapes in both the groups. The compression device was activated in all groups, in the absence of attending anaesthesiologist. This is done to remove the bias due to compressor noise and cuff motion. The observer will be blind to both the groups and the interventions performed. Group allocation will be revealed to anaesthesiologist at the end of the surgery.

Fluid management protocol

The following fluid protocol will be used in all patients in the study:

A maintenance infusion of Ringer's lactate (nirlife® aculife™, aculife healthcare pvt. Ltd.) 4 ml/kg/hour will be started in each patient before induction of anaesthesia. In the event of hypotension (mean arterial blood pressure <60 mmHg for 3 min i.e. consecutive two measurement, 250 ml bolus saline will infused in next 5 min. If blood pressure did not improve (MAP >60 mmHg), Dopamine (10 µg/kg/min) will be started and titrated to maintain MAP >60 mmHg. If there was no improvement by next measurement after 3 min another bolus of crystalloid (saline 250 ml in 5 min) was repeated. If hypotension still persisted or developed again, a bolus of colloid (100 ml gelofusine® B BRAUN MEDICAL(I) Pvt.Ltd. in five min was given) was again given. Blood loss of 250 ml or more was replaced by 1:1 colloid and by Packed Red Blood Cells, if exceeded 1000 ml.

Observations;

The following readings shall be taken at

- Immediately after induction of anesthesia
- 15 min after induction
- 30 min after induction
- 60 min after induction
- 120 min after induction

In all the groups, similar depth of anesthesia shall be maintained by maintaining BIS in a fixed range of 40-50. The mean arterial blood pressure by intermittent noninvasive arterial blood pressure measurement will be measured and maintained within 20% of baseline.

Parameters

Hemodynamic – Heart Rate and Non-Invasive arterial Blood Pressure, End tidal Carbon dioxide (EtCO₂).

We also assess the volume status of patient by noninvasive method of ultrasonography of abdomen to measure diameter of inferior vena cava and femoral vein blood flow velocity before induction of anaesthesia, 10 min after induction of anesthesia, at the end of surgery and in postoperative period.

Urine output for catheterized patients, by urinary bag volume measurement and for non-catheterized patients, by pre-operative and post-operative bladder emptying in graduated burette.

Statistical Analysis Plan (SAP)

Demographic data are presented as mean value \pm SD. For statistical analysis, the SPSS software package (version 20, SPSS Inc., Chicago, IL) was used. Demographic details were compared using a two-tailed Student t test for independent samples for continuous and a chi-square test for nominal and categorical variables. For all other comparisons, a two-tailed Mann–Whitney U test was used. Significance was assumed at a P value of less than 0.05 in all statistical tests with Bonferroni correction applied for secondary outcome parameters.

TABLE 1

	Diazepam	Droperidol	Etomidat*	Ketamine	Lorazepam	Midazolam	Propofol
HR	-9 ± 13	Unchanged	-5 ± 10	0-59	Unchanged	-14 ± 12	-10 ± 10
MBP	0-19	0-10	0-17	0 ± 40	-7-20	-12-26	-10-40
SVR	-22 ± 13	-5-15	-10 ± 14	0 ± 33	-10-35	0-20	-15-25
PAP	0-10	Unchanged	-9 ± 8	+44 ± 47	—	Unchanged	0-10
PVR	0-19	Unchanged	-18 ± 6	0 ± 33	Unchanged	Unchanged	0-10
PAO	Unchanged	+25 ± 50	Unchanged	Unchanged	—	0-25	Unchanged
RAP	Unchanged	Unchanged	Unchanged	+15 ± 33	Unchanged	Unchanged	0-10
CI	Unchanged	Unchanged	-20 ± 14	0 ± 42	0 ± 16	0-25	-10-30
SV	0-8	0-10	0-20	0-21	Unchanged	0-18	-10-25
LVSWI	0-36	Unchanged	0-33	0 ± 27	—	-28-42	-10-20
dP/dt	Unchanged	—	0-18	Unchanged	—	0-12	Decreased

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CI, Cardiac index; dP/dt, first derivative of pressure measured over time; HR, heart rate; LVSWI, left ventricular stroke work index; MBP, mean blood pressure; PAO, pulmonary artery occluded pressure; PAP, pulmonary artery pressure; PVR, pulmonary vascular resistance; RAP, right atrial pressure; SV, stroke volume; SVR, systemic vascular resistance.

*The larger deviations are in patients with valvular disease.

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ASSESSMENT FORM

	0 min	Immediately after the induction	After 15 min	After 30 min	After 60 min	After 120 min
Spo2						
Heart Rate						
MAP						
PETCO2						
BIS						
Femoral vein blood velocity						
IVC Diameter						
IVC distensibility						
Ringer lactate						
Colloid gelofusione						
Dopamine						
PRBC						
Urinary output						

PARTICIPANT INFORMATION SHEET

**PARTICIPANT INFORMED CONSENT FORM (PICF)
(English)**

Participant identification number for this trial: _____

Title of project: Impact of Intra-operative use of peristaltic pneumatic compression device on Haemodynamics vis-à-vis fluid requirement during General Anaesthesia and Surgery:A Randomized Prospective Study

Name of Principal Investigator: Dr. M. KESARI, 091 8449000510

The information regarding the study has been explained in detail to me, in a language that I comprehend, and I have fully understood the contents.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS.

I agree to take part in the above study.

Date:

(Signatures / Left Thumb Impression)

Place:

Name of the Participant : _____

Son / Daughter of : _____

Complete postal address : _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator

Date:

Place:

1) Witness – 1

2) Witness – 2

Signatures

Signatures

Name:

Name:

Address:

Address

Letter No-AIIMS/IE 4/6/25

Reference No: -

Date:-.....

REPORT OF ETHICS COMMITTEE

Department	ANAESTHESIOLOGY
Candidate admitted year	2016
Course and Subject	M.D(ANAESTHESIOLOGY)

To,

M.KESARI

(ANAESTHESIOLOGY)

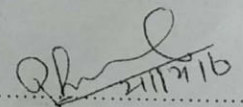
Sub: Thesis Protocol titled: "Impact of Intra-operative use of peristaltic pneumatic compression device on Haemodynamics vis-à-vis fluid requirement during General Anaesthesia and Surgery:A Randomized prospective study".

Ref: - 73/IEC/PGM/2016
(Letter/ Proposal of Student)

Dear Student,

The above mentioned Thesis protocol (perioperative use of intermittent pneumatic pump for Optimum Haemodynamic Goals during General Anesthesia and Surgery: A Randomized prospective study) was discussed in the Ethics Committee meeting held on 21-12-2016 (Date).....

Ethics Committee has unanimously approved your Protocol. This work will be done under the guidance and supervision of your guide. Dr. Mukesh Tripathi


.....
(Name)

Chairperson, Ethics Committee
Seal

Chairman
Institutional Ethics Committee
AIIMS Rishikesh

ORIGINAL/Duplicate for Display

FORM B

[See Rules 6(2), 6(5) and 8(2)]

CERTIFICATE OF REGISTRATION
(To be issued in duplicate)

3. In exercise of the powers conferred under Section 19 (1) of the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 (57 of 1994), the Appropriate Authority District Magistrate, Dehradun hereby grants registration to the Genetic Counselling Centre*/Genetic Laboratory*/Genetic Clinic*/Ultrasound Clinic*/Imaging Centre* named below for purposes of carrying out Genetic Counselling/Pre-natal Diagnostic Procedures*/Pre-natal Diagnostic Tests/ultrasonography under the aforesaid Act for a period of five years ending on **12-01-2019**.
4. This registration is granted subject to the aforesaid Act and Rules thereunder and any contravention thereof shall result in suspension or cancellation of this Certificate of Registration before the expiry of the said period of five years apart from prosecution.

A. Name and address of the Genetic Counselling Centre*/ Genetic Laboratory*/ Genetic Clinic*/ Ultrasound Clinic*/ Imaging Centre* **DIRECTOR, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, VIRBHADRA MARG, RISHIKESH, DEHRADUN.**

B. Name of Applicant for Registration :- **CHIEF MEDICAL SUPERINTENDENT**

B. Pre-natal diagnostic procedures* approved for (Ultrasound Centre).

Non-Invasive

(i) Ultrasound :- **Yes**

Invasive

(ii) Amniocentesis **Yes**

(iii) Chorionic villi biopsy -

(iv) Foetoscopy -

(v) Foetal skin or organ biopsy -

(vi) Cordocentesis -

(vii) Any other (specify) **CT scanner, MRI**

C. Pre-natal diagnostic tests* approved (for Genetic Laboratory)

(i) Chromosomal studies

(ii) Biochemical studies

(iii) Molecular studies

D. Any other purpose

3. Model and make of equipments - **Medicine Deptt. (1) SONOSITE M-Turbo, S.No.WK2RT5**
With 3 probes (i) M.No.C60X/5-2Mhz, S.No.032PYC,
(ii) M.No.HFL 38X/13-6 Mhz, S.No.03ZPC1, (iii) M.No.P21X/5-1 Mhz, S.No.03ZK2Y

Anesthesia Deptt. (1) LOGIQ e Docking Cart V1531088 S.No.438283WX4 (Portable) with three probes
(i) E8C RS, S.No. 435750WX5 (ii) 4C-RS, S.No.436229WX9
(iii) 8L-RS, S.No.156358PD4

4.Registration No. allotted :- **Appropriate Authority/DM/207(C)/JAN/2014**

5. Period of validity of earlier Certificate of Registration -
(For renewed Certificate of Registration only) From :- **13-01-2014 TO 12-01-2019.**

RE Issue Date: **07.12.2017**

Signature of the Appropriate Authority
The Appropriate Authority
DEHRADUN
SEAL