Distribution of Pulmonary Ventilation With the modified Pachon's incentive vs. Another Branded Respiratory Incentive, Through Electrical Impedance Tomography, in a Healthy Volunteers of the City of Cali

NCT ID not yet assigned

June 10, 2022

Objectives and Hypotheses

General Objective

To compare the distribution of pulmonary ventilation by Electrical Impedance Tomography (EIT) during the use of the Modified Pachon's incentive (Incentivo Modificado de Pachon (IMP) by the name in Spanish) and a Branded respiratory incentive "Triflo II®", in healthy volunteers from the City of Cali (Colombia).

Specific Objectives:

- Describe the sociodemographic, anthropometric, clinical and spirometric characteristics of the study participants.
- Determine the global and regional pulmonary impedance through the EIT during the use of the IMP.
- Determine the global and regional pulmonary impedance through the EIT during the use of the Triflo II®.

Hypothesis

Null Hypothesis:

The distribution of pulmonary ventilation, measured by EIT, between the IMP and the Triflo II® in the healthy volunteers of the City of Cali, is NOT similar.

Alternate Hypothesis

YES, the distribution of pulmonary ventilation, measured by EIT, between the IMP and the branded flow incentive "Triflo II®" in healthy volunteers of the City of Cali, is similar.

Methods

Study Design

Crossover clinical trial, in which the measurement of the distribution of pulmonary ventilation by means of EIT will be evaluated, during the use of a Branded flow respiratory incentive "Triflo II®" and the IMP, in a sample of healthy volunteers from the city of Santiago de Cali . Both incentives will be used on all participants, and the order of assignment will be randomized.

Target Population

Healthy adults between 18 - 65 years. The population was calculated taking into account that the greatest use of the incentive reported in the literature is related to chest trauma. According to Botache W, et al In Cali, chest trauma occurs mostly in the population within these age ranges and among the most injured organs are the lungs; using as part of the treatment the respiratory incentive

Population Sample

Sample size of 18 subjects (9 men, 9 women) healthy volunteers from the Municipality of Santiago de Cali. The type of sampling will be non-probabilistic for convenience.

Distribution Age Ranges

Age Range	Men	Wome
18 – 34	3	3
35 – 50	3	3
51 – 65	3	3

Selection criteria

Inclusion criteria:

- People aged between 18-65 years

- People with clinical stability, defined as the absence of any acute illness during the previous 6 weeks and a Charlson index score of 0-1 (12% mortality/year- no comorbidity)
- People with a body mass index (BMI) of 18.5 – 35 Kg/m2(52,53)
- People without mental or cognitive alterations
- People who accept informed consent

Exclusion criteria:

- People with pacemakers, cardioverters or cardio defibrillators.
- People with metal implants
- People with any condition in which the registration in the CT scanner signal is low.
- Women in pregnancy
- Participants with injuries, skin changes or presence of devices that prevent the placement of the electrode belt around the chest.
- People with a high level of physical activity according to the IPAQ questionnaire short version
- People whose spirometry registers obstruction or restriction
- People who do not understand the verbal command of the incentive technique

Abandonment criteria

- Request by the subject to be excluded from the protocol expressed verbally or in writing

Ethical aspects

According to the Declaration of Helsinki, the ethical principles for medical research on human beings, including the investigation of human material and identifiable information, and according to the scientific and technical standards established in Resolution 8439 of 1993, for health research, and according to its Article 11. This research is classified with a minimum risk due to the fact that in this project common procedures will be carried out, such as the anthropometric measurement of the height and weight of the subject in a healthy volunteers, deep and forced breathing maneuvers will be requested that are not expected to have adverse events since the patients are healthy and these procedures do not represent physical or psychological risks. however, for the study, the measurements will be made in a space with a flat floor, with adequate beacons and accompaniment of the researchers in order to mitigate the risk of falls.

Complications of forced spirometry are rare. The most common are coughing fits, bronchospasm, chest pain, dizziness, urinary incontinence or increased intracranial pressure. Very rarely, the patient may experience syncopal symptoms. For this, the spirometry will be performed at the Hospital Universitario del Valle, by a professional trained and experienced in performing these, and in the event of any of these events, the test will be suspended and If the symptoms do not subside, the emergency service will be consulted directly. This test will be performed to rule out the coexistence of any alteration in lung function.

In general, there are very few risks or possible complications with the incentive spirometer, but it is important to stop if you feel dizzy. However, there are rare reports of pneumothorax that have been associated with very aggressive spirometry in people with emphysema (and pulmonary bullae that could rupture), in this case if the patient is uncomfortable the test will be discontinued, the other major risks were ruled out with the result of the spirometry in a normal state, in addition, the technique will be performed and guided by the researcher, who is a physiotherapist with experience in handling the technique and trained in case of any eventuality.

The IMP is a device for therapeutic use, which has an industrial design registration, granted by the Superintendence of Industry and Commerce to the Universidad del Valle under the name of "Inspirometro". So its use is supported.

This research was approved by the Human Ethics Committee of the Universidad del Valle under code 031-022 (Annex 1).

The selected subjects must be previously informed in a clear and concise manner by the researcher about the objective of the research, and the informed consent must be read and explained to the participant and to the person who will be a witness, for subsequent signature. A copy must be delivered to both. The information generated by this study will be strictly confidential; privacy will be maintained and the participant will not be identified in any publication.

To protect the data and security of the participant, the following will be considered:

• The person who will apply the measurements underwent training with the personnel of the commercial house that distributes the Pulmovista equipment (EIT) to certify the qualification in carrying out the measurements.

• The informed consent will be read to each of the people who participate in the study, each and every one of the benefits and risks to which they will be exposed will be explained.

• It will be explained that the information generated is strictly confidential and will be used for academic purposes, its privacy will be maintained and it will not be identified in any publication; all data will be identified with a 4-digit sequential code, which will end with the last 2 numbers of the current date

• The information will be stored digitally in the main investigator's computer, with absolute confidentiality and guaranteeing the use of a password to access it. Strict privacy will be kept regarding the records that may identify you; and it will be stored for 10 years, for future publications or for the development of subsequent projects if the participant so authorizes it.

• There is no conflict of interest in this study.

Study Variables

The variables to be measured are:

Main variables:

- EELI Delta (ΔEELI): Measures the change in the average end-expiratory pulmonary impedance before and after an intervention.
- MTV ROI: Minute regional tidal variation

Secondary variables:

- IPAQ: Instrument that provides information on estimated energy expenditure in 24 hours in the different areas of daily life.
- Charlson index: Relates long-term mortality with the participant's comorbidity
- %FEV1 pred: Percentage of the predicted forced expired volume in the first second
- %FVC pred: Percentage of predicted forced vital capacity
- %FVC/FEV1: Percentage of predicted of relationship between forced vital capacity and FEV1
- Labor Occupation: Includes the labor function of the worker
- Level of schooling: the highest level of studies completed or in progress
- Marital status: situation determined by your family relationships, from marriage or kinship
- Socioeconomic Stratum: Classification in strata of residential properties
- Personal history: Compilation of information on the health of the person and pathologies that he/she suffers from.

- Height: Measurement of the height of the human body from the feet to the roof of the cranial vault.
- Weight: Force with which bodies are attracted towards the center of the earth by the action of gravity
- BMI: Relationship between weight and height
- Heart rate: Number of times the heart contracts in one minute
- Respiratory rate: Number of breaths in one minute
- Oxygen Saturation: Measurement of the amount of oxygen available in the blood
- Dyspnea: Difficulty breathing

Materials and Instruments

The instruments that will be used in the study will be: Height rod, scale, Spirometer, modified Pachon's incentive, Hudson Flow Respiratory Incentive, equipment to measure impedance (Pulmovista), data collection format. And they are described below:

- Modified Pachon's incentive (Incentivo Modificado de Pachon by the name in Spanish): handmade device that mimics conventional respiratory incentives, but is made with recyclable, low-cost materials and is also easy to manufacture. Modified in 2004 in a research work by students from the Universidad del Valle(10), where they analyzed the characteristics of the materials required for its design and carried out laboratory tests, they defined that the IMP allows mobilizing flows that oscillate between 600 cc/sec up to more than 1400 cc/sec which characterizes it as a flow incentive. The materials used for its construction are a non-lubricated buretrol and a Today brand condom, since other condoms that have lubricant present discomfort for handling, makes the condom adhere to the walls of the buretrol, and hinders its displacement.
- Triflo® II Respiratory Incentive: Method of encouraging deep voluntary breathing, which provides participants with visual feedback of inspiratory volume, by means of 3 color-coded balls in three chambers, with mouthpiece and tube. The minimum flow is marked on each chamber: 600, 900 and 1200 ml/Seg. It is used to help with inspiratory muscle training and prolonged maximal inspiration, deep breathing stimulates the alveoli to fully expand, it is also often used to prevent or reverse the formation of pulmonary atelectasis. It is manufactured by HUDSON RCI
- PulmoVista 500®: it is an electrical impedance tomograph, from Dräger. The data is continuously represented in the form of images, curves and parameters to observe ventilation continuously and directly in various lung regions, as well as the changes

that occur in lung volumes at the end of expiration, non-invasively, in time. real and directly next to the bed.

- Spirometer: This is a device that is commonly used to assess how well the lungs are working by measuring how much air you breathe in, how much you breathe out, and how quickly you breathe out. Spirometry is used to diagnose asthma, chronic obstructive pulmonary disease (COPD), and other diseases that affect breathing. Spirometry can also be used periodically to monitor the condition of your lungs and see if treating chronic lung disease is helping you breathe better. For this study, a medgraphics cardiorespiratory diagnostics® brand spirometer will be used, which works with the breeze suite 6.4.1.44 SP4 system.
- Stadiometer: it is a height meter that is fixed to the wall or to a support and is used to accurately measure people, so that when it is placed under it, the stadiometer will rest on their head, indicating the height on the dial. exactly who is using it. For this study, a SECA model 213® stadiometer will be used.
- Scale: Device used to measure weights. For this study, a SECA® brand scale will be used.

For this research, a data collection format was designed:

- Format created by the researcher made up of a section on sociodemographic information (age, date of birth, gender, sociodemographic stratum, occupation, education and marital status), personal and family history (the Charlson index will be applied to assess associated comorbidities, anthropometric data (weight and height), level of physical activity (IPAQ), lung function data (spirometry) and results on ventilation and global and regional lung impedance for each individual.

To measure clinical stability and the level of physical activity, the following instruments will be used:

- Charlson Index: it is a life expectancy evaluation system, depending on the age at which it is evaluated, and the subject's comorbidities. In addition to age, it consists of 19 pathology items with their respective rating, which, if present, have been found to have a specific influence on the subject's life expectancy. In general, absence of comorbidity is considered: 0-1 points, low comorbidity: 2 points and high > 3 points. The prediction of mortality under 3 years: score of 0: (12% mortality/year); from 1-2: (26% mortality/year); from 3-4: (52% mortality/year); and> 5: (85% mortality/year).

- International Physical Activity Questionnaire (IPAQ) short version IPAQ researchers developed several versions of the instrument according to the number of questions (short or long). The short version consists of 7 items and provides information about the time the person spends performing moderate and vigorous intensity activities, walking and sitting. Especially recommended when population monitoring is intended in research

Procedures

The research will be carried out in four stages: Preparation for the study, design and adjustment of instruments, data collection and data analysis. Ordered according to the logical steps to follow within the development of obtaining the required data.

Phase 1: Preparation for the study

In this stage, the search for initial information will be carried out, for this a bibliographic review will be carried out for the present study that includes research published in different databases, related to the validation and comparison of medical devices, the use of the EIT and the studies related to the use of respiratory incentive in the clinical setting and its levels of evidence. Once this is done, the research approach, the study design, the form of selection and sample size, and the writing of the document will be carried out.

For the development of this study, the main researcher will carry out a 24-hour training in the handling of the equipment with the personnel of the commercial house. (Drager).

The informed consent will be designed and the written research work will be sent to the ethics committee to receive endorsement.

Phase 2: Design and Adjustment of Instruments

The data collection instrument will be designed.

For the standardization of anthropometric measurements (weight and height), Standardized Operating Procedures 1 and 2 will be used according to the instructions defined in these

For the measurement of the EIT, the Standardized Operating Procedure 3 designed for projects previously carried out by GIESC will be used. “Effect of two lung reexpansion techniques on the ventilation of participants undergoing cardiovascular surgery. Controlled clinical trial phase II b”

The pilot test will be carried out with 5 healthy subjects who will not be part of the sample, they will be informed about the research, they will be asked to sign the informed consent and the measurements and data collection will be carried out with the designed data

collection format. by the researcher. Said pilot test will be carried out to test and make pertinent corrections in the management of the evaluation instruments and in order to identify the times required in the measurement of the variables.

Phase 3: Data Collection:

Call for participants

For the recruitment of healthy volunteers between 18-65 years of age in the community of Santiago de Cali, taking into account the social distancing established by the current COVID 19 pandemic, direct contact will be made with people from the administrative areas of the Universidad del Valle , from the research groups of the Universidad del Valle, family and friends who will initially be provided with information about the objectives of the research and will be invited to participate.

Social networks will also be used to send information about the research and the contacts (email, cell phone) of the researchers will be left so that people interested in participating can register.

People who decide to register to be included in the study will be contacted and the date, time and place will be organized, taking into account the availability of time, as well as the capacity and the biosafety protocols established in the places where they will be carried out. the measures. The EIT will be performed in the movement laboratory located at the Universidad del Valle and the spirometries at the Hospital Universitario del Valle.

Data collection protocol

Before performing spirometry

If the subject is eligible, a series of recommendations will be made that must be taken into account prior to arrival to take measurements:

1. Not having done physical activity in the last 12 hours prior to the exam.

2. Not having smoked cigarettes in the last 12 hours prior to the exam.

3. Do not consume caffeinated beverages on the day of the exam

4. Comfortable clothes

Performing spirometry

This measurement will be carried out at the Hospital Universitario del Valle, in the physical medicine and rehabilitation unit in the pulmonary function laboratory with the medgraphics cardiorespiratory diagnostics® brand spirometer that belongs to the Universidad del Valle and is under the custody of the Hospital. Academic. The spirometries will be carried out by the researcher, who is a physiotherapist specializing in cardiopulmonary physiotherapy. The day of the test will begin with the completion of the informed consent, this will be read and explained to the participant and will continue to the signature. On this day, the researcher will fill out the sociodemographic data of the participant, weight and height measurement, Charlson index and IPAQ abbreviated questionnaire, according to the instructions defined in the Standardized Operational Procedures 1, 2, 4 and 5 for these procedures in the data collection format. data.

Spirometry will be performed according to the institutional protocol of the Hospital Universitario del Valle. The duration of this procedure will take approximately 1 hour

Randomization

The randomization to choose which will be the first incentive that each participant will use and to which the first ventilation measurement will be carried out by means of EIT, will be carried out by simple randomization, through the "RANDOM.ORG" program (https:// www.random.org/lists/) and http://www.jerrydallal.com/random/permute.htm

These measurements will be made at the facilities of the Universidad del Valle, according to availability. The first measurement will be carried out with the incentive that has been randomly assigned to the participant, the second measurement will be carried out one week after the first measurement was made with the other incentive, with the objective that the washing period is fulfilled, both measurements will be performed by the principal investigator. For the measurement of the EIT, the instructions defined in standard operating procedure 3 will be followed and for the application of the protocol for the use of incentives, the instructions defined in standard operating procedure 6 and 7 will be followed according to the corresponding incentive. The duration of this procedure will be approximately 30 minutes for each measurement.

Moments of electrical impedance tomography measurement

Once the patient is connected to the tomograph, the quality of the signal must be checked. Once it is verified that it is being measured properly, that the patient is well positioned and that the signal is of high quality, the recording will begin. tomograph record; after the first

two minutes of calm breathing have elapsed, the first event will be marked, which will be recorded as "pre", and the use of the corresponding respiratory incentive will begin. The proper use of the device will be previously explained to you through a video that will illustrate the correct way to use it. The participant will receive visual feedback from the device when the condom is raised within the buretrol in the case of the IMP or when the spheres are raised in the branded incentive "Triflo II®"

Three series of ten breaths will be performed, with a 1-minute rest between series. In the last repetition of the third series, the second event will be marked, which will be recorded as "intra".

The maneuver will be finished once the series and repetitions are finished, removing the mouthpiece from the participant's mouth and they will be asked to continue breathing calmly for 2 minutes, after which the third event will be marked, which will be recorded as "post". And the recording of the record will be terminated.

At the beginning and at the end of the intervention, clinical data will be taken (heart rate, respiratory rate and oxygen saturation) and 15 minutes after finishing the test.

Taking into account that the subjects are using a device that is not used routinely in daily life, the perception of the subject in the use of each of the devices will be evaluated to know the degree of comfort of these by means of the scale of Likert and in the same way it will be valued if I generate perception of dyspnea by means of the Borg scale

The session may be interrupted if the participant does not wish to continue with the intervention, if the participant shows intolerance to the maneuver, if the respiratory rate is greater than 25 breaths per minute and if there is use of accessory muscles.

After each measurement is finished with each participant, the equipment will be disinfected

Quality control:

1. To guarantee the quality of the registered information, the main investigator will carry out random reviews in which he will corroborate the coherence between the original information of the tomographer, that of the registration in the formats and that of the database. The detected errors will be corrected.

2. An external person to the study, who will not participate in the measurements, will randomly review the forms once every 15 days to verify the information before entering it into the database. Additionally, once a month a meeting will be held with the research group in order to socialize project progress

Phase 4: Statistical analysis

Descriptive Analysis

The registration of the information will be carried out in the data collection formats designed for this purpose. To then be organized in the Microsoft Excel program. In order to have an initial knowledge of the behavior of each of the variables.

Quantitative variables will be presented as mean and standard error, and qualitative variables as frequencies and percentages. Normality tests (D Agostino Pearson) will be applied to identify data distribution; subsequently, a paired T test will be performed to identify if the changes obtained after the interventions are statistically significant (p less than 0.05). For the statistical procedure, GraphPad Prism version 7.0 will be used.

For the EIT data, the monitoring sessions will be recorded with the participant's code, each recording will be transferred to a USB to be downloaded to the equipment where the information collected is stored for the reconstruction of the impedance measurement through the tool (Electrical Impedance Tomography Data Analysis Tool v6.3, Drager Medical). This Reconstruction will allow us to isolate the main areas of interest (EIT measurement times) and quantify the percentage changes in EELI in response to lung expansion with respiratory incentive.

Anexo 1. Approval by a human subjects protection review board

FACULTAD DE SALUD
Comité de Ética en Investigación en Salud

ACTA DE APROBACION N°(009-022)

Proyecto: **"DISTRIBUCIÓN DE LA VENTILACIÓN PULMONAR CON EL INCENTIVO MODIFICADO DE PACHÓN VS OTRO INCENTIVO RESPIRATORIO COMERCIAL, A TRAVÉS DE TOMOGRAFÍA DE IMPEDANCIA ELÉCTRICA, EN POBLACIÓN SANA DE LA CIUDAD DE CALI"**

Investigador Principal: **"ESTHER CECILIA WILCHES/ NORAELENA MERA QUINTERO/ VICENTE BENAVIDES"**

Código Interno: (031-022)

Fecha en que fue sometido:

DIA	MES	AÑO
16	05	2022

El Consejo de la Facultad de Salud de la Universidad del Valle, ha establecido el Comité de Ética en Investigación en Salud (**CEIS**), el cual está regido por la Resolución 008430 del 4 de octubre de 1993 del Ministerio de Salud de Colombia por la cual se establecen las normas científicas, técnicas y administrativas para la investigación en salud; los principios de la Asamblea Médica Mundial expuestos en su Declaración de Helsinki de 1964, última revisión en 2013; y el Código de Regulaciones Federales, título 45, parte 46, para la protección de sujetos humanos, del Departamento de Salud y Servicios Humanos de los Institutos Nacionales de Salud de los Estados Unidos 2000. Este Comité **certifica que**:

1. Sus miembros revisaron los siguientes **documentos** del presente proyecto:

X	Protocolo de Investigación
X	Instrumentos de recolección de datos
X	Formato de consentimiento informado
X	Soportes solicitados por el CEIS
X	Cartas de las instituciones participantes
	Resultados de evaluación por otros comités (si aplica)

2. El presente proyecto fue evaluado y aprobado por el Comité.
3. Según las categorías de riesgo establecidas en el artículo 11 de la Resolución N° 008430 de 1993 del Ministerio de Salud, el presente estudio tiene la siguiente **Clasificación de Riesgo:**

	Sin riesgo
X	**Riesgo mínimo**

4. Las **medidas** que están siendo tomadas para proteger a los sujetos humanos son adecuadas.
5. La forma de obtener el **consentimiento** informado de los participantes en el estudio es adecuada.
6. **Informará** inmediatamente a las directivas institucionales:

a. Todo desacato de los investigadores a las solicitudes del Comité.
b. Cualquier suspensión o terminación de la aprobación por parte del Comité.
c. Lesiones a sujetos humanos.
d. Problemas imprevistos que involucren riesgos para los sujetos u otras personas.

e. Cualquier cambio o modificación a este proyecto que no haya sido revisado y aprobado por el Comité.
f. El presente proyecto ha sido **aprobado** por un periodo de un **(1) año** a partir de la fecha de aprobación. Los proyectos de duración mayor a un año, deberán solicitar la renovación del aval, adjuntando los documentos solicitados por el CEIS.

7. El **investigador principal deberá** informar al Comité:

a. Cualquier cambio que se proponga introducir en este proyecto. Estos cambios no podrán iniciarse sin la revisión y aprobación del Comité excepto cuando sean necesarios para eliminar peligros inminentes para los sujetos.

b. Cualquier problema imprevisto que involucre riesgos para los sujetos u otros.

c. Cualquier evento adverso serio dentro de las primeras 24 horas de ocurrido, al secretario(a) y al presidente.

d. Cualquier conocimiento nuevo respecto al estudio, que pueda afectar la tasa riesgo/beneficio para los sujetos participantes.

e. Cualquier decisión tomada por otros comités de ética

f. La terminación prematura o suspensión del proyecto explicando la razón para esto.

g. El investigador principal deberá presentar un informe final al terminar el proyecto.

Fecha de Expedición:

DIA	MES	AÑO
10	06	2022

Firma:
Nombre: **BEATRIZ EUGENIA FERNÁNDEZ H.**
Capacidad Representativa: Presidente
Teléfono: 5185677