

**Official title: HEMODYNAMIC CHANGES IN LEFT AND RIGHT LATERAL POSITION DURING  
ONE LUNG VENTILATION**

**Date: 01/05/2025**

## SUMMARY

The aim of this trial is to study the changes of the Cardiac Power Index (CPI) during prone and lateral decubitus position in two and one lung ventilation respectively. Moreover, CPI variations will be compared among patients in left versus patients in right lateral decubitus position. A secondary goal is to compare the changes in hemodynamic parameters after a lung recruitment maneuver during one lung ventilation and a fluid challenge test among patients that respond (responders) or do not respond to fluids (non-responders) according to changes of Stroke Volume Index (SVI) and Mean Arterial Pressure (MAP).

## STUDY OBJECTIVE

The objective of this study is to investigate the changes in Cardiac Power Index (CPI) in the same patients during supine and lateral positions under two-lung ventilation (2LV) and one-lung ventilation (OLV), respectively. Additionally, CPI values will be compared between left and right lateral positions during one-lung ventilation.

Measurements will be conducted with the chest closed, prior to surgical incision.

A secondary objective is to compare the hemodynamic changes, particularly in CPI, following a recruitment maneuver and fluid administration (mini fluid challenge), between the two positions and among patients who respond or do not respond to fluid administration, based on changes in stroke volume (SV) and mean arterial pressure (MAP).

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## MATERIALS AND METHODS

Patients who meet the **inclusion criteria** will be enrolled after **detailed briefing and written informed consent**. A **comprehensive medical history** will be taken during pre-anesthetic evaluation, and a **cardiac ultrasound and spirometry** will be performed preoperatively.

### **Inclusion Criteria:**

- Age over 18
- Physical status ASA I-III (per the American Society of Anesthesiologists)
- Fluent in Greek or English
- Scheduled for **thoracic surgery using a double-lumen endotracheal tube**

### **Exclusion Criteria:**

- Known arrhythmia
- Severe valvular disease

- Severe right or left ventricular dysfunction
- Morbid obesity ( $\text{BMI} \geq 40 \text{ kg/m}^2$ )
- Inability to perform spirometry and/or echocardiography
- Patient refusal to participate

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## Anesthetic Management

Patients will be connected to an anesthetic monitor to observe **heart rate, arterial pressure, and  $\text{SpO}_2$** , and **radial artery catheterization** will be performed for **continuous invasive arterial pressure monitoring**. Thoracic epidural anesthesia will be administered at the **T4–T6 level**, followed by general anesthesia with:

- **Fentanyl** (50–100  $\mu\text{g}$  up to 250  $\mu\text{g}$  intraoperatively)
- **Propofol** (1.5–2.5 mg/kg)
- **Rocuronium** (0.6–1.2 mg/kg)

Maintenance will be achieved with **sevoflurane (1.5–2.5 vol%)**, targeting **MAC 0.8–1.0**. Depth of anesthesia will be monitored using the **Bispectral Index (BIS)** targeting 40–60.

**Protective volume-controlled mechanical ventilation** will be applied with **PEEP 5 cmH<sub>2</sub>O**, **I:E ratio of 1:2**, and **EtCO<sub>2</sub> maintained at 30–40 mmHg** by adjusting the respiratory rate. Fluids will be administered as **crystalloids** in maintenance doses of **1–2 mg/kg** with a maximum of **1500 mL or 20 mL/kg/24 hrs**.

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## Hemodynamic Monitoring

The **radial artery catheter** will be connected to a **transducer** and the **HemoSphere monitor** (Edwards Lifesciences, USA) as well as to the OR monitor. Continuous monitoring will include:

- **SV** (Stroke Volume)
- **SVI** (Stroke Volume Index)
- **HR** (Heart Rate)
- **CI** (Cardiac Index)
- **CPI** (Cardiac Power Index)
- **MAP** (Mean Arterial Pressure)

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## **Study Protocol**

Before induction of anesthesia, baseline values of all hemodynamic parameters will be measured.

After induction of anesthesia, at Time 0 (T0) and while in the supine position and during two lung ventilation, initial measurements of CPI, SVI, MAP, HR, and lung mechanics (Cdyn and Edyn) will be taken, once MAP and HR are stable for at least 3 minutes with changes <10%.

Then, one lung ventilation (OLV) will be initiated in the supine position. This is Time 1 (T1). Afterwards, patients will be placed in the lateral position with ongoing OLV and Time 2 (T2) refers to the point when new hemodynamic and mechanical measurements are taken under the same stability conditions.

A recruitment maneuver (continuous positive pressure of 30 cmH<sub>2</sub>O for 30 seconds) will then be applied. Measurements will be taken before (T2) and after (T3) the maneuver.

After 5 minutes, 250 mL of 0.9% saline will be administered over 10 minutes, and parameters will be assessed before (T4), at 2 minutes (T5), and at 5 minutes (T6).

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## **Responder Classification**

- **SV Responders:** SV increase  $\geq 10\%$
- **SV Non-Responders:** SV increase  $< 10\%$
- **MAP Responders:** MAP increase  $\geq 10\%$
- **MAP Non-Responders:** MAP increase  $< 10\%$

CPI values will also be noted accordingly.

Changes in values will be calculated as:

- $\Delta\text{SVI} = \text{SVI}(T) - \text{SVI}(T+1)$
- $\Delta\text{MAP} = \text{MAP}(T) - \text{MAP}(T+1)$
- $\Delta\text{CPI} = \text{CPI}(T) - \text{CPI}(T+1)$

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## **Data Recording**

Data will be collected via USB from the HemoSphere monitor and recorded in Excel spreadsheets at the end of surgery.

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## **Statistical Analysis**

Based on literature, large differences in CPI between groups are expected with low intra-group variability, allowing for repeated measures analysis with high statistical power ( $\alpha = 5\%$ ), even with a relatively small sample.

For an effect size  $> 0.4$  and power  $= 0.8$ , fewer than 90 subjects are needed. The authors estimate that a sample of approximately 56 patients will be adequate.

- For normally distributed data: mean (sd)
- For non-normal data: median (iqr)
- Categorical variables: presented as n (%)

Normality will be assessed using histograms, Q-Q plots, Kolmogorov–Smirnov, and sometimes Shapiro–Wilk tests.

Comparisons: t-tests (independent and paired), Mann–Whitney U, and Wilcoxon signed-rank tests.

Correlations: scatter plots, Pearson and Spearman coefficients.

Associations: Chi-square and Fisher's exact tests.

Linear mixed-effects models will be used for repeated measures analysis. Post-hoc analyses will include Bonferroni correction when necessary.

Missing data will be excluded from analysis.

Significance threshold is  $\alpha = 5\%$ . Statistical analysis will be performed using R software (version 4.4.1).