



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

### **Title of the Protocol:**

# **A Comparative Study between Thoracic Epidural Anesthesia in Non-Intubated Video-Assisted Thoracosopes and the Conventional General Anesthesia with One Lung Ventilation**

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**What is already known on this subject? And  
What does this study add?**

Video-assisted thoracic surgery (VATS) is usually performed with general anesthesia and single lung ventilation. However, performing thoracic surgery under awake regional anesthesia has several potential advantages including avoidance of airway trauma and ventilator dependence associated with endotracheal intubation, besides promoting enhanced recovery after surgery and shorter mean hospital stay.

**1.INTRODUCTION/ REVIEW:**

Non-intubated Video-Assisted Thoracoscopic Surgery (nVATS), requires an increased anesthesiological effort, accurate patient selection and rigorous planning of airway management in that a switch to general anesthesia and lung separation becomes necessary. Lung separation is obtained with the induction of a surgical pneumothorax, although emphysema and pleural adhesions can slow down the resulting lung collapse (*Deng et al., 2016*).

The reasons for preference of awake patient includes; preservation of diaphragmatic activity besides avoidance of several complications related to general anesthesia such as; deterioration in respiratory functions (like atelectasis, ventilator-induced lung injury, diminished functional residual capacity leading to difficult weaning from mechanical ventilation), impaired cardiac performance and reduced postoperative nausea and vomiting. Lastly, a diminished recourse to anesthetic drugs help the preservation of hypoxic pulmonary vasoconstriction (*Chen et al., 2012*).

The main aim of TEA is to block somatosensory and motor fibers between T1-8 while keeping spontaneous breathing. During procedure, TEA in nVATS patients provided a good preservation of pulmonary functions which are reflected in arterial blood gas values. This can be justified by the increase in diaphragmatic shortening and increased functional residual capacity (FRC). (*Sagiroglu et al., 2018*).

On the downside, paradoxical breathing (Pendelluft effect) can develop between the two lungs, increasing the risk of hypoxemia and hypercapnia, sometimes so evident to require a switch to general anesthesia, in 1% of patients. In most cases, hypercapnia resolves spontaneously, and postoperative PaCO<sub>2</sub> is actually lower than after conventional anesthesia. Moreover, permissive hypercapnia can have positive results on the general outcome. Hypotension, due to the mediastinal shift that occurs during pneumothorax, is a potential issue, but it does not appear to be more relevant than under general anesthesia (*Pompeo et al., 2015*).

## 2.AIM/ OBJECTIVES:

The aim of this study is to investigate the feasibility and the effect of Thoracic Epidural Anaesthesia for awake thoracic surgery to speed up recovery in patients as well as avoiding the complications accompanying General Anesthesia with one lung ventilation.

## 3.METHODOLOGY:

### Patients and Methods:

- **Type of Study:** Prospective randomized clinical study.
- **Study Setting:** This study will be conducted in Ain Shams University Hospitals..
- **Study Period:** Expected for two years starting from 2019.
- **Study Population:**
  - Inclusion Criteria:*
    - ASA less than or equal II.
    - Age group: 21-65 years old.
    - The procedure expected to be completed within 2 hours.
  - Exclusion Criteria:*
    - Patients with expected difficult airway management.
    - Hemodynamically unstable patients.
    - Persistent cough or high airway secretions.
    - Severe Emphysema or clinical signs of active infectious disease.
    - Hypoxemia (PaO<sub>2</sub> <60 mmHg) or hypercarbia (PCO<sub>2</sub> >50 mmHg)
    - Coagulopathy (INR >1.5).
    - Obesity (BMI >30 Kg/m<sup>2</sup>).
    - Infection at the injection site, allergy to local anesthetics.
    - Neurological disorders: seizures, intracranial mass or brain edema.
- **Sampling Method:** Randomized sampling by a computer generated random numbers table.
- **Sample Size:** 40 patients.

Sample size was calculated using PASS 11 program for sample size calculation and according to the (*Pompeo et al., 2004*) study, the mean PaO<sub>2</sub> perioperatively in the awake group =  $-3 \pm 1.5$  mmHg and in the second group =  $-6.5 \pm 1.83$  mmHg. Sample size of 40 cases per group (total 40) can detect this difference with power 100% and  $\alpha$ -error 0.05.

- **Ethical Considerations:** Approval of the research ethical committee of faculty of medicine, Ain Shams University will be obtained and informed written consents will be taken from all the participants. The thoracic epidural placement will be performed by the most experienced person of the study team.

- **Study Tools:**

- **Anesthetic sheet.**

- **Visual analogue scale:** The Visual Analogue Scale (VAS) consists of a 10 cm straight line with the endpoints defining extreme limits of 'no pain at all' (0 cm) and 'pain as bad as it could be' (10 cm). The patient is asked to mark his pain level on the line between the two endpoints. The distance between 0 and the mark then defines the subject's pain score.

- **Anesthetic plan:**

In the anesthesia clinic, an informed written consent will be taken from every patient one day before the surgery. The VAS will be explained to the patients. Anesthesia will be provided according to the hospital protocol in respect to preoperative investigations, fasting hours and intra-operative monitoring and drugs.

- **Study Interventions:** The study will include 60 patients fulfilling the inclusion criteria. They will be randomized into 2 equal groups by a computer generated random numbers table, each consisting of 30 patients, namely group A and group B.

- **Group A:** Awake Patients will receive sole Thoracic Epidural Anesthesia.

- **Group B:** Patients will receive General Anesthesia with one lung ventilation.

Preoperatively, Intravenous access will be established and lactated ringer solution will be infused. Monitors for non-invasive blood pressure, heart rate, electrocardiogram (ECG), pulse oximetry (SpO<sub>2</sub>), and capnography for end tidal CO<sub>2</sub> (ETCO<sub>2</sub>). Invasive arterial line is inserted for serial perioperative ABGs

Patients will be observed for any complications either related to the procedure e.g: hematomas or related to drugs injected e.g: hypotension, bradycardia, hypoxemia, nausea, vomiting or any other adverse effects and will be managed.

- In case of hypotension (drop of blood pressure >20% of baseline reading), 10-30mg of ephedrine diluted over 10ml normal saline 0.9% will be given intravenously by titration according to the blood pressure.
- In case of bradycardia, when it is associated with hypotension or any signs of impaired perfusion, 0.5mg of atropine will be given and can be repeated every 3-5min with a maximum of 3mg.
- In case of fall in peripheral SpO<sub>2</sub>, supplemental oxygen will be given to keep SpO<sub>2</sub> above 94%.

- In case of postoperative nausea and vomiting (PONV), ondansetron 4mg diluted in 10ml normal saline 0.9% will be given intravenously slowly over 10 min.

Patients in thoracic epidural anesthesia (TEA) group will pre-medicated using midazolam 3-4 mg intravenous (IV) and fentanyl 50 mcg IV. Then patients will placed in the setting position. Under aseptic precautions, skin infiltration with local anesthesia will be done using a 5ml syringe containing 5ml of 1% lidocaine. An epidural catheter will be inserted between T3—T4 and T4—T5 for thoracic procedures meeting the inclusion criteria. A test dose (5 ml) of 2% lidocaine will be given, followed by 15-20 ml of bupivacain 0.5% and 50 mcg of fentanyl. The objective is to achieve sensory and motor block between C7 and T7 levels. At this level diaphragmatic respiration is maintained. In case of persistent hemodynamic instability or persistent hypoxemia, the patients will be transferred to the other group.

Patients will receive general anesthesia (GA) as follows, after proper assessment of the airway and anticipation of difficult airway, all patients will receive premedication in the form of 3-4 mg midazolam IV, ranitidine 50 mg IV as H<sub>2</sub> receptor antagonist, metoclopramide 10 mg IV and dexamethasone 4 mg IV as post-operative nausea and vomiting (PONV) prophylaxis. Start preoxygenation with 100% O<sub>2</sub> on 8 L/min for 3 min via face mask. Induction of anesthesia with propofol (2mg/kg) and fentanyl (1 mcg/kg). Tracheal intubation and double endotracheal tube insertion will be facilitated with cisatracurium 0.1 mg/kg. and confirmation of it is position will made by fiberoptic bronchoscopy, Anesthesia will be maintained with isoflurane (1-2 %) and cisatracurium (0.05 mg/kg per dose). After the end of the operation, anesthesia will be discontinued, and extubation of the patient will be done after full neuromuscular recovery after reversal of muscle relaxant by neostigmine (0.05 mg/kg) and atropine (0.02 mg/kg).

Postoperative pain and opioid consumption will be assessed after regaining of sensation using the VAS. Post-operative analgesia will be offered in regular doses of Paracetamol 1gm IV every 6 hours for the following 48 hours. Rescue analgesia will be given when VAS  $\geq$ 3, in the form of an injection of Pethidine 50 mg diluted in 10ml normal saline 0.9%, to be given intravenously slowly over 10 min.

- **Measured outcomes**

- **Primary outcome:**

Perioperative changes in blood gases [ Time Frame: Immediately before operation, intraoperatively per hour, and postoperatively per 2 hrs till 24h ]

Ratio of arterial oxygen tension to fraction of inspired oxygen (PaO<sub>2</sub>/FiO<sub>2</sub>), arterial carbon dioxide tension (PaCO<sub>2</sub>). Hypoxemia is defined as peripheral oxygen saturation (SpO<sub>2</sub>) < 92% on room air with a need for oxygen supplementation.

- **Secondary outcomes:**

- Postoperative pain using the Visual Analogue Scale (VAS), [ Time Frame: Postoperatively at 3h,12h and 24h ].
- Postoperative opioid (Pethidine) consumption [ Time Frame: Postoperatively during the 24h after regaining of sensation ].
- Hospital stay [ Time Frame: from day of operation to discharge; average, 5 days ]
- Perioperative changes in cardiocirculatory variables including heart rate (HR) and mean arteial pressure (MAP) [ Time Frame: Immediately before the operation, intraoperatively per hour, and postoperatively per 2 hrs till 24h ]
  - Bradycardia is defined as:  $HR \leq 50$  bpm
  - Hypotension is defined as a decrease in systolic blood pressure  $>20\%$  of basal.
  - Hypertension is defined as an increase insystolic blood pressure  $>20\%$  of basal.
- The onset of ambulence. Rate of occurence of falling after ambulence will be recorded in each group. [Time Frame: During the 24 hours after regaining of full motor power].
- Number of episodes of PONV [Time Frame: During the 24 hours postoperatively].
- **Statistical 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 parametric data, median and range for quantitative non-parametric data and as numbers and percentage for qualitative data. Suitable analysis will be done according to the type of data obtained.  $P < 0.05$  will be considered significant.

#### 4.REFERENCES:

- Chen KC, Cheng YJ, Hung MH, et al.** Nonintubated thoracoscopic lung resection: a 3-year experience with 285 cases in a single institution. J Thorac Dis 2012;4(4):347-51.
- Deng HY, Zhu ZJ, Wang YC, et al.** Non-intubated video-assisted thoracoscopic surgery under loco-regional anaesthesia for thoracic surgery: a meta-analysis. Interact Cardiovasc Thorac Surg 2016;23:31-40.
- Pompeo E, Mineo D, Rogliani P, et al.** Feasibility and results of awake thoracoscopic resection of solitary pulmonary nodules. Ann Thorac Surg 2004;78(5), 1761-1768.
- Pompeo E, Sorge R, Akopov A, et al.** ESTS. Non-intubated Thoracic Surgery Working Group. Non-intubated thoracic surgery-A survey from the European Society of Thoracic Surgeons. Ann Transl Med 2015;3(3):37.



**Sagirolu G, Yanik F, Karamusfaoglu YA, et al.** May awake video-assisted thoracoscopic surgery with thoracic epidural anesthesia use routinely for minimally invasive thoracic surgery procedures in the future? *Int Surg J* 2018;5:1602-9.



