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COMPARISON OF EFFECTIVENESS OF NON-INVASIVE VENTILATION WITH A FACE MASK IN ADULT PATIENTS UNDERGOING GENERAL ANESTHESIA: TWO HANDED VENTILATION TECHNIQUE C-E VS TWO HANDED VENTILATION TECHNIQUE V-E

UNIVERSITY OF ANTIOQUIA
ANESTHESIOLOGY AND REANIMATION SECTION

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1803

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-

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I. Administrative Information

1. Title:

Comparison of the Effectiveness of Non-Invasive Ventilation with a Facial Mask in Adult Patients Undergoing General Anesthesia: Two-Hand C-E Ventilation Technique vs. Two-Hand V-E Ventilation Technique. Double-Blind Randomized Clinical Trial

2. Protocol Registration

2a Protocol Registration: To be completed in Clinical Trial once finalized

2b Data Registration according to World Health Organization recommendations in Table 1.

Table 1. Data Registration according to WHO

Data	**Information**
Registration and Identification Number	
Registration Date	
Secondary Registration Number	
Funding Sources	Authors. Hospital Alma Máter de Antioquia.
Primary Sponsor	Hospital Alma Máter de Antioquia.
Secondary Sponsor	University of Antioquia, Faculty of Medicine
Public Contact	Aldair Sayed Vides Villamizar.
Scientific Contact:	Juan Pablo Vásquez Lainez.
Public title	VENTMASK 1
Scientific title	Comparison of the Effectiveness of Non-Invasive Ventilation with a Facial Mask in Adult Patients Undergoing General Anesthesia: Two-Hand C-E Ventilation Technique vs. Two-Hand V-E Ventilation Technique. Double-Blind Randomized Clinical Trial
Recruitment Country	Colombia.
Study Problem	Comparison of the Effectiveness of Non-Invasive Ventilation with a Facial Mask in Adult Patients Undergoing General Anesthesia: Two-Hand C-E Ventilation Technique vs. Two-Hand V-E Ventilation Technique. Double-Blind Randomized Clinical Trial
Interventions	Two-Hand V-E Maneuver Facial Mask Ventilation.
	Two-Hand C-E Maneuver Facial Mask Ventilation.
Inclusion and Exclusion Criteria Inclusion Criteria	**Inclusion Criteria** - Adult patients over 18 years old - Scheduled for elective surgery - Require general anesthesia - Consent to participate in the study

	Exclusion Criteria - Presence of predictors of difficult ventilation: presence of a beard, obstructive sleep apnea/hypopnea syndrome - Anticipated difficult airway - Classified as ASA IV or higher - Oxygen saturation less than 92% upon admission - Requirement for supplemental oxygen
Study Type	Controlled clinical trial with two parallel groups, randomized 1:1, superiority design, blinded to the patient and data analyst.
Recruitment Start Date	
Target Sample Size	206 patients
Study Status	Protocol Development
Primary Outcome	Determine if the V-E technique is superior to the C-E technique for two-hand facial mask ventilation in adults undergoing general anesthesia with neuromuscular relaxation.
Secundary outcomes	Determine if there are statistically significant differences between the intervention and control groups in: ○ Mean end-tidal CO2 in mmHg ○ Proportion of ineffective ventilation ○ Mean ventilation in milliliters ○ Operator satisfaction ○ Operator's perception of ease ● Estimate if there is an interaction effect for the pre-planned subgroups of oropharyngeal cannula use, sex, age, and body mass index. ● Estimate if there are statistically significant differences in hypoxemia. ● Describe adverse events by group.

3. Versión de Protocolo Tabla 2.

Version	Date	Modifications	Responsible
1	March 2024	Initial version	ASV, JPV, MAZ

4. Funding

Support will be sought from entities that promote research, including the Hospital Alma Máter de Antioquia..

5. Roles y responsibilities

5.a Tabla 3

Name	Assignment	Contributions
Aldair Sayed Vides Villamizar	Principal Investigator	Protocol development, dissemination of results.
Juan Pablo Vásquez Lainez	Co investigator	Protocol development, dissemination of results.
Mario Andrés Zamudio Burbano	Co investigator	Protocol development, statistical analysis, dissemination of results.

Roles del personal adjunto investigación

Name	Assignment	Contributions
Anesthesiologists HAMA (Hospital Alma Máter de Antioquia)	Research Collaborator	Conducting both interventions

II. Introduction

6. Theoretical Framework
6.a Background and Justification

Globally, 312 million surgeries are performed annually, which equates to one operation for every 25 people (Weiser 2015). In Colombia, 695,974 medical and surgical procedures were carried out in 2021, and it is estimated that around 60% of these involve general anesthesia (INS 2022). During the induction of general anesthesia, anesthetic drugs provide different levels of sedation and anesthesia. As the patient progresses to deeper planes, airway reflexes and spontaneous ventilation are lost (ASA 2018), making positive pressure ventilation essential.

Difficult mask ventilation, defined by the ASA (American Society of Anesthesiologists) as "the inability to administer adequate ventilation (e.g., confirmed by the detection of end-tidal carbon dioxide) due to one or more of the following issues: inadequate mask seal, excessive gas leak, or excessive resistance to gas entry and exit" (Apfelbaum, J. L. 2022), has an incidence between 1.4% and 2.2%, as found in two studies (Kheterpal 2006;

Kheterpal 2009), which included 22,660 and 50,000 patients, respectively. Although rare, complications arising from airway management are associated with morbidity and mortality outcomes, such as the "can't oxygenate, can't ventilate" scenario, which occurs in approximately 1 in every 50,000 general anesthesias and accounts for around 25% of anesthesia-related deaths (Cook, T. M; 2012). Other outcomes, such as brain damage, occurred in 14.3% of patients during anesthesia (Cook, T. M. 2011).

Therefore, it is essential to have backup airway management tools to prevent the aforementioned outcomes. This is where non-invasive airway management takes center stage, with mask ventilation being the main technique. Although often considered intuitive (DuCanto, J; 2023), mask ventilation has been shown to be difficult to learn and apply in both hospital and out-of-hospital settings. This is evident in a survey conducted among emergency medicine residents, pediatric residents, and pediatric medicine programs, where the goal was to assess residents' knowledge of bag-mask ventilation (BMV) and identify predictors of a well-developed mental model of BMV. Emergency medicine residents scored higher (mean (SD)) than the other two groups on a scale of 6 (2.71 (1.26) vs. 2.01 (1.07), P = 0.004) and were significantly more likely to identify certain maneuvers: oral airway (81% vs. 52%, P = 0.006), nasal airway (57% vs. 29%, P = 0.006), and the two-person technique (14% vs. 3%, P = 0.042). Only 15% of all residents were able to identify 4 or more essential maneuvers (Eppich, W. J. 2010).

There are different methods to hold the mask during face mask ventilation: the one-hand method and the two-hand method. Although the one-hand method is the most commonly used, the two-hand method is superior, as demonstrated by a randomized crossover study of 42 patients. The minute ventilation with one hand was 6.32 ± 3.24 L/min, and with two hands, it was 7.95 ± 2.70 L/min; tidal volume was 6.80 ± 3.10 mL/kg PBW with one hand and 9.60 ± 2.31 mL/kg PBW with two hands, with a significant difference of 1.63 (95% CI, 1.16-2.10) L/min and 1.80 (95% CI, 1.29-2.32) mL/kg PBW, respectively (Joffe, A.M. 2010).

Two techniques are described for two-hand ventilation: the bilateral C-E maneuver and the V-E maneuver. Some studies comparing both maneuvers in special populations observed better performance with the V-E maneuver. For example, Jain.D et al (2021) compared both maneuvers in edentulous populations, with the main outcome being expired tidal volume. They found a difference of -161 mL (-188 to -135; 95% CI, P < 0.001) in favor of the V-E maneuver. Similarly, Bharadwaj, M. S et al (2022) studied an obese population, comparing expired tidal volume per kilogram (kg) of predicted (ideal) and actual weight. They found a mean for current weight in the C-E group of 6.5 ± 0.9 mL/kg, while for the V-E maneuver, it was 9.0 ± 0.9 mL/kg (P < 0.001); for predicted weight, it was 8.7 ± 1.5 mL/kg and 12.3 ± 1.9 mL/kg (P < 0.001), also in the obese population. Fei.M et al found a higher failure rate of 44% for the C-E maneuver, while it was 0% for the V-E maneuver, with a greater expired tidal volume (371 vs. 720 mL, P < 0.001) and no difference in peak airway pressure. Additionally, the efficacy of these maneuvers was evaluated when performed by inexperienced personnel in a prospective crossover study designed by Gerstein, N.S et al

(6). Using pairwise analysis, they found a difference in expired tidal volume for the V-E maneuver of 110 mL: V-E: 379 mL vs. C-E: 269 mL (95% CI; 65-157, P < 0.0001).

Most of the mentioned studies were included in a meta-analysis conducted by Piedrahita, P et al (8), where it was corroborated, with low-quality evidence, that the difference found so far in expired tidal volume showed a mean difference between the groups of 2.52 mL/kg (95% CI, 0.18-4.85; P=0.035) in favor of the V-E maneuver. Additionally, a lower failure rate in ventilation with the V-E maneuver was demonstrated, though with high heterogeneity.

The meta-analysis by Piedrahita, P et al not only demonstrated the differences between the two maneuvers but also identified possible variables that could potentially impact the results, such as the use of neuromuscular relaxants, which was not applied in any of the studies conducted so far. However, it is established that to define difficult mask ventilation, optimal conditions for the technique are required, including neuromuscular relaxation, as evidenced by Soltész, S. et al (2017). They sought to evaluate the influence of complete neuromuscular blockade in patients who had 3 or more risk factors for difficult mask ventilation. They measured tidal volume before and after the application of the neuromuscular relaxant, finding that 30 seconds after the administration of rocuronium, tidal volume increased by 48%, from a baseline of 350 mL (interquartile range 260-492 [range 80-850]) to 517 mL (interquartile range 373-667 [range 100-1250]) (P < 0.001). There is still no knowledge about whether ventilating patients with one or the other mask maneuver under neuromuscular relaxation would make a difference.

Additionally, it was observed that in most studies, the intervention was performed by trainees, with only one study involving anesthesiologists, which could impact or reduce the gap between both maneuvers when performed exclusively by experienced personnel (Piedrahita, P 2022). Therefore, there is still uncertainty as to whether the V-E technique is superior to the C-E technique for face mask ventilation in patients undergoing general anesthesia.

Justification

Airway management is a routine part of an anesthesiologist's work when subjecting patients to different degrees of sedation, eventually reaching general anesthesia. It is also crucial in emergency care, where general practitioners, emergency physicians, and prehospital care technicians/technologists (APH) manage the airway, each with varying degrees of training and experience. In these scenarios, the doctor or APH provider will determine whether to maintain the airway using invasive or non-invasive methods to achieve proper ventilation. Factors such as patient characteristics, which may predict difficult mask ventilation combined with difficult laryngoscopy, include: Mallampati classification III or IV, obesity (BMI over 30 kg/m²), presence of teeth, history of obstructive sleep apnea, short thyromental distance, limited mandibular protrusion, cervical mass, limited neck extension,

presence of a beard, male gender, or age over 46 years (Langeron, O, 2000; Kheterpal, 2013).

However, it has been observed that predictions about difficult mask ventilation or difficult intubation only correspond to actual difficult airway scenarios 25% of the time (Nørskov, A. K., 2015). Furthermore, difficult intubation and difficult mask ventilation were unanticipated in 93% and 94% of cases, respectively. Other factors that influence patient outcomes include the patient's current condition based on the context, such as elective surgery versus an emergency scenario. This can be the same patient at two different times, but the approach may vary depending on the physician's training and experience (Rosenblatt, W. H., 2023), whether it is an APH technician/technologist, a general practitioner, an emergency physician, or an anesthesiologist. These decisions are also influenced by the availability of equipment.

Mask ventilation is often considered intuitive (DuCanto, J, 2023), but it has been demonstrated to be difficult to learn and apply in both hospital and prehospital settings (Eppich, W. J., 2010). In such scenarios, the face mask should always be available and serves as the initial approach before invasive airway management or rescue if intubation or a supraglottic device fails (Frerk, C., 2015). Therefore, proper training in face mask ventilation skills, including the two-hand technique, is necessary to improve the seal, mandibular protrusion, and neck extension, targeting the determinants of difficult mask ventilation as defined by the ASA: "The inability to provide adequate ventilation (e.g., confirmed by detection of end-tidal carbon dioxide) due to any of the following: inadequate mask seal, excessive gas leak, or excessive resistance to gas entry or exit" (Apfelbaum, J. L., 2022).

For two-handed mask ventilation, two techniques have been described: the C-E technique, in which the thumb and index fingers of each hand form a "C" around the mask while the third, fourth, and fifth fingers pull the jaw towards the mask in an "E" shape, and the V-E technique, in which the thumbs and thenar eminence of each hand press against the sides of the mask in a "V" shape while the rest of the fingers perform the "E" jaw traction (Piedrahita, P., 2022).

Current evidence points to better performance of the V-E maneuver compared to the C-E maneuver (Piedrahita, P., 2022). However, the performance of these maneuvers has not been uniformly evaluated with the use of adjuncts to face mask ventilation, such as the Guedel airway, or in patients under neuromuscular blockade.

Given the lack of scientific evidence, the results of our research would not only impact the work of anesthesiologists but also extend to emergency services and prehospital settings. This would lead to improved patient outcomes by enhancing knowledge of two-hand mask ventilation and raising the quality of care provided to patients

7. Research Objectives and Hypotheses

Objectives

Primary Objective

- Determine if the V-E technique is superior to the C-E technique for two-hand facial mask ventilation in adults undergoing general anesthesia.

Secondary Objectives

- Determine if there are statistically significant differences between the intervention and control groups in:
    - Mean end-tidal CO2 in mmHg
    - Proportion of ineffective ventilation
    - Mean ventilation in milliliters
    - Operator satisfaction
    - Operator's perception of ease
- Estimate if there is an interaction effect for the pre-planned subgroups of oropharyngeal cannula use, sex, age, and body mass index.
- Estimate if there are statistically significant differences in hypoxemia.
- Describe adverse events by group.

Hypotheses

Operational Hypothesis: Non-invasive two-hand facial mask ventilation using the V-E technique is superior to the C-E technique in adult patients undergoing general anesthesia in terms of effectiveness, measured in milliliters per kilogram..

8. Study Design

Controlled clinical trial with two parallel groups, randomized 1:1, superiority design, blinded to the patient and data analyst.

III Methods: Participants, Interventions, and Outcomes

9.Description of Study Characteristics

Study Setting

The study will be conducted at the Hospital Alma Máter de Antioquia, a 660-bed institution that performs 1200 surgeries per month, providing a sufficient sample size. Approximately 40% of these surgeries are performed under general anesthesia, ensuring access to the target population. Additionally, the intervention administrators consider this a routine practice in their professional activities. This institution does not attend to obstetric patients

Study Type

Randomized clinical trial

Population

Patients over 18 years old undergoing general anesthesia.

Reference Population

Patients from the Hospital Alma Máter de Antioquia, Medellín-Antioquia, over 18 years old undergoing general anesthesia..

Study Population

Patients from the Hospital Alma Máter de Antioquia, Medellín-Antioquia, over 18 years old undergoing general anesthesia, who consent to the V-E and C-E facial mask ventilation interventions during anesthetic induction

Sample

Patients from the study collection who undergo general anesthesia during the study collection period

10. Eligibility Criteria

Inclusion Criteria

- Adult patients over 18 years old
- Scheduled for elective surgery
- Require general anesthesia
- Consent to participate in the study

Exclusion Criteria

- Presence of predictors of difficult ventilation: presence of a beard, obstructive sleep apnea/hypopnea syndrome
- Anticipated difficult airway
- Classified as ASA IV or higher
- Oxygen saturation less than 92% upon admission
- Requirement for supplemental oxygen

11. Interventions

A patient over 18 years old who is scheduled for general anesthesia surgery at the Hospital Alma Máter de Antioquia will be identified. After validating the inclusion and exclusion criteria, the patient will be approached and asked to participate in the study, with a detailed explanation of the study's objective and procedures. Upon confirming their acceptance and signing the informed consent (see appendices), they will be randomly assigned in equal proportion to one of the two comparison groups: V-E facial mask ventilation maneuver or C-E facial mask ventilation maneuver. Before starting the intervention, the anesthesiologist in charge will be shown an explanatory video on how to perform the assigned maneuver according to the randomization.
The V-E maneuver is achieved by placing the thumbs and thenar eminence of each hand on the sides of the mask, creating a "V" shape, while the rest of the fingers perform a jaw thrust described as an "E" shape. This will be performed after anesthetic induction when the patient is unconscious and apneic. The C-E maneuver is achieved by placing the thumb and index finger of each hand on the mask in a "C" shape, while the third, fourth, and fifth fingers of both hands perform a jaw thrust towards the mask in an "E" shape. This will also be performed after anesthetic induction when the patient is unconscious and apneic.

Once the patient arrives in the operating room, basic ASA monitoring will be performed, including a 5-lead electrocardiogram, pulse oximetry, blood pressure, and capnography. Prior to this, it will be verified that the anesthesia machine is functioning properly, the oropharyngeal cannula is the appropriate size for the patient (measured from the labial commissure to the external auditory meatus), and the mask is the appropriate size for the patient, covering from the nasal bridge to the chin. Preoxygenation will be performed with 8 forced vital capacities using an oxygen flow of 10 liters per minute. Rocuronium will be used as a muscle relaxant at a dose of 0.3 mg/kg or higher, considering this is the effective dose 95 of the drug, and a minimum of 2 minutes will be waited before starting the intervention. Ventilation will be performed through the anesthesia machine ventilator with the following ventilatory parameters: pressure-controlled mandatory ventilation with a peak inspiratory pressure of 20 cmH2O, respiratory rate of 12, PEEP of 5, and inspiratory time of 2 seconds. The intervention will be evaluated according to the previously noted objectives, visualizing the parameters of interest on the screen. A video will be recorded capturing these parameters for later review by the outcome evaluator.

After monitoring the patient, performing preoxygenation, induction, and muscle relaxant time, the intervention will be initiated by the anesthesiologist in charge of the case according to the maneuver to which the patient has been randomized (either V-E or C-E). The intervention will end after 7 ventilations have been performed. Following this, the intervention will be repeated with the oropharyngeal cannula, again performing 7 ventilations, which will be recorded, and the intervention will be concluded.

Subsequently, the anesthesiologist will be evaluated after the procedure using a global satisfaction scale of the LIKERT type, for ease and comfort of the intervention:

1: Very dissatisfied
2: Dissatisfied
3: Neutral
4: Satisfied
5: Very satisfied

12. Outcomes

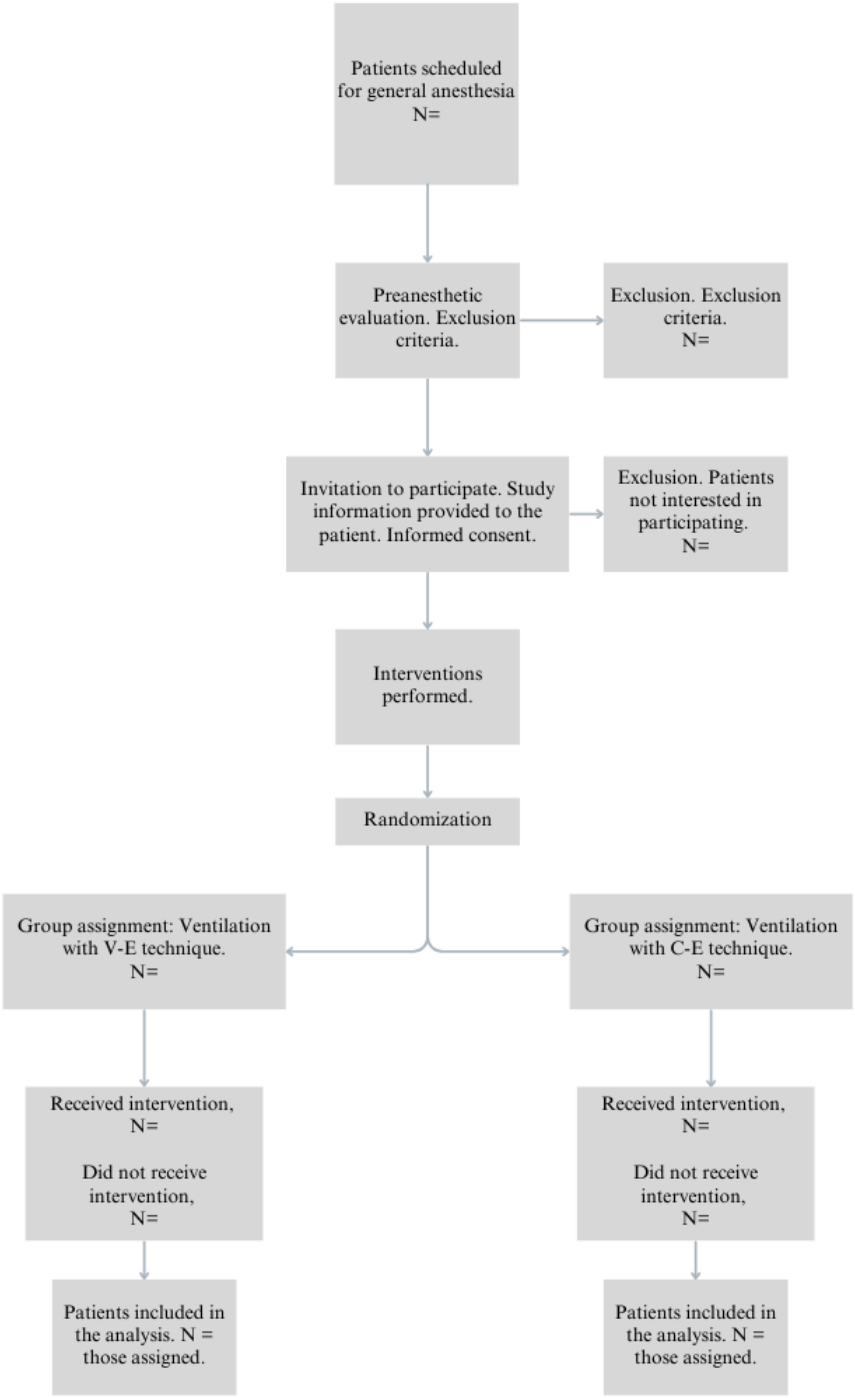
Primary Outcome

Average ventilation in milliliters per kilogram of body weight for seven ventilations recorded on the anesthesia machine at the end of expiration.

Specific Outcomes

Average CO2 in mmHg for seven ventilations recorded on the anesthesia machine at the end of expiration.
Proportion of ineffective ventilation, defined as ventilation less than 1.5 ml/kg.
Operator satisfaction.
Operator's perceived ease of use, on a Likert scale from 1 to 5, with 1 being very easy and 5 being very difficult.
Interaction effect for preplanned subgroups: use of oropharyngeal airway, sex, age, and body mass index.
Hypoxemia, defined as SpO2 less than 92%.
Adverse events by group.

13. Participants' timeline. Figure 1



14. Sample Size

Considering the primary outcome of facial mask ventilation, defined as ml/kg of weight, and based on the meta-analysis conducted by Piedrahita and collaborators, we found an expected mean for the control group of 1 ml/kg with a standard deviation of 2.4, and for the intervention group, a mean of 1.4 with a standard deviation of 2.4

With a superiority approach, an alpha error of 0.5, and a beta error of 20%, expecting a difference of at least 0.8 ml/kg, we calculated a sample size of 99 patients per group. The sample size is adjusted for drop-in, considering that there may be cases where the patient does not ventilate with the C-E technique and requires a switch to the V-E technique, approximately 5%. The sample size is corrected with the following formula:

$$N^{*} = N / 1 - R_{0} - R_{1}$$

where (R_0) is the drop-in rate. Corrected sample size: 206, i.e., 103 per arm.

15. Recruitment

To complete the sample size, active follow-up will be conducted by the investigators of both the outpatient and inpatient surgical programs. The participant timeline is specified in **Figure 1.**

Methods: Assignment of Interventions

16. Assignment

16.a Generation of the Random Allocation Sequence

The sequence will be generated using the latest version of R software with permuted blocks of 2, 4, and 6 participants with variable block sizes, and one stratification variable: use of an oropharyngeal cannula.

16.b Allocation Concealment Mechanism

The allocation will be kept in an opaque envelope that does not allow the assigned group to be seen.

16.c Implementation

The envelope will be opened only by one of the investigators after completing the inclusion criteria and signing the informed consent

17.Blinding

Patient: Will be blinded as they will be under general anesthesia

Outcome Evaluator Will be blinded as their analysis will be conducted on videos recorded by the research team

V. Methods: Data Collection, Management, and Analysis

18. Data Collection Methods 19. Data Management

The plan for data management, entry, coding, security, and storage to ensure data quality will be as follows:

- Collection:: One of the anesthesiologist investigators will record the data on pre-designed physical forms, ensuring the security, confidentiality, and permanence of the data for subsequent analysis.

- Data Submission: Once the data is collected, it will be entered into a platform in the Google Docs system, ensuring proper randomization and patient information.

- Coding: The data will be entered via magnetic media into the Google Drive platform with a license provided by the University of Antioquia.

-Security: Access to the collected information will be through an email password known only to the investigators. Periodic backups will be made to ensure data security.

- Storage: The completed folder in the drive system will be deleted ten years after the study is concluded.

- Analysis: Once the information is fully collected, it will be sent to the investigators who will analyze the data, completely blinded to the intervention groups.

20. Statistical Analysis

The statistical analysis will be conducted in two phases. First, descriptive statistics will be performed, with qualitative variables presented as frequencies and percentages, and quantitative variables described according to their nature after normality tests. If the data are normally distributed, participants will be described using means and standard deviations; otherwise, medians and interquartile ranges will be used.

In a second phase, we will conduct Bayesian statistical inference tests with non-informative priors according to Table 4

Table 4 Statistical analysis by outcome

Outcome	Hypothesis	Measure of association	Statistic
Facemask ventilation: defined as ml/kg of body weight	Ha: µintervention> µcontrol Ho: µintervention≤ µcontrol	Difference of means (95% Confidence Interval)	Bayesian model based on Markov chains
Mean CO2 in mmHg at the end of exhalation	Ha: µintervention>≤ µcontrol Ho: µintervention≤ µcontro	Difference of means (95% Confidence Interval)	Bayesian model based on Markov chains
Proportion of ineffective ventilation	Ha: Pintervention < Pcontrol Ho: Intervention ≥ Pcontrol	Relative Risk RR	Bayesian model based on Markov chains
Mean ventilation in milliliters	Ha: µintervention> µcontrol Ho: µintervention≤ µcontro	Difference of means (95% Confidence Interval)	Bayesian model based on Markov chains
Operator satisfaction	Ha: µintervention> µcontrol Ho: µintervention≤ µcontro	Difference of means (95% Confidence Interval)	Bayesian model based on Markov chains

Operator's perception of ease	Ha: μintervention> μcontrol Ho: μintervention≤ μcontro	Difference of means (95% Confidence Interval)	Bayesian model based on Markov chains
Interaction effect for the pre-planned subgroups of oropharyngeal cannula use, sex, age, and body mass index	Ha: There are no differences in the mean Ho: Intervention ≥ Pcontrol	Interaction effect	Bayesian multiple linear regression in the presence of the described factors
Hypoxemia	Ha: Pintervention < Pcontrol Ho: Intervention ≥ Pcontrol	Relative Risk RR	Bayesian model based on Markov chains
Adverse events by group	Ha: Pintervention < Pcontrol Ho: Intervention ≥ Pcontrol	Relative Risk RR	Bayesian model based on Markov chains

Intention-to-Treat Principle

The principle of intention-to-treat will be maintained for all analyses, meaning that if there is a "drop-in" from the control group to the intervention group, the analysis will be conducted according to the group assigned during randomization. Therefore, the denominator will remain the same number for all analyses.

VI. Methods: Monitoring

21. Data Monitoring

A data monitoring committee will not be established.

22. Harms – Adverse Events

All adverse events occurring during the study follow-up—up to the recording of the primary outcome, which marks the end of the interventions—will be reported in accordance with the Good Clinical Practice guidelines. Reporting will take place within the first 24 hours after the event occurs.

23. Audit

Data quality audits will be conducted at 25%, 50%, and 75% of the sample, without performing hypothesis testing to avoid multiplicity of hypothesis tests.

III. ETHICS AND DISSEMINATION

24. Ethical Approval of the Research

This clinical trial engages in a critical investigation designed to evaluate the ethical considerations associated with comparing the effectiveness of two non-invasive ventilation maneuvers using facial masks in adults undergoing general anesthesia. Since this study involves real patients, it is crucial to recognize the direct impact on the participants' health and to carefully address a series of key ethical issues.

We consider that this clinical un research holds significant value, as it evaluates a potential intervention that could improve patients' clinical outcomes, not only in controlled environments such as operating rooms but also in other contexts, such as emergency services and prehospital care.

Regarding patient selection, it will be based primarily on scientific and methodological grounds. Patients classified as ASA I and II without the presence of predictors of difficult airway or difficult ventilation will be included, as these could have a substantially higher risk of harm or experiencing more severe complications. Additionally, patients who do not meet the aforementioned scientific criteria will not be excluded.

In accordance with the guidelines set forth in Resolution No. 8430 of 1993 by the Ministry of Health of Colombia (Ministerio de Salud, 1993) and the Declaration of Helsinki of 2013 (World Medical Association, 2013) regarding the ethical aspects of health research involving human beings, this study is considered a Type C research: studies with greater than minimal risk. For this study, approval will be sought from the Ethics Committee of Hospital Alma Máter de Antioquia.

The principle of respect for individuals' autonomy, especially regarding participation in the study, will be ensured through the completion of informed consent and respect for the participant's autonomy. Participants will be explicitly informed about the voluntary nature of their participation in the research, as well as the possibility of withdrawal if they decide to do so at any time they deem appropriate.

Accurate information will be provided to each participant about the purpose and scope of the research. The investigator will explain the content of the informed consent, which must be read and signed beforehand.

Regarding the principle of beneficence, this research seeks to promote the well-being of the research participants with minimal risk and harm, determining strategies that optimize both acute and chronic pain control in this pathology.

The principle of non-maleficence is taken into account for the proper handling of participants' data and the standardization of the proposed analgesic techniques, which are common in clinical anesthetic practice. Additionally, the confidentiality and custody of participants' data will be ensured during the data collection, processing, and analysis processes through the encoding of formats at all stages of the research and during the report preparation and publication of results.

Identity information (identification, name) and contact details of the participants will be presented with general sample data. Furthermore, in reports and publication of results, the personal identity of the participants will be protected.

The research has an academic, non-profit purpose. Participation is entirely voluntary and does not involve any economic obligation for the participants. Participants will be informed of these conditions before any activity begins.

According to the American Medical Association, the 7 requirements for clinical research in human beings will be met (Emanuel EJ et al., 2000):

1. **Scientific Value**: The proposed interventions are part of the usual clinical practice of anesthesiology, will be carried out by expert personnel, and adhere to all required biosafety standards. These interventions aim to determine the best facial mask ventilation maneuver.
2. **Scientific Validity**: All scientific norms and protocols, including the scientific research method, are considered.
3. **Fair Selection of Participants**: Selection will involve randomization with concealment of interventions.
4. **Risk/Benefit Ratio**: The objective is to identify the best facial mask ventilation technique, additionally measuring the impact of the use of adjuvants and the effect of neuromuscular relaxation, which has proven to be of vital importance when addressing the airway, gaining prominence in difficult airway scenarios in various settings such as emergencies, prehospital, and operating rooms.
5. **Independent Review**: External anesthesiologists and subject matter experts will review the research protocol and its methodology, and all their recommendations will be considered.
6. **Informed Consent**: As previously outlined.

7. **Respect for the Patient and Their Decisions**: The patient will receive cordial and respectful treatment at all times, questions will be resolved, and the patient's wish not to participate in the study or to withdraw from it will be accepted if required.

Finally, the potential benefits that could be obtained from the research outweigh the associated risks, given that facial mask ventilation is a common practice in operating rooms performed by anesthesiologists who will carry out the intervention. Additionally, as mentioned earlier, patients presenting criteria for difficult airway management, which could increase the risk in these patients, will be excluded.

25. Protocol Amendments

The development of the protocol will facilitate its adoption and review, which will help minimize changes. However, in the event of an unforeseen situation or circumstance that significantly impacts the study, a discussion and review will be conducted to determine the necessity of modifications. Any changes will be subject to prior notification and communication with the Ethics Committee of Hospital Alma Máter de Antioquia, ensuring that no amendments are made without the committee's prior approval.

26. Informed Consent

For this study, a specific informed consent document was designed, detailing the research objectives, clearly explaining its purpose, and establishing the voluntary participation of each patient. All participants will have the opportunity to read, ask questions, and complete the informed consent before undergoing the surgical procedure, following an appropriate explanation in language tailored to each patient. This consent form will also be reviewed by the Ethics Committee of Hospital Alma Máter de Antioquia and will be included in the appendices.

27. Confidentiality

All data collected during the study, both written and digital, will be reserved for research purposes and kept strictly confidential. Data may only be disclosed in cases of force majeure as requested by the Ethics Committee or the patient themselves. Digital information will be securely stored in databases accessible only to the principal investigators. Written data, including informed consent forms, will be kept in locked cabinets with no access granted to unauthorized individuals.

28. Declaration of Interest

The investigators have no conflicts of interest regarding this study. The implementation and use of facial mask ventilation are entirely detached from any political interests, focusing solely on improving ventilation across various scenarios. The sole purpose of the study is to generate and disseminate scientific knowledge relevant to anesthetic practice.

29. Data Access

Researchers will have access to the collected data once the study is completed. This data will be stored in a database coded to prevent revealing participants' identities and to avoid

compromising the study's methodological design. Access credentials will only be available to research assistants.

30. Additional Care and Post-Study
No participant will receive financial compensation for participating in the study.

32. 33. Dissemination Policy and Expected Impacts and Outcomes of the Research

Data Analysis and Results Release:
Data analysis will be performed by one of the principal investigators with training in clinical epidemiology. The findings will then be compiled into a report with conclusions, approximately three months after data collection from the last participant.

The research findings are planned to be published in an indexed scientific journal. The publication will aim to:

1. **Knowledge Generation**

Expected Outcome/Product	Indicator	Beneficiary
Determine if two-hand facial mask ventilation using the V-E technique is better compared to the two-hand C-E technique.	Submitted for scientific publication	National and International Scientific Community

2. **Social Responsibility**

Expected Outcome/Product	Indicator	Beneficiary
- Better Ventilation - Less Hypoxemia - Greater Operator Comfort	Tidal volume measured in ml/kg Oxygen saturation Perception of comfort Likert scale	Patient Anesthesiologists, Emergency physicians, General practitioners working in emergency services, technicians, and technologists in prehospital care.

3. **Strengthening of care at the Hospital Alma Máter de Antioquia.**

Expected Outcome/Product	Indicator	Beneficiary
Create a care protocol at the Hospital Alma Máter de Antioquia	Care protocol	Patients of the Alma Máter Hospital of Antioquia.

4. **Social appropriation of knowledge**

Expected Outcome/Product	Indicator	Beneficiary
Dissemination of knowledge.	Results dissemination in the academic community of the Alma Máter de Antioquia Hospital.	Academic community and academic staff of the Alma Máter de Antioquia Hospital

IV. ADMINISTRATIVE ASPECTS

20. Products and deliverables generated from the research

21. Activity Schedule (Table).

Number	Activity	Start	End	Time
1	Literature Review	1	3	Months
2	Development of the protocol	2	3	Months

3	Submission of the protocol to the program committee	3	4	Months
4	Submission of the protocol to the ethics committee of HAMA	4	5	Months
5	Development of data collection form and databases	5	7	Months
6	Data collection	7	17	Months
7	Data analysis	17	19	Months
8	Preparation of final report and publication article	19	21	Months

22. Presupuesto (Tabla)

ITEMS	VALUE	SOURCE
Scientific Staff		
Field Researcher	5.000.000	Own Resources
Thesis Supervisor	15.650.000	University of Antioquia
Operating Expenses		

Statistical Software and Databases	**1.000.000**	**Perioperative Medicine Research Group**
Stationery	**200.000**	**Perioperative Medicine Research Group**
Computing equipment	**2.500.000**	**Own Resources**
Academic events		
Attendance at conferences	**6.000.000**	**Own Resources**
Publication		
Writing and editing of the publication article	**2.500.000**	**Perioperative Medicine Research Group**
TOTAL	**32.850.000**	

V. ANNEXES (Mandatory)

a. Table of variables

Variable	Operational definition	Type	Scale	Unit or Code
X 1	Age	Continuous quantitative	Ratio	Years
X 2	Sex	Qualitative	Nominal	0. Man 1. Woman
X 3	Weight	Continuous quantitative	Ratio	Kilograms
X 4	Height	Continuous quantitative	Ratio	Centimetres
X 5	Body Mass Index (BMI)	Quantitative	Interval	1. Low weight (<18,5) 2. Normal (18,5 a 24,9) 3. Overweight (25 a 29,9) 4. Grade I Obesity (30 a 34,9) 5. Grade II Obesity (35 a 39,9) 6. Grade III Obesity (>40)
X 6	Types of Surgery	Qualitative	Ordinal	1. Orthopedics 2. General Surgery 3. Gynecology 4. Vascular 5. Otorhinolaryngology 6. Neurosurgery 7. Urology 8. Plastic Surgery
X 7	Identification number	Qualitative	Nominal	Identification number
X 8	Case number	Qualitative	Ordinal	Number from 1 to 206
X 9	Functional class	Qualitative	Ordinal	1. I 2. II

				3. III 4. IV
X 10	ASA Classification	Qualitative	Ordinal	1. I 2. II 3. III 4. IV
X 11	Presence of a beard	Qualitative	Nominal	0.Yes 1. No
X 12	Presence of obstructive sleep apnea	Qualitative	Nominal	0.Yes 1. No
X 13	Upper lip bite test	Qualitative	Ordinal	1. Clase I 2. Clase II 3. Clase III
X 14	Mallampati	Qualitative	Ordinal	1. I 2. II 3. III 4. IV
X 15	Thyromental distance	Qualitative	Nominal	0. Greater than or equal to 6 centimeters 1. Less than 6 centimeters
X 16	Sternomental distance	Qualitative	Nominal	0. Greater than or equal to 13 centimeters 1.Less than 13 centimeters
X 17	Rheumatoid arthritis	Qualitative	Nominal	0.Yes 1. No
X 18	Arterial Hypertension	Qualitative	Nominal	0.Yes 1. No
X 19	Diabetes mellitus	Qualitative	Nominal	0.Yes 1. No
X 20	Chronic Obstructive Pulmonary Disease	Qualitative	Nominal	0.Yes 1. No
X 21	Heart Failure	Qualitative	Nominal	0.Yes 1. No
X 22	Coronary Disease	Qualitative	Nominal	0.Yes 1. No
X 23	Asthma	Qualitative	Nominal	0.Yes 1. No
X 24	Operator's age	Discrete quantitative	Ratio	Years
X 25	Operator's sex	Qualitative	Nominal	0. Man 1. Woman
X 26	Years of experience in anesthesiology	Discrete quantitative	Ratio	Years
X 27	Muscle relaxant dose	Continuous quantitative	Ratio	Milligrams of the medication

X 28	Muscle relaxant time	Continuous quantitative	Ratio	Minutes
X 29				
X 30	Desaturation (Oxygen saturation less than 90%)	Qualitative	Nominal	0.Yes 1. No
X 31	Laryngospasm	Qualitative	Nominal	0.Yes 1. No
X 32	Bronchospasm	Qualitative	Nominal	0.Yes 1. No
Outcome variables				
X33	Operator satisfaction	Quantitative	Discrete	1.Very dissatisfied 2.Dissatisfied 3.Neutral 4.Satisfied 5.Very satisfied
X34	Operator's perception of ease	Quantitative	Discrete	1.Very difficult 2.Difficult 3.Neither easy nor difficult 4.Easy 5.Very Easy
X34	Volume without oropharyngeal cannula (milliliters) No. 1	Quantitative	Continuous / Ratio	Milliliters
X35	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No. 1	Quantitative	Continuous / Ratio	Millimeters of mercury
X36	Volume without oropharyngeal cannula (milliliters) No 2	Quantitative	Continuous / Ratio	Milliliters
X37	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No.2	Quantitative	Continuous / Ratio	Millimeters of mercury
X38	Volume without oropharyngeal cannula (milliliters) N°3	Quantitative	Continuous / Ratio	Milliliters
X39	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No.3	Quantitative	Continuous / Ratio	Millimeters of mercury

X40	Volume without oropharyngeal cannula (milliliters) N°4	Quantitative	Continuous / Ratio	Milliliters
X41	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No.4	Quantitative	Continuous / Ratio	Millimeters of mercury
X42	Volume without oropharyngeal cannula (milliliters) N°5	Quantitative	Continuous / Ratio	Milliliters
X43	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No. 5	Quantitative	Continuous / Ratio	Millimeters of mercury
X44	Volume without oropharyngeal cannula (milliliters) N°6	Quantitative	Continuous / Ratio	Milliliters
X45	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No. 6	Quantitative	Continuous / Ratio	Millimeters of mercury
X46	Volume without oropharyngeal cannula (milliliters) N°7	Quantitative	Continuous / Ratio	Milliliters
X47	Carbon dioxide without oropharyngeal cannula (millimeters of mercury) No. 7	Quantitative	Continuous / Ratio	Millimeters of mercury
X48	Volume with oropharyngeal cannula (milliliters) N°1	Quantitative	Continuous / Ratio	Milliliters
X49	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) No.1	Quantitative	Continuous / Ratio	Millimeters of mercury
X50	Volume with oropharyngeal cannula (milliliters) N°2	Quantitative	Continuous / Ratio	Milliliters
X51	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) N°2	Quantitative	Continuous / Ratio	Millimeters of mercury

X52	Volume with oropharyngeal cannula (milliliters) N°3	Quantitative	Continuous / Ratio	Milliliters
X53	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) No.3	Quantitative	Continuous / Ratio	Millimeters of mercury
X54	Volume with oropharyngeal cannula (milliliters) N°4	Quantitative	Continuous / Ratio	Milliliters
X55	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) N°4	Quantitative	Continuous / Ratio	Millimeters of mercury
X56	Volume with oropharyngeal cannula (milliliters) N°5	Quantitative	Continuous / Ratio	Milliliters
X57	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) N°5	Quantitative	Continuous / Ratio	Millimeters of mercury
X58	Volume with oropharyngeal cannula (milliliters) N°6	Quantitative	Continuous / Ratio	Milliliters
X59	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) N°6	Quantitative	Continuous / Ratio	Millimeters of mercury
X60	Volume with oropharyngeal cannula (milliliters) N°7	Quantitative	Continuous / Ratio	Milliliters
X61	Carbon dioxide with oropharyngeal cannula (millimeters of mercury) N°7	Quantitative	Continuous / Ratio	Millimeters of mercury

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1803

b. INFORMED CONSENT

VERSION No: 002 – DATE: 17/05/2024
PARTICIPANT No. _____ out of 206

PROJECT TITLE:
"COMPARISON OF NON-INVASIVE VENTILATION WITH FACIAL MASK IN ADULT PATIENTS UNDERGOING GENERAL ANESTHESIA: TWO-HAND V-E VERSUS TWO-HAND C-E VENTILATION TECHNIQUES"

PRINCIPAL INVESTIGATOR:
Aldair Sayed Vides Villamizar
Tel: 3017492294
Email: aldair.vides@udea.edu.co
Workplace: Universidad de Antioquia- Facultad de Medicina

Study Site:
Surgery Service, Hospital Alma Máter de Antioquia
Supporting Entities:
Hospital Alma Máter de Antioquia, Perioperative Medicine Research Group, Faculty of Medicine, Universidad de Antioquia
Sponsoring Entity:
Perioperative Medicine Research Group, Faculty of Medicine, Universidad de Antioquia

Introduction

The Perioperative Medicine Research Group, part of the Anesthesiology section of the Surgery Department at the Faculty of Medicine, Universidad de Antioquia, invites you to voluntarily participate in a study aimed at identifying the most effective technique for two-hand facial mask ventilation, comparing the V-E maneuver with the C-E maneuver. According to the guidelines outlined in Resolution No. 8430 of 1993 by the Colombian Ministry of Health and the 2013 Helsinki Declaration regarding the ethical aspects of health research with human beings, this is considered a type C investigation: research with greater than minimal risk.

Two non-invasive airway management interventions will be carried out as part of standard anesthesiologist practice. These aim to improve the effectiveness of non-invasive lung ventilation using a two-hand facial mask, a technique that is important in difficult airway scenarios.

The principal investigator believes you meet the inclusion criteria for the study, which are: being over 18 years old, scheduled for elective surgery, requiring general anesthesia, and consenting to participate in the study.

It is important to note that this study will not alter the routine care or management you will receive during your surgery, nor the perioperative care. The only change will be the technique used for facial mask ventilation after anesthetic induction.

Purpose

The aim is to determine if the V-E technique is superior to the C-E technique for two-hand facial mask ventilation in adults undergoing general anesthesia. We will define parameters such as CO2 levels at the end of expiration (in mmHg), proportion of ineffective ventilation, ventilation volume in milliliters, operator satisfaction, and ease of use as perceived by the operator.

Participant Selection

Based on the established inclusion criteria, and once the patient agrees to participate, a random selection will be made between the two facial mask ventilation techniques being compared.

Type of Intervention

If you choose to participate, on the day of your surgery, the study and its purpose will be explained to you, and you will be randomly assigned to one of the two comparison groups: the V-E facial mask ventilation maneuver or the C-E facial mask ventilation maneuver. Upon arrival in the operating room, you will undergo a complete monitoring of vital signs. Before the intervention, we will ensure that the anesthesia machine is functioning properly. During the procedure, an oropharyngeal airway device will be inserted, which will be measured to ensure it is appropriate for your size, along with the facial mask that will be fitted to your face. You will be instructed to breathe actively and "deeply" into the facial mask. Then, anesthesia drugs will be administered, after which the anesthesiologist will perform facial mask ventilation while the researcher collects the necessary data for the study.

Voluntary Participation

It is important to clarify that your participation is voluntary, meaning you are free to accept or refuse to participate in the study. You can withdraw at any time without needing to provide an explanation, and this will not affect your medical care. The research team is available to answer any questions and clarify any terms you may not understand.

If you decide not to participate, this will have no impact on your surgical and anesthetic care, which will proceed as originally planned**.**

Duration

The study will last approximately 24 months. Once the intervention has been received and the airway management has been defined with a different device, such as a laryngeal mask or endotracheal tube, no further follow-up will be required**.**

Risks and Discomforts

By participating in this research, you will be exposed to the risks of each ventilation technique, which are similar to those encountered in routine non-invasive ventilation. These risks include:

- Bronchial aspiration
- Laryngospasm
- Bronchospasm
- Hypoxemia
- Hypercapnia
- With the use of the oropharyngeal airway:
    - Dental trauma (loss of or fractured teeth)
    - Oral trauma
    - Bleeding

However, the incidence of these risks is low. The benefits of providing effective lung ventilation and ensuring adequate oxygenation are notable. In case of any adverse effects, you will receive follow-up and treatment from the attending anesthesiologist, who will determine the appropriate course of action**.**

Benefits

The main benefit of the study is to contribute knowledge that may have an impact on health teams and, in turn, on future patient outcomes. Additionally, you will benefit from better ventilation, aiming to reduce the incidence of hypoxemia. Anesthesiologists will gain valuable insight into which technique is superior and how this can affect airway rescue scenarios. No financial incentives will be provided to you or your family**.**

Confidentiality

Your participation data will be protected and treated confidentially, using a code to identify each case without revealing your identity. At no point will data or results that could identify your participation be published. However, medical regulatory authorities and the Ethics Committee may request your records if necessary, always adhering to professional confidentiality.

Participant's Obligations

You are not obligated to do anything other than authorize the use of relevant data for the study.

Researcher's Obligations

1. Collect the data from the intervention in an organized and appropriate manner.
2. Address any issues that arise during the study period.
3. Answer any questions related to the procedures, risks, benefits, and other study matters.
4. Request evaluations from the relevant specialists or services as needed based on the anesthesia performed.
5. Maintain patient confidentiality and protect their data.
6. The study has been approved by the Ethics Committee of Hospital Alma Máter de Antioquia. The researchers are qualified medical professionals with valid certifications to practice.
7. Communicate the results of the study once it is completed.

Any complications resulting from the surgical procedure will be handled by the healthcare providers, as is standard practice. This is because the surgical intervention will not be modified for the purposes of this study.

Signing this document does not waive any legal rights you may have**.**

Expected Results

The results will be published in a journal that can be accessed nationally and/or internationally. The dissemination of the results will encourage the widespread use of these techniques in the population, bringing benefits and reducing risks.

Questions

Before signing this document, you should read it thoroughly and ask the research team any questions until you are satisfied with the responses. If you have any doubts later, you can contact the principal investigator, Dr. Aldair Sayed Vides Villamizar at 3017492294.

Before signing, please answer the following questions:

DATE: Day _____ Month _____ Year _____

- Have you been informed about the study by the research team? ___
- Have you read and understood the entire document? ___
- If you had doubts, were all your questions answered? ___

PARTICIPANT:
Consent to Participate in the Study

I, _____, with ID number _____ from _____, confirm that I have read, been explained the information regarding the study, and had the opportunity to ask questions which have been answered. I understand that my participation is voluntary and that I can withdraw at any time without explanation, without affecting my medical care or legal rights. I understand that the researchers, the institutional ethics committee, and judicial authorities will be the only ones allowed to access my health records. I agree to the collection, processing, reporting, and transfer of the data collected during this study to locations chosen by the principal investigator, and that these data will only be used for this research.

RESEARCHER:
The study details, purpose, methodology, benefits, risks, and duration were explained to the participant, and any questions were addressed.

Name and signature of researcher ID: _____ Medical Registration: _____

WITNESS 1:

Name and signature of witness ID: _____

WITNESS 2:

Name and signature of witness ID: _____

c. Data collection formats

https://docs.google.com/forms/d/1ks5Pepha1s-G4rGn2QTar7Y2cOctE8Yu4_HrOit31Kk/edit?ts=6647d9f1

External evaluator format
https://docs.google.com/forms/d/157Ym14ETm66nTvyEKQ4ZBIh4G--P7Dk5ecWXf6r46cI/edit

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