

Study Protocol for a Randomised Controlled Trial comparing the Effect of Lung Recruitment Manoeuvres as an adjunct to conventional Chest physiotherapy in Post-operative Paediatric Congenital Heart Disease patients on Mechanical Ventilation.

Dr. Lajwanti lalwani¹, Dr. Athuruddin kazi², Dr. Nazli quazi³, Dr. Zahiruddin quazi⁴,
Dr. Abhay gaidhane⁵, Dr. Amar taksande⁶, Dr. Mangesh choudhari⁷

1- Assistant Professor, Dept. of Cardiovascular and Respiratory Sciences, Ravi Nair Physiotherapy College(RNPC), Datta Meghe Institute of Medical Science(DMIMS), Sawangi, Wardha. (PhD Scholar)

2- HOD & Professor Dept. of Cardiovascular and Respiratory Sciences, Ravi Nair Physiotherapy College, (DMIMS), Sawangi, Wardha.

3- Professor, Dept. of physiology, JNMC, DMIMS, Sawangi, Wardha.

4- Director (Research & Development), Professor Dept. of Community Medicine, JNMC DMIMS, Sawangi, Wardha.

5- Professor and HOD, Dept. of Community Medicine, JNMC, DMIMS, Sawangi, Wardha.

6- Professor Department of Paediatrics, JNMC DMIMS, Sawangi, Wardha.

7- Assistant Professor, Dept. of Cardiac Anaesthesia, JNMC, DMIMS, Sawangi, Wardha.

Dr. Lajwanti Lalwani,
Assistant Professor, Dept. of Cardiovascular and Respiratory Sciences, RNPC, DMIMS,
Sawangi, Wardha.

Email: lajo.lalwani28@gmail.com

Phone no- 8605234269

Conflict of Interest- None.

Abstract- Background- Congenital heart diseases (CHD) are major congenital anomaly that are present during birth. Repair and corrective surgeries are performed as a line of treatment and is followed by chest physiotherapy(CPT) to prevent any pulmonary complication.

Lung Recruitment manoeuvres (LRM) is an intervention mostly performed by anaesthetic or respiratory therapist to recruit the alveoli that are expandable and to reduce the area of atelectasis and increase the exchange of gases for patients on mechanical ventilation.

Comprehensive literature search was done and have not come across any studies showing the efficacy of combined lung recruitment manoeuvre [LRM] and [CPT]. So study was conducted with aim to compare the effect of LRM as an adjunct to CPT in post-operative paediatric CHD patients on mechanical ventilation. A RCT.

Methodology-The design is randomised, parallel Superiority group, assessor-blinded, controlled trial in postoperative paediatric congenital heart disease patients on Mechanical Ventilator. The study aims to answer the research question comparing standard(conventional)CPT with combined standard CPT along with lung recruitment

manoeuvre. The study will include 128 Post operated paediatric CHD patients on Mechanical ventilation for more than 6 hrs with inclusion criteria of operated case of CHD with the age group of 2-14 years intubated more than 6 hours. Subjects were grouped into two groups. Group A –Control Group [CPT] and Group B – Experimental Group [CPT along with LRM Group]. Patients were assessed pre-treatment and 15 minutes post treatment on various outcomes.

Expected Results - The trial can generate the evidence for lung recruitment manoeuvre as an additional to conventional CPT in terms of safety and efficacy. If the finding of the study are positive for LRT then it will be utilized to improve the patient care in post-operative paediatric CHD patients on mechanical ventilator decrease in morbidity, & stay in the ICU will be observed.

Keywords- Congenital heart diseases [CHD], Lung Recruitment Manoeuvre [LRM], Chest Physical Therapy [CPT].

Background-

Congenital heart diseases [CHD] are defects that are present during birth and is usually associated with structural and functional heart issues.¹ Congenital heart diseases are classified in various types (a). cyanotic and Acyanotic CHD, (b). condition with shunt and without shunt.² In India incidence of CHD is quite high and it is approximated that every year around 180,000 CHD children are born.³

The line of treatment of children born with CHD are mainly surgeries either corrective or palliative surgery depending upon the type of defect present and the treatment needed.² After the surgery the postoperative period is taken care by surgeons, anaesthetics, nurses, and respiratory physiotherapist. Postoperative role of each team member is well distributed. Patients are intubated and main goal after cardiac surgery of team members is to help in early extubation without any pulmonary or cardiac problems.⁴ The physiotherapist role is one of the vital role to prevent post pulmonary complications so regular chest physiotherapy is given consisting of positioning, modified postural drainage positions, suctioning, facilitated breathing techniques, and techniques for airway clearance and thus maintaining bronchial hygiene for early extubation.⁵⁻⁸ Evidences also favour the use of chest physiotherapy in post-operative cases.^{5,9}

Another intervention know as Lung Recruitment Manoeuvre [LRM] also known as open lung ventilation or alveolar recruitment. LRM aims to rise the transpulmonary pressure to increase the exchange of gases via flow inflation bag or through ventilator.¹⁰ Lung Recruitment manoeuvres (LRM) is an intervention mostly performed by anaesthetic or respiratory therapist to recruit the alveoli that are expandable and to reduce the area of atelectasis and increase the exchange of gases for patients on mechanical ventilation.⁵ This intervention is mainly used in patients under the influence of general anaesthesia and mainly in the cases of Acute Respiratory Distress Syndrome[ARDS].¹⁰ Evidences also shows the use of LRM in improving oxygenation in paediatric population.¹⁰⁻¹² LRM is also used in cardiac surgeries mainly coronary artery bypass surgery [CABG]. A study done by Moussa Riachy et al in 2017 stated that after valve replacement surgery having cardiopulmonary bypass if repetitive lung recruitment is applied every 4 hourly resulted in short term benefit as compared to standardised single recruitment manoeuvre but time to extubation was earlier in repetitive lung recruitment technique as compared to standard single recruitment treatment.¹³

Scientific Rationale -

Conventional manoeuvres is often the first modality to treat acute atelectasis and preventing pulmonary complications in postoperative patients on mechanical ventilation.⁵ Generally

Postoperative cardiac patients are extubated generally after six hours if they require long duration more than six-eight hours then respiratory parameters are compromised. Studies had showed the positive effect of lung recruitment manoeuvre in mechanically ventilated patients.^{10,11} We have done literature search to the best of our knowledge, have not come across any of the study done on lung recruitment in CHD patient but have come across only one study conducted by Morandi, Tiffany¹⁴ on “Safety and efficacy of lung recruitment Manoeuvres in post-operative paediatric cardiac surgical patients”. from one university so we wanted to carry forward the evidence in Indian setup and also wanted to evaluate LRM in such patients who require prolong ventilation and build up the knowledge of using LRM in such cases to decrease the weaning time and which leads to decrease in ICU and length of hospital stay and which will also decreases the health care cost associated with it. There is lack of evidence on safety and efficacy of LRM along with chest physical therapy in cardiac patients as LRM are used and are effective in many ARDS in both adult and paediatric population. We can also generate data for the safety use of this intervention by monitoring the adverse events. Thus overall postoperative CHD patients health care cost and morbidity can be decreased.

Objectives

Primary objectives:

1. To assess the effect of lung recruitment Manoeuvres as an additional to conventional CPT on Extubation time.
2. To assess the effect of lung recruitment Manoeuvres as an additional to conventional CPT on adverse event associated with intervention.
3. To assess the effect of lung recruitment Manoeuvres as an additional to conventional CPT on length of ICU stay.
4. To assess the effect of lung recruitment Manoeuvres as an additional to conventional CPT on length of hospital stay.

In post-operated paediatric congenital heart disease patients on mechanical ventilation.

Secondary objective:

1. To assess the outcome of LRM as an additional to conventional CPT on oxygenation. (PaO₂& Spo₂)
2. To assess the outcome of LRM as an additional to conventional CPT on Ventilation (PaCO₂)
3. To assess the outcome of LRM as an additional to conventional CPT according to various types of CHD. (Cyanotic & Acyanotic)
4. To assess the outcome of LRM on hemodynamic.

In post-operated paediatric congenital heart disease patients on mechanical ventilation.

Hypothesis:

Null hypothesis: The Lung Recruitment Manoeuvres as an additional to conventional CPT is not more efficacious (superior) than the Conventional chest physiotherapy treatment in post-operated paediatric congenital heart disease patients on mechanical ventilation by a clinically

and statically relevant amount.

Research question- Whether lung Recruitment Manoeuvre as an additional to conventional CPT will be effective in postoperative paediatric CHD patients on mechanical ventilation on respiratory parameters & on weaning time.

P- Paediatric Operated case of congenital heart disease patient on mechanical ventilation.

L- Lung recruitment Maneuver.

C- Conventional chest physiotherapy with lung recruitment technique.

O- Respiratory parameters & Hemodynamics.

WORK PLAN:

Methodology:

Study location- Study will be carried out in the SICU (CVTS DEPT.), Acharaya Vinoba Bhave Rural Hospital (AVBRH), Ravi Nair Physiotherapy College, Sawangi(Meghe) Dept of Cardiovascular and Respiratory Sciences after approval from Institutional Ethics Committee(IEC) of DMIMS, (DU). (ACADEMIC HOSPITAL)

Ethical_and_research_governance_approval- Approval was obtained from IEC. Approval number- **DMIMS (DU)/IEC/2018-19/7242.**

Research design- We will conduct a randomised, parallel **Superiority** group, assessor-blinded, controlled trial in postoperative paediatric congenital heart disease patients on Mechanical Ventilator. Ethical committee approval was taken. Allocation ratio will be 1:1.

Study Participant: Post operated paediatric CHD patients on Mechanical ventilation for more than 6 hrs with following inclusive and exclusive criteria will be enrolled.

Inclusion criteria:

1) Children with both gender in the age range of 2-14 years post- operated cases of congenital heart disease (Cyanotic& Acyanotic) on Mechanical ventilation for at least six hours will be included.

Exclusion criteria:

1. Patient below 2 years of age (due to unavailability of proper evidence in neonates and safety issue is taken into account. no harm principle of bioethics is applied)

2. Patients with H/O of any respiratory disease, Thoracic deformity, Bronchopleural fistula, Patient on intercostals catheter with continuous leak. Patient with unstable hemodynamic hypotension Systolic B.P < 65 mmHg in infants , <70 mmHg in 1-4 years , <80 in 5-12 years and <90 mmHg in more than 12 years, life threatening arrhythmias, Acute heart failure.

Patients will be explained and written informed consent /assent will be collected either from the patient or from a parents.

A trained person along with anaesthetist will perform the lung recruitment manoeuvres.

Randomisation and allocation-concealed -Participants will be randomised, using a computer generated random sequence randomisation system, in a 1:1 ratio. random-Allocation concealment will be an independent nurse who will prepare the envelopes writing the treatment group as control or interventional in a paper and putting inside an envelope in the ICU another independent nurse open the envelope and informs the physiotherapist about the treatment group in which this patient will be enrolled .

Blinding -Study outcome will be assessed by the ICU in charge who will be blinded to the treatment group.

Intervention/procedure.

In this study patients will be divided into 2 groups.

1. Control group will receive only conventional chest physiotherapy
2. Experimental/interventional group will receive conventional chest physiotherapy and additional lung recruitment manoeuvre.

1. **Control group**- Conventional chest physiotherapy technique includes: Percussion-Vibration. ShakingPositioning.⁵

Control group- Conventional chest physiotherapy technique includes:

- a. Percussion- will be performed with hands cupped with alternate flexion and extension movement at the wrist.
- b. Vibration –hands will be located directly on chest and during the process of expiration a vibration force is applied using the weight of the body in the direction of the normal rib movement.
- c. Shaking - hands will be located on chest and during exhalation coarse movement are given in the direction of ribs.
- d. Positioning-various positioning in supine and side lying will be given mainly to help in the process of cleaning the lung secretions that balances ventilation and perfusion ratio.

In control group the conventional chest physiotherapy will be given 2-3 times a day or as per the need of the patient depending upon the chest assessment. Each session will last for 15-20 min or as per the requirement and clinical status of the patient. each time pre intervention reading will be taken and post intervention reading of outcome measure will be recorded by the blinded ICU in charge.

2. **Experimental group** will receive conventional chest physiotherapy and lung Recruitment manoeuvre.

a. **Lung Recruitment manoeuvre protocol**- lung recruitment will be performed by the trained person under supervision of anaesthetist the ventilator will be set to achieve a tidal volume(TV) of 6 cc/kg. The increment in PEEP will be 1-2 cmH₂O and this incremental will be maintained for 1 min. With the Increase in PEEP the TV will be noted and TV should increase with the increase in PEEP and as soon as TV is observed to decreased the increase in PEEP is stopped. Then PEEP is decreased in the similar manner of 1-2 cmH₂O and observing for 1 min after each session and again TV is noted till a significant decrease in TV with a small decrease in pressure level or a large

decrease in dynamic compliance will be observed because this is the point of decruitment . The patient will be then taken back on the original mode of ventilation with the PEEP adjusted to the original PEEP on an average Recruitment will be done in 4-6 hrs interval but will be repeated sooner if there will be a loss of PEEP or ventilator disconnection.¹⁴ Maximum PEEP range given will be upto 10-15 cmH₂O. further pilot study will confirm the exact PEEP level.

LRT will be given 2-3 times a day or as per the need of the patient depending upon the chest assessment. Each session will last for 15-20 min or as per the requirement and clinical status of the patient. each time pre intervention reading will be taken and post intervention reading of outcome measure will be recorded by the blinded ICU incharge.

Criteria for discontinuing -The session will be terminated at once if any of the terminated criteria were observed in the children such as hemodynamic instability ,arrhythmias or as the treatment will proceed till the required period was achieved or the or the treating the treating physical therapist point out that it appropriate to stop. Adverse event if occur who will be informed - (ICU in charge)

Intervention will be continued till the patient is extubated

Outcome measures- the outcome will be assessed by ICU incharge who will be unaware of the treatment (blinded)

Primary outcome are

1. Lung compliance- compliance of lung is the extensibility of lung to expand and to return of lung in normal resting.¹⁵ In a normal individual on mechanical ventilation, generally compliance is more than 50–100 ml/cmH₂O. Decreased compliance is observed in stiff lung or thorax or both.¹⁵

Tool for measurement- ventilator.

2. Oxygenation –measured using ABG and value of Pao₂ and SpO₂ corresponds to oxygenation.

Ventilation status can be assessed by observing PaO₂ and SaO₂ levels. The PaO₂ is the quantity of oxygen dissolved in the arterial blood. A normal value range of PaO₂ is 80-100mmHg. The SaO₂ shows the quantity of oxygen bound to haemoglobin. SaO₂ normal range is 95-100%.

Tool for measurement- ABG analysis by collection blood.¹⁶

3. Ventilation by measuring PaCo₂ -The PaCO₂ is defined as “a measure of the partial pressure that dissolved carbon dioxide exerts in the plasma and is directly related to the amount of carbon dioxide being produced by the cells.” The PaCO₂ if deranged it notify the respiratory cause. normal value is 35-45 mmHg.¹⁶

Tool for measurement- ABG analysis by collection blood sample.

4. Extubation time –the mechanical ventilation time which the patient will be submitted to will be measured in hrs it will be measured from the time of tracheal intubation to the time of extubation.

Tool for measurement- calculating hrs with the flow sheet.^{17,18}

Secondary outcome-

1. Adverse event (pneumothorax, arrhythmias, BP fall)
2. various types of CHD(cyanotic ,acynotic, mixed & complex)
3. length of ICU stay (in days)
4. length of hospital stay (in days)
5. (BP,HR,RR)

heart rate & RR – will be recorded bpm Tool for measurement- using monitor.

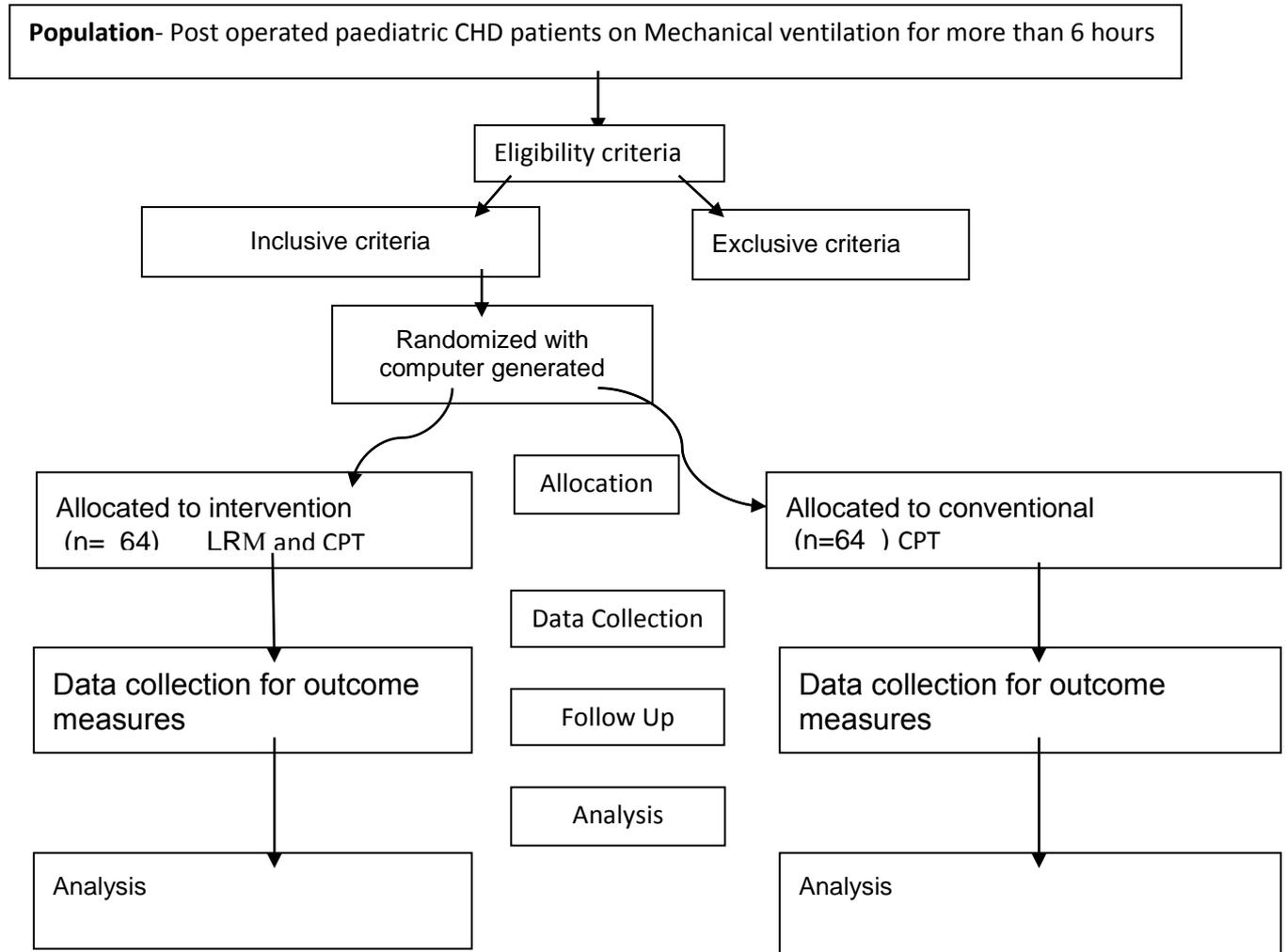
time constants -All the variables will be measured 2 min before the intervention known as pre intervention reading and post intervention reading will be taken 15 mins after the intervention

Outcome measures	Tool	Assessor	Time point
Lung compliance	Ventilator	ICU in charge (who will be blinded)	2 minutes pretreatment and 15 min after treatment
PaO2	ABG Analyser	ICU in charge (who will be blinded)	2 minutes pretreatment and 15 min after treatment .
PaCO2	ABG Analyser	ICU in charge (who will be blinded)	2 minutes pretreatment and 15 min after treatment .
Ventilator stay	Paper Sheets	ICU in charge (who will be blinded)	Time at which the patient is extubated.
Adverse event (pneumothorax, hypotension)	X –ray, monitor	ICU in charge (who will be blinded)	Hypotension– during treatment and pneumothorax After treatment X ray once in 2 days.
length of ICU stay	Note sheets	ICU in charge (who will be blinded)	admission date in the icu and the day of shifting to the ward
length of hospital stay	Note sheet	ICU in charge (who will be blinded)	Day of admission in the hospital and the day patient got discharged.
BP, HR, RR	Monitor	ICU in charge (who will be blinded)	Pre intervention and post intervention

Data analysis plan-

Analysis will be done by the statistician using standard method. Primary outcome will be compared between the intervention and control group applying principles of intension to treat [ITT]. Effect size will be estimated.

Flow diagram



Justification for proposing the host institute / mentor-

CVTS department is the one of the central institute in India and most of the cases operated are congenital heart disease so feasibility of conducting the research is available.

Acknowledgement-

SOURCE OF FUNDING-**Datta Meghe University Of Medical Sciences, Sawangi, Wardha.**

TECHNICAL HELP- CS Sandiip Adwani

Competing interests- No competing interest

References-

[1] Saxena A. Congenital heart disease in India: a status report. Indian J Pediatr. 2005

- Jul;72(7):595–8.
- [2] Junghare SW, Desurkar V. Congenital heart diseases and anaesthesia. *Indian journal of anaesthesia*. 2017 Sep;61(9):744.
 - [3] Saxena A, Mehta A, Sharma M, Salhan S, Kalaivani M, Ramakrishnan S, et al. Birth prevalence of congenital heart disease: A cross-sectional observational study from North India. *Ann Pediatr Cardiol*. 2016;9(3):205–9.
 - [4] Silva MEM da, Feuser MR, Silva MP, Uhlig S, Parazzi PLF, Rosa GJ da, et al. Pediatric cardiac surgery: what to expect from physiotherapeutic intervention? *Rev Bras Cir Cardiovasc Orgao Of Soc Bras Cir Cardiovasc*. 2011 Jun;26(2):264–72.
 - [5] Pryor JA, Prasad SA. Physiotherapy techniques. *Physiotherapy for Respiratory and Cardiac Problems: Adults and Paediatrics*. 4th ed. Churchill Livingstone/Elsevier, Edinburgh. 2008 Mar 6:134-217.
 - [6] Ahmad AM. Essentials of Physiotherapy after Thoracic Surgery: What Physiotherapists Need to Know. A Narrative Review. *Korean J Thorac Cardiovasc Surg*. 2018 Oct;51(5):293–307.
 - [7] Cavenaghi S, Ferreira LL, Marino LHC, Lamari NM. Respiratory physiotherapy in the pre and postoperative myocardial revascularization surgery. *Braz J Cardiovasc Surg*. 2011 Sep;26(3):455–61.
 - [8] Stiller K. Physiotherapy in Intensive Care: Towards an Evidence-Based Practice. *CHEST*. 2000 Dec 1;118(6):1801–13.
 - [9] Miskovic A, Lumb AB. Postoperative pulmonary complications. *BJA Br J Anaesth*. 2017 Mar 1;118(3):317–34.
 - [10] Jauncey-Cooke J, East CE, Bogossian F. Paediatric lung recruitment: a review of the clinical evidence. *Paediatr Respir Rev*. 2015 Mar 1;16(2):127–32.
 - [11] Kheir JN, Walsh BK, Smallwood CD, Rettig JS, Thompson JE, Gómez-Laberge C, et al. Comparison of 2 Lung Recruitment Strategies in Children With Acute Lung Injury. *Respir Care*. 2013 Aug 1;58(8):1280–90.
 - [12] Neves VC, Koliski A, Giraldo DJ. Alveolar recruitment Manoeuvre in mechanic ventilation pediatric intensive care unit children. *Rev Bras Ter Intensiva*. 2009 Dec;21(4):453–60.
 - [13] Riachy M, Ibrahim I, Sleilaty G, Faraj C, Khayat G, Jebara S, Haddad F, Hayek G, Yazigi A. Single or repetitive lung recruitment manoeuvres after cardiac valve replacement surgery.
 - [14] Morandi T. Safety and efficacy of lung recruitment Manoeuvres in post-- operative pediatric cardiac surgical patients (Doctoral dissertation, The University of Arizona.).
 - [15] Grinnan DC, Truwit JD. Clinical review: respiratory mechanics in spontaneous and assisted ventilation. *Critical Care*. 2005 Oct;9(5):472.
 - [16] Díaz, A., Gracia, F., Monterrey-Alvarez, P., Sirias Baca, A. V., Santos, B., Enamorado, T., Vásquez-Céspedes, J., Parajeles-Vindas, A., Ramírez-Navarro, D., Díaz de la Fe, A., Portillo-Rivera, L., Ramírez, N. E., & Rivera, V. M. (2020). Central American and Caribbean Consensus for the Treatment of Multiple Sclerosis and Therapeutic Attitudes Facing the COVID-19 Pandemic. *Journal of Current Medical Research and Opinion*, 3(09). <https://doi.org/10.15520/jcmro.v3i09.338>
 - [17] Pellegrino R, Vieggi G, Brusasco V, Crapo RO, Burgos F, Casaburi RE, Coates A, Van Der Grinten CP, Gustafsson P, Hankinson J, Jensen R. Interpretative strategies for lung function tests. *European Respiratory Journal*. 2005 Nov 1;26(5):948-68.
 - [18] Castro AA, Calil SR, Freitas SA, Oliveira AB, Porto EF. Chest physiotherapy effectiveness to reduce hospitalization and mechanical ventilation length of stay, pulmonary infection rate and mortality in ICU patients. *Respiratory medicine*. 2013 Jan 1;107(1):68-74.

