# Comparison between inhalational anesthetic (sevoflurane) and intravenous anesthetic (propofol infusion) for maintenance of sedation during Endoscopic retrograde cholangiopancreatography

Principle investigator
Dr. Vijai Kumar
Senior Lecturer

Department of Anesthesiology SIUT Karachi

Dated: 01-07-2021

# INTRODUCTION

The number and complexity of gastrointestinal (GI) procedures is increasing rapidly [1]. Over 50 million GI endoscopic procedures were performed in the United States alone in 2017, including approximately 19 million colonoscopies [2]. The complexity of endoscopic procedures has increased, By using this technique, a patient can get both advantages such as Therapeutic and Diagnostic. ERCP technique even made this procedure easier for patients who were at the high risk in conventional surgery [10]. It became a challenge for using the anesthetic technique with the changing status of patient periodically, in most of the cases sedation is widely used. Although it is a risky procedure, for that general anesthesia is necessary because of patients who are undergoing ERCP in Co-morbidities [7] Propofol is widely used agent for sedation for GI endoscopy [6]. Advantages of propofol include its rapid effect site equilibration and short elimination half-time even after prolonged infusion. Thus, the depth of sedation can be adjusted rapidly, and patients recover quickly without residual psychomotor effects. However, propofol has a narrow therapeutic index, meaning that patients may rapidly transition to deeper levels of sedation, including general anesthesia, and apnea, airway obstruction, hypoxemia and/or hypotension can result. Thus, propofol should be titrated to effect, and administered by clinicians who are able to manage airway and hemodynamic compromise.Sevoflurane is relatively new inhaled anesthetic that also permits rapid emergence due to its low blood solubility. It has been successfully used as an alternative to propofol for various day care procedures.

## OPERATIONAL DEFINATIONS

### SEDATION

**.** A drug induced depression of consciousness during which patient can not be aroused easily but respond purposefully following repeated or noxious stimulation

### RECOVERY TIME

- Time period from cessation of drugs to regain consciousness (Orientation to time and place)

**OBJECTIVE**

The aim of the study is to find out the comparison between two drugs of moderate sedation in patients undergoing ERCP. One drug is propofol and another one is sevoflurane. Both agents will be compared regarding sedation, hemodynamic changes in patients undergoing ERCP. For sedation we use Ramsay Sedation score.

**HYPOTHESIS:**

Propofol infusion will cause less hemodynamics instability than sevoflurane.

**MATERIAL AND METHOD**:

- **Study design**: Randomized Controlled trial study is used.
- **Study Setting**: Department of Anesthesiology, Sindh institute of urology and transplantation (SIUT).
- **Duration:** 6 months after approval from ethical review committee of SIUT.
- **Sample size**: Based on the previous estimate of hypotension in sevoflurane group was found in 33% of patients and 8.8% in propofol infusion group with power of 80% & 5% level of significance. A total no of 86 patients will be part of study, out of which 43 will be selected for each group. [11]

**INCLUSION CRITERIA:**

- Patients between age group of 20-60 years
- Both male and female patients.
- ASA status I-II
- Elective ERCP procedure.

**EXCLUSION CRITERIA:**

- Patients allergic to any study drug.
- ASA III-IV like Patients with uncontrolled DM, HTN and renal insufficiency.
- BMI over 36 KG/m2 (Morbid obese)
- Sleep Apnea
- Gastroesophageal reflux disease (GERD)
- Pregnancy

**DATA COLLECTION PROCEDURE**

This study will be conducted after approval of ethical committee of SIUT. For research 86 patients will be selected for the elective ERCP. Pre-operative assessment will be taken such as history of patients, general physical examination, systematic examination, and laboratory investigations will be part of assessment. Patients will be divided in two groups based on agents used for the research study. Both the groups will be induced by injection midazolam 0.06 mg/kg and injection nalbuphine 0.1 mg/kg . Anesthesia will be maintained in…….

**Group A** Sevoflurane inhalation to achieve MAC Amnesia 0.25%.

**Group B** Propofol infusion at 50 ug/Kg/min.

When Ramsay Sedation Scale **5** is achieved than surgeon will be allowed to insert endoscope. Inj **Ketamine** 0.5mg/kg will be used for Rescue sedation .Upon arrival in operation theatre standard monitoring which includes pulse oxymeter (SPO2), noninvasive blood pressure (NIBP), electrocardiogram (ECG) electrodes will be applied, and baseline readings will be recorded. After that venous access will be secured on a non-dominant hand by 20G IV cannula, i/v fluid (R/L or N/S) will then be started by 8 ml/kg/h and O2 will be given by nasal mask at 4 L/min. All baseline parameters will be taken, after that readings will be taken at 5 min, 10 min, 15 min,20 min and so on till procedure ends.

Complications such as respiratory depression, coughing, gagging, nausea and vomiting will be recorded during the procedure and treated accordingly. If SpO2 goes down below 92% for more than 10 seconds or patient develops apnea, it will be considered oxygen desaturation.

It will be managed by O2 inhalation and supporting airway. A heart rate under 40beats per minute will be considered bradycardia and it will be managed by inj Atropine 10 ug/Kg I/V. Mean arterial pressure level that is lower than 60 mmHg or 20% less than the baseline will be regarded as hypotension and it will be managed by fluid bolus or vasopressors.

Complications such as respiratory depression, coughing, gagging, nausea and vomiting will be recorded and treated accordingly. After the procedure, patient will be awakened and shifted to HDU.

**DATA ANALYSIS:**

For data analysis SPSS software will be used of version 22. Mean and standard deviation will be computed for variable such as age, height, BMI, RSS, HR, SBP, DBP and MAP at 0,1,3,5,10 min. For determining the differences in the hemodynamics mean unpaired “t” test will be used between groups. Categorically Variables such as gender, ASA and post op complications like gagging, PONV, Apnea and cough will be presented as frequencies and percentages.

Chi-square test will be followed and used between 2 groups, there proportion difference will be compared using P value

**PERFORMA**

GROUP A ▭ GROUP B ▭

| | |
|---|---|
| **CASE#** | |
| **DATE** | |
| **Serial #** | |
| **AGE** | YEARS |
| **SEX** | MALE FEMALE |
| **WEIGHT** | KG |
| **HEIGHT** | Cm |
| **MALAMPATI SCORE** | |
| **ASA** | |
| **BMI** | Kg/m2 |

| | Haemodynamic Monitoring | | | | Respiratory Monitoring | | | Sedation monitoring |
|---|---|---|---|---|---|---|---|---|
| Time in min | HR b/n | SBP mmHg | DBP mmHg | MAP mmHg | SpO2% | R/R/min | END TIDAL CO2 | Ramsay sedation score |
| Base line | | | | | | | | |
| 5 min | | | | | | | | |
| 10 min | | | | | | | | |
| 15 min | | | | | | | | |
| 20 min | | | | | | | | |
| 25 min | | | | | | | | |
| 30 min | | | | | | | | |
| 35 min | | | | | | | | |
| 40 min | | | | | | | | |
| 45 min | | | | | | | | |
| 50 min | | | | | | | | |
| 55 min | | | | | | | | |
| 60 min | | | | | | | | |

## Ramsay Sedation Scale

| | |
|---|---|
| 1 | Patient is anxious and agitated or restless, or both |
| 2 | Patient is co-operative, oriented, and tranquil |
| 3 | Patient responds to commands only |
| 4 | Patient exhibits brisk response to light glabellar tap or loud auditory stimulus |
| 5 | Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus |
| 6 | Patient exhibits no response |

Source: Ramsay MA, Savege TM, Simpson BR, Goodwin R. Controlled sedation with alphaxolone-alphadalone. Br Med J. 1974;2:656-9.

## COMPLICATION DURING AND AFTER ERCP

| DURING PROCEDURE | YES | NO |
|---|---|---|
| APNEA | | |
| COUGH | | |
| GAGGING | | |
| POST-OPERATIVE NAUSEA AND VOMITING | | |

| Ketamine used as Rescue Sedation | Yes | No | Number of doses given |
|---|---|---|---|

| RECOVERY TIME | MINUTES |
|---|---|

**REFRENCES**


- Philip BK, Lombard LL, Roaf ER, Drager LR, Calalang I, Philip JH. Comparison of vital capacity induction with sevoflurane to intravenous induction with propofol for adult ambulatory anesthesia. *Anesth Analg.* 1999; 89:623–7. [PubMed] [Google Scholar]
- Fish WH, Hobbs AJ, Daniels MV. Comparison of sevoflurane and total intravenous anaesthesia for daycare urological surgery. *Anaesthesia.* 1999; 54:999–1006.
- 75 Million Endoscopies Performed Annually According to iData Research Procedure Analysis. Available at https://idataresearch.com/75-million-endoscopies--performed-annually-according-to-idata-research-procedure-analysis/ (Accessed on February 04, 2019).
- Gourda BG, Singh PM, Penugonda LC, et all. Significantly reduced hypoxemic events in morbidity obese patients undergoing gastrointestinal endoscopy: Predictors and practice effect. J Anaesthesicol Clin Pharmacol 2014: 30: 71.
- Ladas SD, Satake Y, Mostafa I, Morse J. Sedation practices for gastrointestinal endoscopy in Europe, North America, Asia, Africa and Australia. *Digestion.* 2010;82:74–6
- Mazanikov M, Udd M, Kylänpää L, et al. Patient-controlled sedation with propofol and remifentanil for ERCP: a randomized, controlledstudy. *Gastrointest Endosc.* 2011; 73:260–266.
- Mohammed, N., Cluff, K., Griffith, J., & Loflin, B. (2019). A noninvasive, electromagnetic, epidermal sensing device for hemodynamics monitoring. *IEEE transactions on biomedical circuits and systems*, *13*(6), 1393-1404.
- Salminen, P., Laine, S., & Gullichsen, R. (2008). Severe and fatal complications after ERCP: analysis of 2555 procedures in a single experienced center. *Surgical endoscopy*, *22*(9), 1965-1970.
- Siegel JH, Kasmin FE. Biliary tract diseases in the elderly: management and outcomes. *Gut.* 1997; 41:433–435.

- Motiaa, Y., Bensghir, M., Jaafari, A., Meziane, M., Ahtil, R., & Kamili, N. D. (2016). Anesthesia for endoscopic retrograde cholangiopancreatography: target-controlled infusion versus standard volatile anesthesia. Annals of Gastroenterology: Quarterly Publication of the Hellenic Society of Gastroenterology, 29(4), 530.