

BISPECTRAL INDEX MONITORING OF
SEDATION IN SPONTANEOUS VENTILATION.
CLINICAL TRIAL IN SCHEDULED
COLONOSCOPIES

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Bispectral Index Monitoring of Sedation in Spontaneous Ventilation. Clinical Trial in Scheduled Colonoscopies

SUMMARY:

Objective: To compare the monitoring of anesthetic depth in endoscopy rooms using the BIS monitor versus conventional monitoring as a guide for sedation, allowing to offer the best care in terms of patient safety. For this we must ensure that the patient is comfortable, without pain and in the absence of motor response, creating the ideal conditions for the patient and the endoscopist.

Methodology: Randomized double-blind clinical trial in patients undergoing scheduled colonoscopies in endoscopy rooms of the Galdakao-Usánsolo Hospital. We will compare the percentage of optimal sedation (defined as BIS parameter between 65 and 85 or score on the Ramsay scale 2 or 3) as well as the need for rescue medication and incidence of complications among the experimental group in the that sedation is guided by BIS and the control in which the anesthetist is blind to the BIS result.

Expected results: It is expected that the use of the BIS decreases the chances throughout the colonoscopy in which it is necessary to deepen the level of sedation at the request of the patient (presence of pain or dissatisfaction) and / or the endoscopist (patient maintained movement that prevents the realization of the test). No significant differences are expected in total medication dose and major complications.

HYPOTHESES AND OBJECTIVES:

Main hypothesis: The percentage of adequate sedation in the experimental group, guided sedation by BIS, will be 20% higher than in the control group guided by Ramsay.

Secondary hypotheses:

- 1.- The need for rescue medication would increase in the control group.
- 2.-The incidence of hemodynamic, respiratory and other complications would increase in the control group.
- 3.- The total dose of anesthetic medication will be higher in the control group.
- 4.- Satisfaction with the test will be similar in both groups.

Main objective:

Measure and compare the percentage of superficial sedation between the two groups.

Secondary objectives:

- 1.- Measure and compare the doses of rescue medication necessary between the two groups.
- 2.- Measure and compare the incidence of respiratory, hemodynamic and other complications observed during the performance of the test and relate them to the level of sedation.
- 3.- Measure and compare the dose of hypnotic and analgesic medication used in sedation between the two groups.
- 4.- Compare the level of satisfaction with the test between the two groups.

METHODOLOGY:

- Design: Randomized clinical trial in which the results of two groups of patients are compared.
- Experimental Group (BIS): group of patients in whom sedation is adjusted using as main parameters the information obtained by the BIS sedation monitor (BIS VISTA, Aspect Medical Systems, USA). The BIS target value between 65 and 85, corresponding to a light or moderate sedation, will be considered, noting the parameters obtained at each significant moment of the test.
- Control Group: sedation based on subjective monitoring of the level of sedation, using the Ramsay scale as a reference.

Scope: The endoscopy rooms of the Galdakao-Usánsolo Hospital, which annually performs around 5,000 colonoscopies (4,917 colonoscopies documented in 2016).

Subjects: The reference population is adult patients undergoing a scheduled colonoscopy at the Hospital.

Eligibility criteria:

This target population of the study must meet the following inclusion criteria:

- Patients older than 18 years.
- Scheduled colonoscopy indication.

- Classification of physical status ASA I, II and III, with the exception of patients with lung, kidney and / or liver disease.
- Body Mass Index (BMI) less than 35 kg / m².
- Intact neurological capacity.
- Acceptance to participate in the study after the contribution of written informed consent.

Exclusion criteria:

- Under 18 years old.
- ASA IV.
- BMI greater than 35 kg / m².
- Refusal to participate in the study.
- Allergy to any of the medications used in sedation, or its components.
- Known mental or neurological disease.
- Renal and / or Hepatic Insufficiency.
- Moderate - severe Chronic Obstructive Pulmonary Disease (COPD) or Obstructive Sleep Apnea (SAHS).
- Chronic opiate users.

Sample size calculation: Based on data from a pilot study conducted in our center, we know that the percentage of patients leaving the sedation ranges BIS 65-85 is around 30%. Assuming a percentage of losses of 20% we would need 90 patients per group. It has been calculated with nQuery Advisor v7.0.

ACTING PROTOCOL:

With patients who meet the selected criteria, we will proceed as follows:

- 1) Oral information to the patient of the scientific study to be developed, with completion of the informed consent and delivery of the information sheet.
- 2) Non-invasive monitoring in the corresponding endoscopy room. Continuous electrocardiography, heart rate, respiratory rate, non-invasive blood pressure, transcutaneous pulse oximetry and capnography will be assessed.
- 3) Positioning of the BIS monitoring system sensor (BIS Quatro™ sensor - BIS VISTA™ monitor - Aspect Medical System) in all patients, regardless of the group to which they are

randomized. To do this, the patient's forehead should be carefully cleaned using a gauze pad soaked in alcohol and left to dry. The sensor is then placed following the manufacturer's instructions.

4) Application of oxygen therapy with nasal glasses maximum 5 L / min connected to a capnography line.

5) Administration of anesthetic drugs following the following protocol: Propofol 1% using the TCI system (Target Controlled Infusion) and Remifentanyl (opioid) intravenously. The rhythms of infusion will be adapted according to the anesthesiologist's judgment to achieve the highest possible degree of comfort, tolerance and analgesia of the patient, depending on the different stimuli provoked during the colonoscopy.

6) All patients will be kept under observation in a space annexed to the endoscopy rooms until their recovery and home discharge, as is usual practice in the Unit. The scale of Aldrete will be used to proceed with the discharge, a score higher than 9 being necessary for this. Patients who do not drive should be advised to perform dangerous or precision activities after 6 to 24 hours after sedation.

These values will be recorded in a paper record during the colonoscopy. This information will be transferred to a database to be carried out in collaboration with the Clinical Research Service of the Galdakao-Usánsolo Hospital.