



THE ROLE OF RMT DURING COVID-19 PART 1:

RISK REDUCTION,
TREATMENT &
RECOVERY

MEET THE EXPERTS



Presenter
Richard Severin, PT,
DPT, PhD(c), CCS



Presenter
Sigfredo Aldarondo, MD
Pulmonologist
Chief Medical Officer



Host
Nina Bausek, PhD,
MSC Geneticist
Chief Scientist

LEARNING OUTCOMES

1. Understand the impact of COVID-19 on respiratory and systemic physiology
2. Discuss COVID-19 epidemiology and mechanisms of transmission
3. Discuss COVID-19 severity and stages of disease
4. Explore the effects of COVID-19 and other respiratory infections on the respiratory system
5. Discuss the role of RMT before, during and after respiratory infections

COVID-19: THE PANDEMIC

Epidemiology:

- The virus outbreak was first reported in the city of Wuhan, China, in 2019.
- To date, COVID-19 has been reported from 188 countries
- To date*, > 24 million people have been infected with COVID-19
- To date*, > 821,000 people have died from COVID-19 (mortality rate: 3.4%)

Specificities of the COVID-19 outbreak:

- SARS-CoV-2 has a high transmission rate ($R_0=3-4$ vs $R_0=2$ in SARS-CoV)
- Transmission route:
 - Mainly droplet infection
 - Airborne transmission uncommon but possible
 - Superspreading events

* Data accessed 8/27/2020 <https://covid19.who.int/>

EFFECTS OF RESPIRATORY PATHOGENS

Acute infections by respiratory pathogens cause 3.5 million deaths every year, worldwide.

The most common community acquired respiratory pathogens:

- *Streptococcus pneumoniae* (pneumococcus),
- *Haemophilus influenzae*,
- *Moraxella catarrhalis*
- *Staphylococcus aureus*
- Influenza viruses
- Respiratory syncytial virus (RSV)
- Rhinovirus
- Others

EFFECTS OF SARS-COV2

Phase 1: SARS-Co-V2:

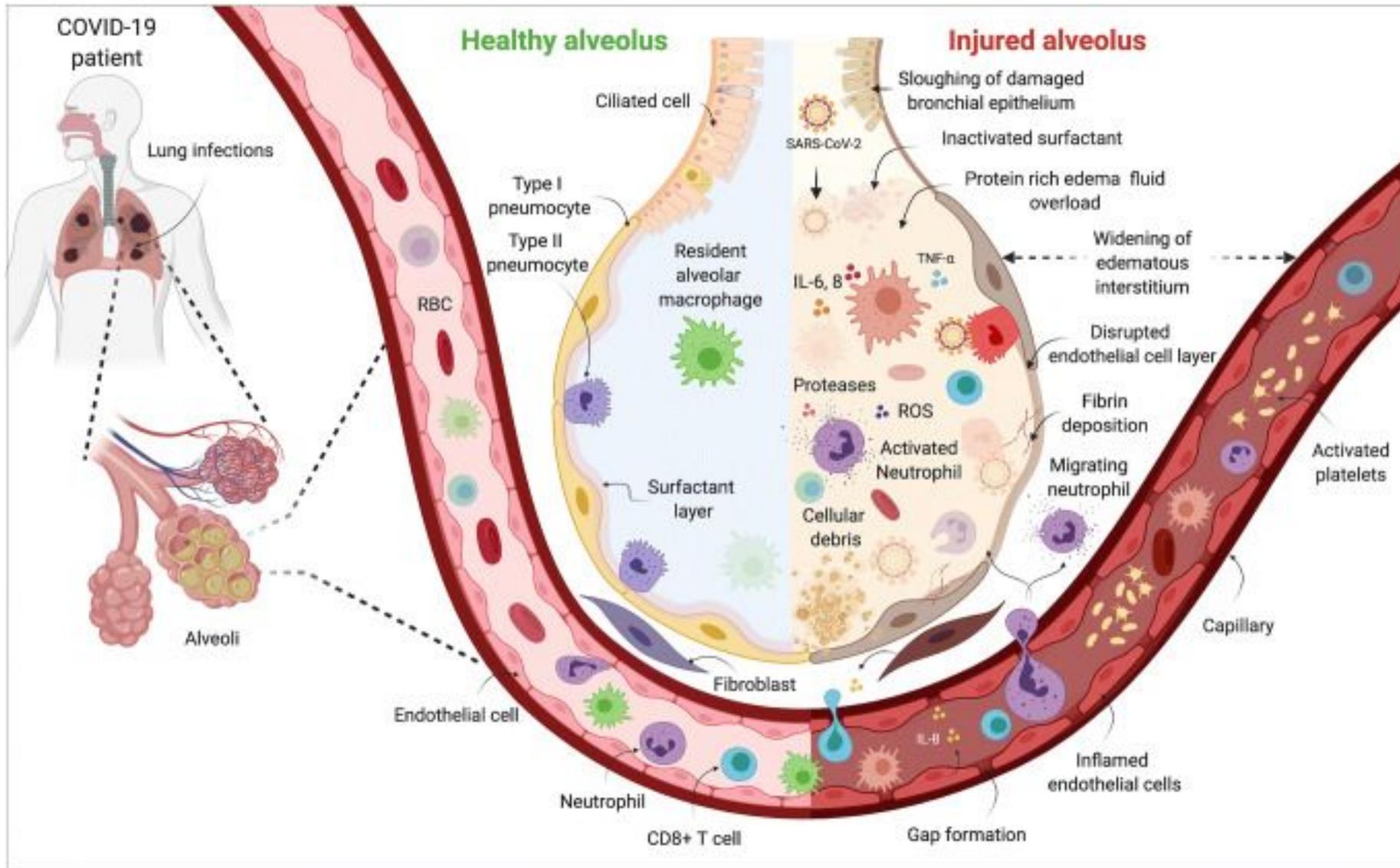
- Passes through mucosal membranes of the nasopharynx and larynx
- Enters the lungs via the respiratory tract
- Binds to ACE-2 protein on epithelial cells
 - Levels of ACE-2 expression may correlate with susceptibility!
- SARS-Co-V2 may enter the bloodstream via the lungs (viremia)
- Targets organs that express ACE-2: Lungs, Heart, Kidneys, Gastrointestinal Tract
- Symptoms: Fever, Cough, Shortness of Breath

EFFECTS OF SARS-COV2

Phase 2: Acute Phase (Severe):

- Respiratory/Pulmonary infection
- Immunopathogenesis, cytokine storm
- Possible progression to ARDS (5% of cases)
- May progress to multi organ failure and death
(*mortality rate: 2.4% Feb 2020*)

RESPIRATORY EFFECTS OF SARS-COV2



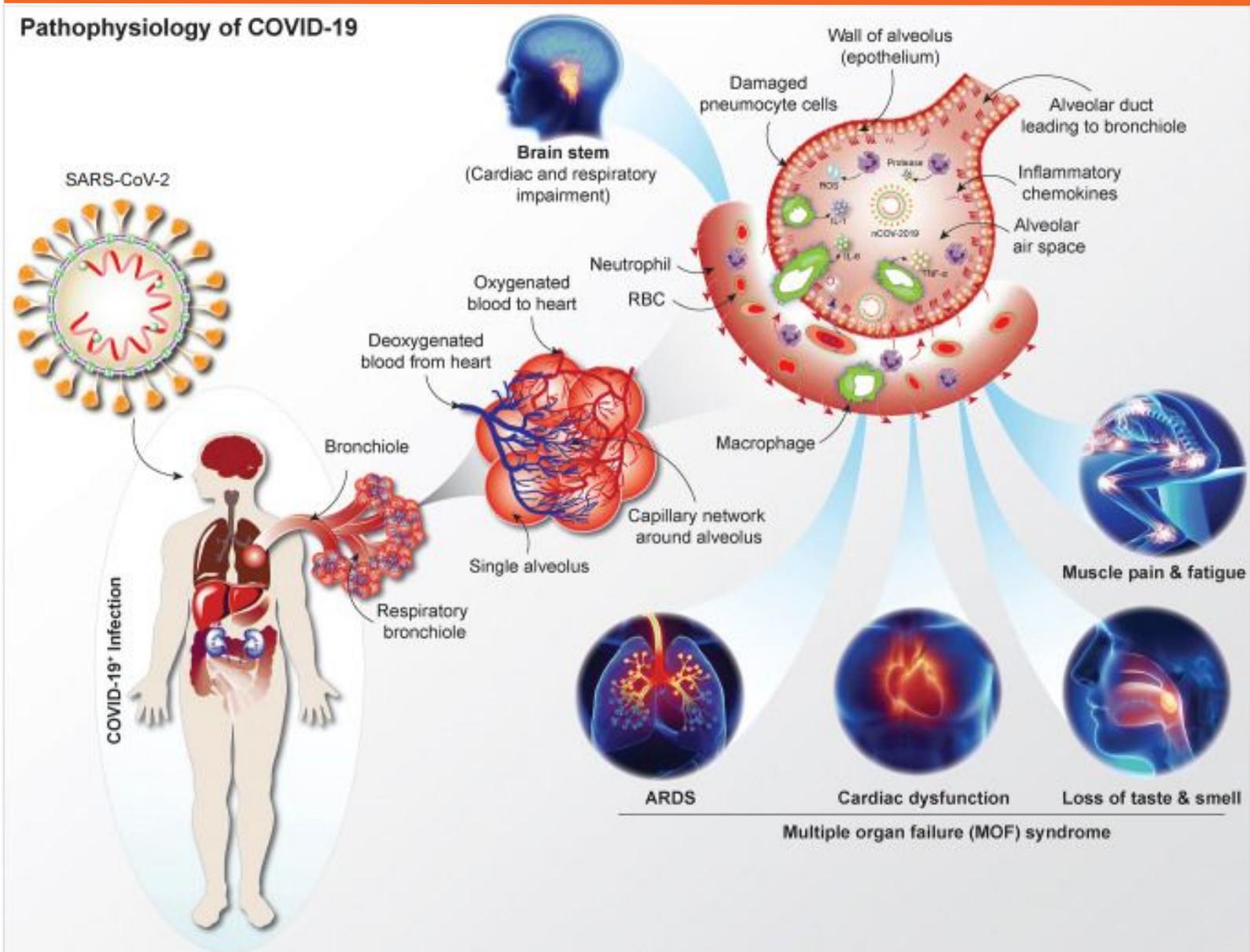
- Bronchial epithelial damage
- Pulmonary edema
- Local inflammation
- Platelet activation
- Vascular endothelial damage

Image source:

Machhi J, Herskovitz J, Senan AM, et al. The Natural History, Pathobiology, and Clinical Manifestations of SARS-CoV-2 Infections [published online ahead of print, 2020 Jul 21]. *J Neuroimmune Pharmacol.* 2020;1-28.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7373339/>

PATHOPHYSIOLOGY OF COVID-19



- Respiratory viral droplets infect ACE-2 expressing epithelial, endothelial, neuronal and immune cells
- Viral replication triggers dysfunctional innate immune response
- Systemic inflammation can cause cytokine storm and may lead to multiple organ failure

Image source:

Machhi J, Herskovitz J, Senan AM, et al. The Natural History, Pathobiology, and Clinical Manifestations of SARS-CoV-2 Infections [published online ahead of print, 2020 Jul 21]. *J Neuroimmune Pharmacol.* 2020;1-28.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7373339/>

EFFECTS OF SARS-COV2

Phase 3: Recovery Phase:

- Reduced pulmonary function
- Respiratory muscle function
- Increased susceptibility to respiratory pathogens

RESPIRATORY MUSCLES DURING INFECTION

- In healthy adults, respiratory muscle capacity (indicated by MIP) is 2.5 to 3 times larger than required for ventilation during normal breathing - making breathing HIGHLY EFFECTIVE
- In people with reduced respiratory muscle performance (age, obesity, lung disease, heart failure) the demand on the respiratory muscles is increased 3-fold, increasing the work of breathing
- During respiratory infection, the work of breathing may also be increased
- Inflammation of the lower airways can cause insufficient ventilation, leading to chest distress and dyspnea, and with alveolar damage may lead to ARDS
- Prior impairment of respiratory muscles/respiratory muscle weakness (RMW) may enhance dyspnea and respiratory distress during infection



RMW DURING COVID-19

Definition of RMW:

- MIP < 70% of predicted value

Reasons for RMW:

- Respiratory Muscle Atrophy or Impairment due to:
 - Increased work of breathing
 - Respiratory infection

Symptoms of RMW:

- Dyspnea, Fatigue, reduced QoL

Consequences of RMW:

- Inability to meet increased demand for ventilation (dyspnea, fatigue)
- Inability to prevent/delay respiratory distress or failure
- Increased risk of MV
- Increased risk of adverse outcome

RESPIRATORY MUSCLE TRAINING (RMT)



RMT is a direct treatment of RMW by strengthening:

- **Inspiratory Muscles:**
 - Diaphragm, external intercostals, accessory muscles
- **Expiratory Muscles:**
 - Internal intercostals, abdominals
- **Muscles** of deglutition and phonation

BENEFITS OF RMT

CLINICAL EVIDENCE: REDUCE SYMPTOMS OF COPD IN TWO WEEKS USING THE BREATHER

- **Strengthens:**
 - **Inspiratory Muscles:** diaphragm, external intercostals, accessory muscles of neck
 - **Expiratory Muscles:** internal intercostals, abdominals
- **Other Benefits:**
 - Generates improved **airflow** through vocal folds
 - Decreases **shortness of breath**
 - Improves respiratory support for **safe swallow** function
 - Promotes **protective cough** and assists in airway clearance

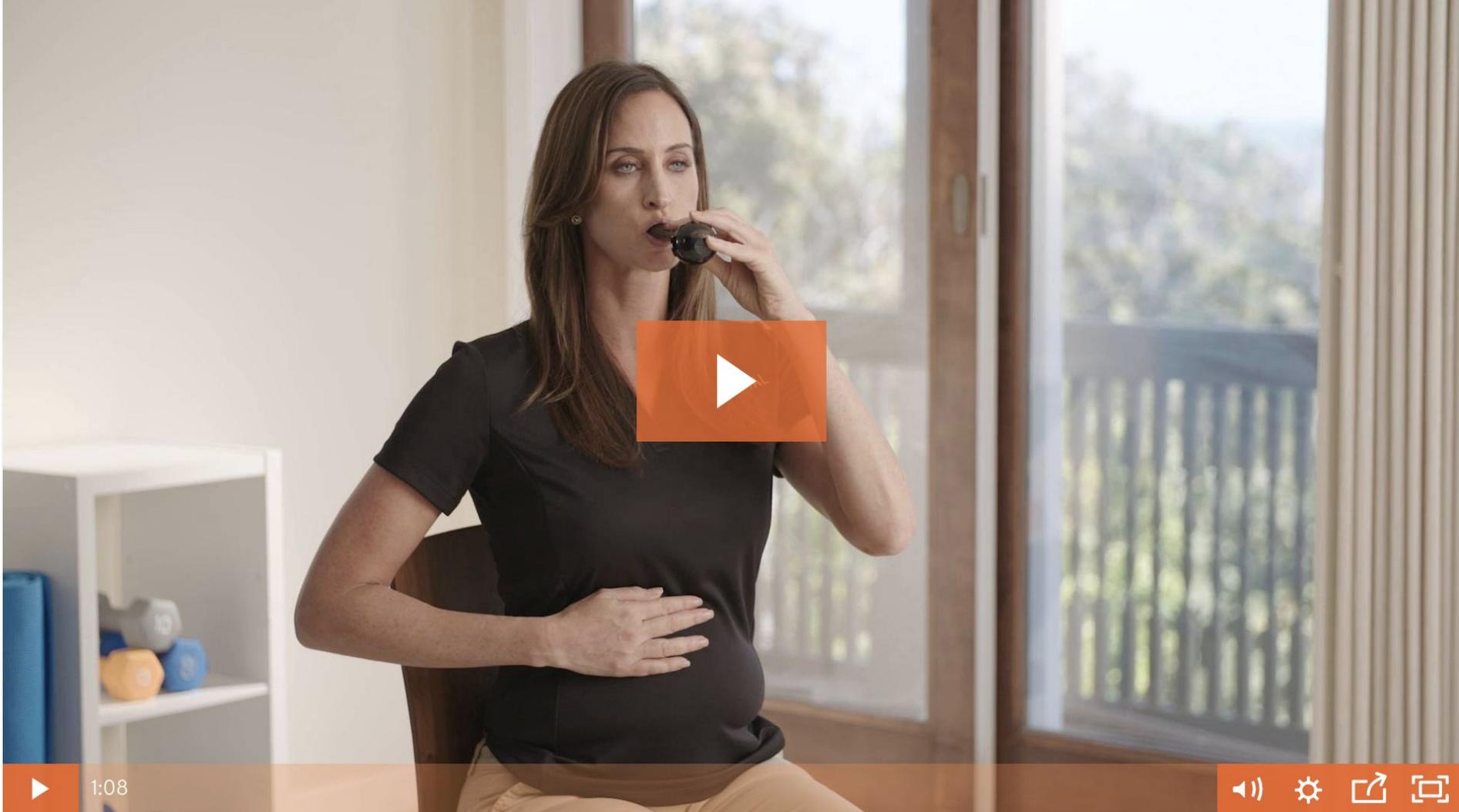
GENERAL PROTOCOL

1. Sit upright and hold the mouthpiece between your lips
2. Breathe in and out through the Breather using deep slow breaths
3. At training onset, set both inhale and exhale dials to 1 and 1
4. Regularly adjust dial settings so you can manage 10 breaths at 60-70% effort
5. Do 2 sets of 10 breaths 2 times per day
6. Repeat 6 days per week

Benefits should become apparent between 2 to 4 weeks of training.



GENERAL PROTOCOL DEMONSTRATION



RMT DURING PREHABILITATION

Preventive Strategies:

- Assess respiratory muscle performance in at risk patients **before** infection.
 - Risk factors include:
 - Age (The Elderly)
 - Smoking
 - Obesity
 - Chronic Lung Disease
 - Heart Failure
 - Dyspnea/Exercise Intolerance
- Assess by MIP/MEP or TIRE
- Build up respiratory muscle strength by using RMT
- Effects can be seen after 2 to 4 weeks, depending on baseline
- **RMT can help increase resilience to complications from respiratory pathogens**

RESPIRATORY STRENGTH: ACTIVE INFECTION

During acute stages of infection, the built-up respiratory muscle performance may help to reduce the risk of:

- Respiratory distress
- Respiratory failure
- Mechanical ventilation

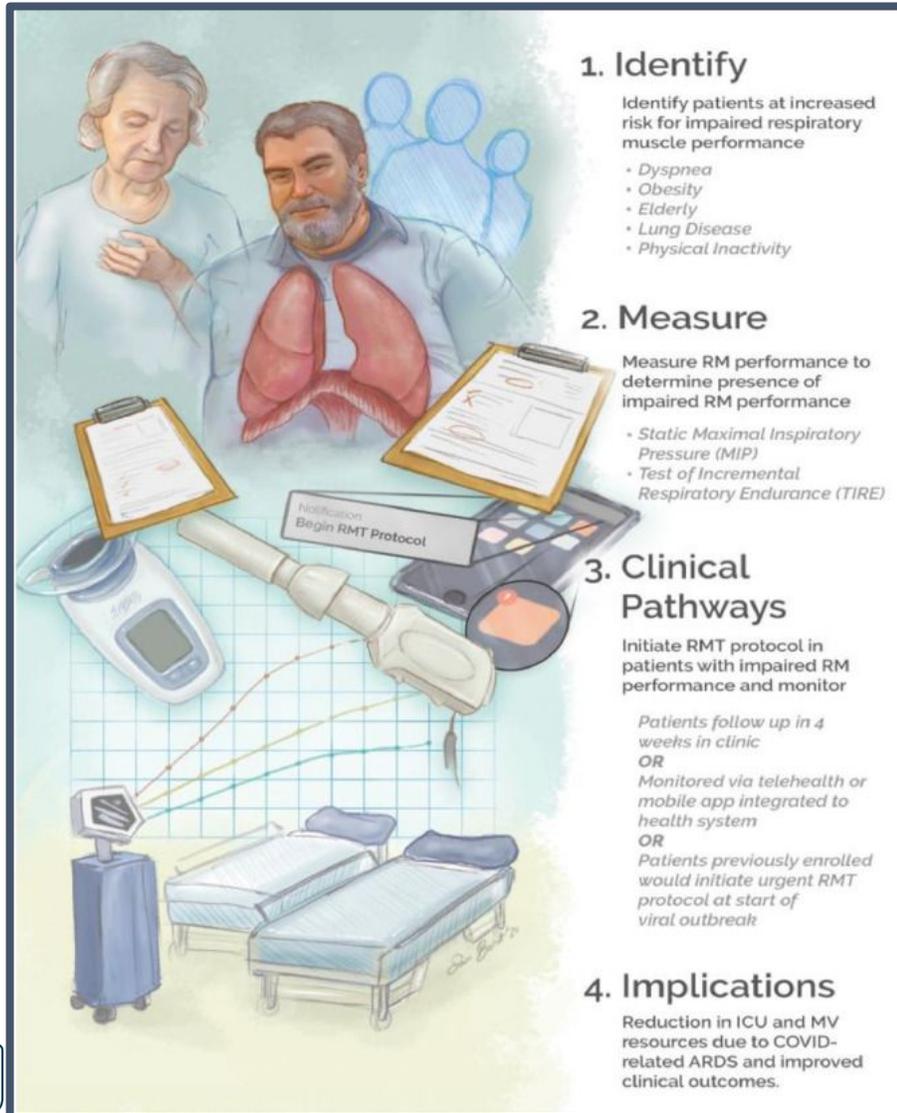
In case of mechanical ventilation, the built-up respiratory muscle performance may help to reduce the risk of:

- Prolonged mechanical ventilation
- Reduced risk of pulmonary complications

RMT DURING REHABILITATION

- RMT can be initiated in the post-acute stage, particularly after severe cause of disease
- RMT restores respiratory muscle strength that may have been lost due to atrophy during hospitalization and mechanical ventilation
- Rebuilding respiratory muscle performance can help to:
 - Increase exercise tolerance and mobility
 - Reduce the risk of downstream respiratory infections
 - Improve quality of life
 - Reduce readmission rates
- Increased resistance against subsequent complications

THEORETICAL RISK REDUCTION MODEL



1. Identify patients at increased risk for impaired respiratory muscle performance
2. Measure respiratory muscle performance to determine presence of impaired respiratory muscle performance
3. Clinical Pathways - initiate RMT protocol in patients with impaired respiratory muscle performance and monitor

Source: Severin R, Arena R, Lavie CJ, Bond S, Phillips SA. Respiratory Muscle Performance Screening for Infectious Disease Management Following COVID-19: A Highly Pressurized Situation [published online ahead of print, 2020 Apr 25]. *Am J Med.* 2020;S0002-9343(20)30347-8.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7182755/>

A woman with long brown hair and blue eyes is shown in profile, looking upwards and to the right. She is holding a blue and white nebulizer in her mouth. The background is a bright, out-of-focus indoor setting with greenery.

STAY TUNED

THE ROLE OF RMT DURING COVID-19 PART 2:

IMPLEMENTATION,
TELEHEALTH &
CONTINUED CARE



Thank You!

Any Questions?

care@pnmedical.com

877-414-4449



PN MEDICAL

Q: Has The Breather been used in clinical trials?

A: Yes, The Breather has been investigated in several clinical trials, as well as in a range of pilot studies.

To summarize some of the main outcomes that were observed:

1. A clinical study in COPD patients showed that 2 weeks of RMT using the Breather increased MIP by 31% and 6MWD by 55 ft.
2. In a case study, a patient with SCI used the Breather for 6 weeks, and improved his MIP by 113%, his MEP by 117%, and his peak cough flow by 67%.
3. In a home health setting, 4 weeks of using the Breather led to a 92% increase in peak expiratory flow and a 116% increase in maximum phonation time in COPD patients.
4. Additional studies using the Breather have shown for example that using the Breather nicely activates the hyolaryngeal muscles, as shown by sEMG, which is an important point for using the breather with dysphagia patients.
5. Also, the athlete's version of the Breather, Breather Fit, has been tested by the military, where it dramatically increased selection rate for special forces recruitment.
6. We have a number of ongoing studies as well. One IRB, funded by Mayo Clinic, has an aim to demonstrate the benefit of using The Breather in pre and post surgery for LVAD patients.

Recent Studies Published Using The Breather -

<https://www.pnmedical.com/category/clinical-trials/breather/>

Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com



Questions Answers

Q: How long would you suggest that a patient use the same Breather device before replacing it with a new one? Is there a need to replace it?

A: The Breather Device has a one year warranty

Q: What pressure does each number on the breather represent?

A: The pressures generated by the specific settings of the Breather are flow dependent, and differ in healthy people/athletes/those with respiratory impairment. Please have a look at our website for typical pressure ranges.

Q: Does Medicare cover these devices? Do I need the physician to write a script for the Breather device?

A: You don't need a script to use the Breather but you need your eval and treat order as normal. Facilities typically purchase these for the patients. I have not seen medicare cover these in my experience.



Questions Answers

Q: What do you recommend as most objective and accurate test or measurement to assess RMW?

A: The definition of RMW is that the respiratory muscle strength is reduced to equal or less to 70% of predicted value, assessed by maximum inspiratory or expiratory strength (MIP/MEP). Additional indicators for/manifestations of RMW include dyspnea, reduced exercise tolerance, dysphagia, dysphonia, etc.

Q: Orders are usually the CPTs that will be billed not component of the code ie ther ex vs quad , trunk and respiratory ms ex. too limiting that way.

A: The code used is based on the intent of tx. For example it could be billed as ther ex, neuromuscular re-ed, Speech tx, etc. We recommend reaching out to your company's clinical department for guidance related to coding policy.

Q: With COPD Patients demonstrating decreased breath support, would you use voice tx code or speech tx code?

A: It depends on your setting, state and MACS or Fiscal Intermediaries but I've seen speech code used in that scenario.



Questions Answers

Q: Would Med A cover the device?

A: The Breather is used as a tool during treatment, so the facility usually purchases those under the Med A coverage, and then they are distributed to the patients. It's very cost effective.

Q: Do you need an order from an MD?

A: No, you don't need an order from a physician in home health or skilled nursing. You need an order for a valid treatment, and the Breather is a tool you would use for that treatment.

Q: What have you found to be a common reason for a medicare denial?

A: I have worked on denials for part a and b throughout my career, but I have not seen any related to RMT related to RMW.

Q: Can the breather be ordered by physician via SLP so that it can be covered by Medicare? Can breather used be in conjunction with LSVT?

A: Ask your HH Manager how things are billed to medicare. I have not seen the Breather reimbursed in my setting by medicare but it is worth a try. Many companies will purchase these for the patients due to the return on investment coming in outcomes and appropriate length of stay saving money in the long run. This would compliment LSVT well.



Questions Answers

Q: What studies have been done with the Breather in various disciplines and disease states?

A: I recommend you [Go Here To Read The Latest Studies](#). We update the list monthly that have been published using our devices.

The Breather has been used in COPD studies where it has been shown to improve respiratory muscle strength, exercise tolerance and reduce the symptoms of dyspnea in COPD. This was an independent trial.

In another study the Breather has been used in home health with COPD patients over four weeks. It has been shown to improve peak expiratory flow and maximum phonation time roughly by about a hundred percent over four weeks.

The Christian University of Texas, Dr. Watts has shown by surface EMG how the Breather actually activates the submandibular muscles here while you're using it during inspiration as well as during expiration. He saw a really nice activation during inspiration and expiration. This ties back to the question before, should we treat both parts of the breath cycle? Absolutely, because you're actually training those muscles with both parts using the Breather.

Go here to see the latest studies that have been published. It's updated monthly - [Go Here To Read The Latest Studies](#)

Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com



Q: How do you know the patient's baseline resistance, and when they're ready to increase resistance?

A: The baseline can be established either by using a manometer, or by observation during a set of RMT. Puffing cheeks on exhale or light headedness are indicators to reduce the settings, low effort to complete a set would indicate that the settings should be increased. Use your clinical judgement to determine the optimal training intensity for each individual patient. Please note that settings for inhale and exhale should always be determined independently of each other, as the muscle groups for inhale and for exhale gain strength at different speeds.

Q: Is it possible to implement RMT with a patient with a trach?

A: Yes, that is possible, but you have to use your clinical judgement. Maybe try whether the patient can finger occlude first? I have used RMT with patients with a trach and I have them finger occlude while they do the Breather. It's real easy to take their hand off if they start to feel panicky or short of breath. This is a great way to increase respiratory muscle strength towards goals of using the Passy-Muir valve, or goals of capping the trach, or eventual goals of discharging. The use of RMT is very appropriate here. It's important to have your tools on hand to monitor vitals, and checking in with the patient on how they're feeling.



Questions Answers

Q: What do you recommend as most objective and accurate test or measurement to assess RMW?

A: The definition of RMW is that the respiratory muscle strength is reduced to equal or less to 70% of predicted value, assessed by maximum inspiratory or expiratory strength (MIP/MEP). Additional indicators for/manifestations of RMW include dyspnea, reduced exercise tolerance, dysphagia, dysphonia, etc.

Q: What is the recommended training protocol ? What is the training load?

A: Please have a look at our website for specific use case protocols. Our standard training protocol recommends 2 to 3 sets of 10 breaths twice a day at around 70% of maximum effort. However, clinical judgement should be used to tailor the protocol to each individual patient. Several SLPs that we are closely working with recommend for example 5 sets of 5 breath at target effort, if that feels more achievable for the patient. In addition, many patient benefit from a few breaths as a warm up before eating to improve swallow function and reduce aspiration.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Does it make sense to vary the inspiratory and expiratory part of RMT (ie do inspiratory or expiratory only)?

A: In most cases it is beneficial to train both parts of the breath cycle. For example, if your inspiratory muscles get stronger by doing inspiratory muscle training and you start increasing your exercise tolerance and being more active, you also want your expiratory muscles to be strong, to then excrete the CO₂ that you're producing, because expiration usually is just passive. So it's really good to get those muscles strong as well. Or for example, if you want to improve your cough effectiveness, you need really strong expiratory muscles, but you also need really strong inspiratory muscles to draw the air in before you produce an effective cough.

However some patients with dysphagia or swallow problems may prefer in some instances to only train the expiratory muscles to really focus on these, your muscles. So before they have a meal, they try to warm up and engage those expiratory muscles just in order to, if they aspirate, really cough out effectively. And it might make sense to do maybe one or two sets of five breaths on a really high expiratory setting. But in general we would recommend to train both parts of the respiratory cycle.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: I am wondering if you would be able to compare The Breather to EMST-150, specifically in terms of improving swallowing physiology?

A: In contrast to the EMST-150, the Breather strengthens both inspiratory and expiratory muscles to improve swallow physiology. Breather and Breather Fit offer a wider range of pressures that can be generated and may therefore be suitable for a more expansive patient range. Based on these assessments, benefits of both devices should be comparable, with the added benefit of strengthening the inspiratory muscles, causing reduction in dyspnea and increasing exercise tolerance, by the Breather. The Breather has been used extensively in patients with swallow impairment.

Q: Are you aware of any community support groups that help discharge patients be successful? My thought is around a community chronic disease support group.

A: The American Lung Association has support groups across the nation. Info can be found on their website and they may have a local chapter for you. Many senior centers offer groups related to diagnosis as well.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Q: How does the Breather compare to Incentive Spirometry (IS)?

A: IS helps you to breathe deeply and to learn the proper breathing pattern again, to really take a deep breath. And that helps clearing the lungs and to establish a breathing pattern. But what incentive spirometry doesn't do is to actually improve respiratory muscle strength. So incentive spirometry you doesn't provide any of the benefits that you get from RMT. So you don't get reduced dyspnea, you don't get the exercise tolerance, you don't improve your cough effectiveness.

And it is also been shown the incentive spirometer is used in most institutions still to prevent postoperative pulmonary complications (PPC) such as pneumonia and atelectasis, and that evidence actually is really outdated now. It has been shown that RMT provides much better results here if you use it before surgery or after surgery as soon as possible, upon extubation, that you can really reduce the incidence of PPC by up to 50%. That has been shown. RMT reduces the length of stay, and the length of stay in the ICU. So especially in the perioperative setting the incentive spirometer should really be replaced by RMT. If your patients really like to use the incentive spirometer, by all means continue using it. But we really recommend that you maybe have a respiratory muscle training as an adjunct therapy there, and to actually get them to improve the respiratory muscle strength.



Questions Answers

Q: Can RMW be determined without using a manometer?

A: While a bona fide diagnosis of RMW can not be confirmed without establishing MIP or MEP using a manometer, the underlying diagnosis, patient history and present symptoms can give a good indication of RMW. While dyspnea and exercise intolerance are good indicators for RMW, additional symptoms such as fatigue and reduced hr QOL may also imply the presence of RMW. Dr Aldarondo may want to elaborate on that.

Thank you Nina, the presence of increased respiratory muscle work as well as cachexia may be predictors of established RMW. As RMT has no side effects, it should be considered in all cases of suspected RMW due to its beneficial effects.



Questions Answers

Q: What is the difference between resistive and threshold devices?

A: With a threshold device, you have to overcome an initial pressure to open a valve, and that's the target pressure. Once the valve is opened, there is no resistance to the airflow anymore.

The difference to resistive devices like The Breather is that the resistance that your muscles are working against is constant throughout the entire breath cycle, so your inspiratory and expiratory muscles are working for the entire 2 to 3 seconds during inhale and during exhale. This puts a more sustained workload on the muscles.

In 2019, this was demonstrated in a study commissioned by Dr Watts of **Texas Christian University**. They confirmed considerable muscle activation using sEMG during both inspiration and expiration through The Breather. [Texas Christian University Clinical Study \(Poster\)](#)

Direct comparisons between both methods have shown that both threshold and resistive devices strengthen the respiratory muscles, but that the curve of activation looks different, confirming this sustained muscle activation with resistive devices such as the Breather.

[Read The Evidence Of Resistive Vs Threshold](#)



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Q: Benefit of RMT To Reduce The Work Of Breathing Work of Breathing?

A: RMT reduces the work of breathing by improving respiratory muscle strength and ventilation. Direct evidence for reduced work of breathing due to Respiratory Muscle Training (RMT) has been provided by studies in COPD patients (<https://www.physiology.org/doi/abs/10.1152/jappl.1988.65.6.2726>) and in healthy individuals (<https://www.ncbi.nlm.nih.gov/pubmed/20187286>).

Q: Do you need a prescription?

A: No prescription needed. The Breather is a medical grade product and registered as a Class 1 device with the FDA. Click here for quick access to the Breather: <https://www.pnmedical.com/product/the-breather/>

Q: Is it covered by Medicare?

A: Medicare does not cover The Breather or any other RMT device; however, RMT may be covered if prescribed by a healthcare provider (used for therapeutic exercise; treatment of speech, language, voice, communication; group treatment) Stay tuned to PN Medical emails for an upcoming webinar regarding documentation and reimbursement changes (PDPM and PDGM).



Questions Answers

Q: Evidence for use of the Breather in Dysphagia?

A: Expiratory muscle strength is essential for optimal cough and swallow function. Strengthening of the expiratory muscles by regular application of the Breather can alleviate the symptoms of dysphagia by improving cough volume and acceleration, and reduces the risk of penetration and aspiration associated with dysphagia. Please see our website for further evidence:

<https://www.pnmedical.com/category/therapeutic-use/speech-swallow/>

Q: How is this related to SLP scope of practice to increase participation with PT if dysphagia and effective communication isn't the target?

A: In the example, the SLP evaluated the patient and determined breath support was a deficit impacting communication and quality of life. Communication is within the SLP scope of practice. Further, treating this underlying impairment also impacted their functional endurance increasing PT and OT participation.

Q: In order to maintain a consistent pressure within the airway, do you encourage a nose clip with the mouthpiece, or a mask to seal off the nose?

A: We recommend using nose clips and monitoring a tight seal of the lips around the mouthpiece to ensure consistent airway pressure.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Are there any studies related to using the RMT with a partially paralyzed diaphragm?

A: Yes, there are 2 case studies demonstrating the benefits of RMT on diaphragmatic paralysis:

<https://www.ncbi.nlm.nih.gov/pubmed/19111633>,

https://www.atsjournals.org/doi/10.1164/ajrccm-conference.2019.199.1_MeetingAbstracts.A3744, as well as a

clinical study showing that RMT effectively reverses diaphragm asymmetry after stroke:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4668180/>.

Q: Why is Breather not recommended for patients with Myotonic dystonia and how can it be modified for this client group?

A: There have been no clinical investigations in the use of RMT for myotonic dystonia. Use of the Breather for respiratory muscle strengthening is only recommended under strict supervision of the attending physician in order to prevent respiratory muscle fatigue or overexertion.

Q: Contraindications

A: During initial training, we recommend careful monitoring for episodes of acute exacerbation or excessive fatigue. Caution is advised before initiation of therapy for: active hemoptysis, untreated pneumothorax, recent esophageal surgery, acute upper airway stenosis (true vocal fold mass, vocal fold paralysis in adducted position, subglottic stenosis), recent oral, facial or skull trauma / surgery, acute sinusitis, epistaxis, hemodynamic instability, tympanic membrane rupture or acute middle ear pathology (otitis, labyrinthitis).

Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com



Questions Answers

Q: What about issues of having the Breather stick?/Whistle sounds/defective device?

A: Most issues of “sticky” diaphragms on the Breather or whistle sounds derive from inadequate or insufficient cleaning of the device. Please visit our website for manufacturer’s recommended cleaning:

<https://www.pnmedical.com/lessons/breather-how-to-clean/> Should the problem persist, please contact our customer service.

Q: I have pulmonary hypertension which is presumed to have been caused by undiagnosed sleep apnea. Will the Breather help? I do use a CPAP machine now.

A: Yes, RMT has been shown for sleep apnea, improving both quality and quantity of sleep, especially in mild to moderate cases:

<https://www.pnmedical.com/therapeutic-use/other-diseases/effect-of-rmt-on-sleep-architecture-in-obstructive-sleep-apnea/>.

In addition, RMT has proven effective in Pulmonary Hypertension (https://erj.ersjournals.com/content/52/suppl_62/PA1718), so the Breather may offer a holistic approach to both disorders here.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: I have a hole in my neck from the removal of a trach. is it safe for me to use the Breather? If you were intubated 2+ years ago and the opening in your neck has not completely closed, is it still okay to use the Breather? The hole from the intubation will eventually need surgery. Should The Breather training be put off until the surgery can be completed? Would it be harmful to use The Breather before the surgery ?

A: Use of The Breather may be possible if you are able to cap or close the trach stoma during RMT. Please discuss with your surgeon/physician for confirmation related to your individual condition and guidance.

Q: How does the patient know when they are using 60% capacity. I have a breather and don't know how to measure effort.

A: For accurate measurement, a manometer can be used in series with the Breather. Accessory kits are available from: (<https://voiceaerobicsdvd.com/product/rmt-accessory-kit/>). However, subjective effort perception is normally sufficient for training success: AT 60% of maximum capacity, one set of 10 reps through the Breather should feel “somewhat hard”, with the potential of doing another 3 to 4 reps at the same setting before getting out of breath. If you can do another 10 reps without break, the settings are too low, if you can't finish a set of 10, it's too high. Always remember that inspiratory and expiratory setting should be determined and set independently of each other, as inspiratory muscles often gain strength quicker than expiratory muscles.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: How can a multidisciplinary team screen for possible benefit from respiratory muscle training and identify which discipline would be best to target it? (without tools to assess)

A: Best guidance is the primary diagnosis or chief complaint. For example, in the case of dysphagia as chief complaint, Speech Therapy would be the most suitable discipline to apply RMT. In the case of dyspnea and exercise intolerance due to COPD or heart failure, PT, OT or RT may be suitable - dig deeper to determine what function the intolerance is impacting. There may be times any of the disciplines could address RMW. As an interdisciplinary team, determine which discipline will integrate RMT in treatment while others may play more of a supportive role. For example no RT available, PT provides training in RMT, OT reinforces carryover of use of Breather and logging use with ADL training. For quick access to the training log visit: <https://www.pnmedical.com/wp-content/uploads/2019/03/The-Breather-Training-Journal-4-Week-Version-1.pdf>

Q: Could you compare/contrast with the emst150?

A: Devices that provide EMT only, which are predominantly used for cough, airway clearance and swallow problems (EMST-150, Resistex), fail to address the importance of the inspiratory muscles for these functions.

While EMT undoubtedly has a beneficial effect on dysphagia and swallowing, studies on people with neurological disease have shown that “(the) number of swallows per bolus and swallowing time correlated to maximal inspiratory pressures (MIPs) but not to maximal expiratory pressures (MEP).” Inspiratory muscle strength therefore is essential for swallowing function, a fact that is widely neglected. The Breather provides both IMT and EMT and offers a more balanced effect, training all respiratory muscles, increasing both MIP and MEP, which should enhance the effect on swallowing function in dysphagia.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Would you recommend The Breather to be used with IOPI? Or use one before the other?

A: IOPI measures tongue and lip pressures, which may improve in tandem with respiratory muscles strengthening when RMT is carried out. However, RMT can only establish direct impact on respiratory muscles, not in the tongue and or lip muscles, as there are too many anatomic and functional variables to correlate the two muscle groups.

Q: Would this be recommended for Passy Muir users ?

A: We recommend integrating RMT with using a Passy Muir Valve, since improving RMW and glottic function is expected to improve phonation further.

Q: Is the pressure itself measurable?

A: The pressure generated can be measured by using a manometer in series while using the Breather. Manometer kits for use with the Breather are available from <https://voiceaerobicsdvd.com/product/rmt-accessory-kit/>.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Why can't you hold The Breather by your teeth? How does that affect the training?

A: The mouthpiece is ergonomically designed to support people with poor lip strength, and to prevent air leakage due to tighter lip seal. It also stimulates the muscle network around the lips. Holding the mouthpiece by the teeth puts undue pressure on the jaw and makes it harder to achieve lip seal around the mouthpiece.

Q: I've had my Breather for awhile now and I am at setting 6 inhale & 5 exhale. I assumed I should simply just continue, at these settings, for my maintenance, correct?

A: Congratulations on getting your respiratory muscles into great shape!

Good news, you can continue improving your strength! We offer the Breather Fit for athletes and people who start RMT from a higher baseline. **Breather Fit** offers higher training intensities due to increased resistance at each setting, which could take your respiratory muscle strength to the next level. Check it out here:

<https://www.pnmedical.com/product/breather-fit/>



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Respiratory muscle dysfunction due to direct effect of virus or indirect due to lung changes and or being placed on a ventilator?

A: It's a hard question to answer, as those patients at high risk (obese, elderly) may already be compromised, and mechanical ventilation, as well as inactivity due to the disease will contribute to respiratory dysfunction. However, it is unlikely that the virus itself is causing respiratory dysfunction, although some contribution during viremia cannot be excluded. Compromise of the respiratory muscles is a consequence of the illness, a secondary problem, rather than a direct consequence.

Q: Will we have the opportunity to discuss how the Breather is viewed in light of concerns of aerosol-generating procedures during current COVID-19 precautions in center locations? Thank you

A: We will discuss this in part II of this webinar, so stay tuned.



Questions Answers

Q: Is there any benefit to using resistive trainers over pressure threshold trainers? Or any contraindications for using a pressure threshold trainer over a resistive trainer? Thank you.

A: Independent research comparing the effects of threshold and resistive RMT on respiratory function, exercise capacity and hrQOL in COPD patients demonstrate clinically relevant efficacy of both methods in improving different respiratory and health status related parameters. In addition, resistive RMT has proven superior to threshold RMT with regards to hrQOL, exercise capacity and endurance, including VO2max.

Q: Improvement with training due to improved motor control, rather than changes to muscles? How close are the training breathing patterns to normal breathing patterns (training specificity)? Thanks

A: RMT improves the envelope of function, improving MIP and increasing efficiency, it may also improve airway compliance, there may be also an increase in thickness, just like other muscles respond to training. There may be changes in contractility and excursion. This is still under investigation. The change respiratory muscle metaboreflex in response to RMT may also be of importance here. This may improve efficiency or increase tolerance is still under investigation. We see changes in respiratory muscle activity; improving muscle strength makes them more efficient so they can reduce their activity and don't have to be hyperactive anymore, like eg in COPD.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: How does the "Breather" compare to a incentive spirometer and/or flutter valve?

A: OPEP devices offer some resistance, they are airway clearance devices, but only work on exhalation, and don't work on the inspiratory muscles. However, OPEP devices support airway clearance and pulmonary hygiene, and may be a good adjunct device to RMT.

Dr. Aldarondo :Unlike RMT, Incentive spirometry does not offer resistance and therefore the patient will not see any gains with respiratory muscle strength or endurance .

Q: Do patient fatigue while doing their 20 breaths session?

A: The target effort of RMT should be set so the patient trains in the zone of around 70% of maximum effort, without fatiguing the respiratory muscles. The diaphragm is resistant to fatigue unless worked at extensively over a longer period of time.



Questions Answers

Q: Are there advantages to separate the inspiratory and expiratory training cycles for the COVID population since their RV is significantly diminished?

A: Inspiratory muscle strengthening is probably the main contributor to diaphragm strengthening and addressing dyspnea, while expiratory muscle training may be less effective in this setting, but offering combined RMT may be useful.

Q: How effective is the resistive breather in someone who currently still chooses to smoke? Our home health company provides breathers for our clients at no charge, I want to use them wisely.

A: Research has shown that strengthening of the respiratory muscles is beneficial in smokers, improving muscle strength and pulmonary function (<https://pubmed.ncbi.nlm.nih.gov/30953791/>), making RMT a useful therapy approach.

Q: Will you be giving certificates to attendees of this webinar? :)

A: I gave my direct email for those needing a certificate



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Can you touch on lung cancer patients, specifically those who experience fluid overload requiring occasional thoracentesis. RMT good or bad?

A: The patient w lung cancer may inherently experience generalized weakness and the direct impact of the neoplasm(compromised ventilation,pleural effusions,upper airway dysfunction e.g.vocal cord paralysis,etc) on the respiratory apparatus will potentiate this resulting in severe [dyspnea. In](#) a stable lung cancer patient with respiratory muscle weakness,RMT may offer additional benefit,as long as other factors are addressed satisfactorily e.g. draining a pleural effusion.

Q: The Breather is too expensive for my patients. Do you have suggestions for a cheaper version, or thoughts on other breathing practices such as Qigong?

A: Advice depends on your underlying health problem. If possible, exercise does train your respiratory muscles somewhat, and breathing strategies such as Qigong and ypgic breathing offer health benefits, including activation of the autonomic nervous system and stress reduction.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: Does the RMT suggested focus only on diaphragmatic breathing? Is there any purpose for clavicular breathing?

A: As the diaphragm is the main breathing muscles, and strengthening of the diaphragm is tightly linked to the observed benefits including reduced dyspnea, increased exercise tolerance, oxygenation, cardiac parameters, and posture, RMT focusses on diaphragmatic breathing. However, RMT as well as adjunct breathing strategies promote full inhalation/exhalations, activating all respiratory muscles, including those of the chest, neck and shoulder regions.

Q: Can you give any ideas of goals to use for a PT specifically regarding use of the Breather?

A: I know this PT personally and I will reach out and provide her with support

Q: Can you have an SLP on the next webinar?

A: I referred this person to our website for our webinars featuring SLPs using RMT



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: I was startled to hear Dr. Aldarondo say that they see major transmission of Covid 19 through touching objects. The CDC has emphasized that aerosolized particles are the main source of transmission. So my question is how much transmission through paper, plastic, counter surfaces, etc, are they seeing?

A: While direct transmission via droplets seems to be the major transmission route, transmission via fomites on surfaces is considered a main contributor as well. Here are some articles of interest:

<https://pubmed.ncbi.nlm.nih.gov/32729311/>, <https://pubmed.ncbi.nlm.nih.gov/26597631/>

Q: Can COVID pass thru the placenta and infect the infant?

A: This subject is still highly debated. According to the literature, virus material appears to be able to pass the placenta, but direct vertical transmission (ie infected newborns) has not been confirmed yet to our knowledge.



Questions Answers

Q: Is there any treatment you recommend upon a positive COVID-19 test, before onset of symptoms?

A: Make sure you practice self-quarantine to protect others, and protect yourself by e.g. stop smoking, take you asthma medication etc. Watch your symptoms, and when fever persists, dyspnea develops and hypoxemia is present, search advice or report to hospital, especially if you are part of a high-risk group (asthmatic, diabetic, obese, etc). RMT is not indicated at the active stage of infection.

Q: Has there been an anti thrombotic that has been more beneficial for these patients?

A: There is a propensity of venous and arterial thrombotic events, and anticoagulant therapy has to be individualized. Monitoring has to be proactive to monitor for lower extremity thrombosis, as well as for arterial thrombosis, and anticoagulation is very indicated here, and may include anti-thrombotics as well as conventionally used heparin. D-Dimer titres should be monitored closely and guide treatment.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

Questions Answers

Q: What is the difference between this and the standard post up incentive spirometer ?

A: Incentive spirometers offer no resistance and therefore don't increase respiratory muscle strength. They may improve lung recruitment, but the evidence for that is actually quite poor as well.

Q: How much investigation has there been into the etiology of endothelial cell damage to the capillaries?

A: As with anything COVID-19 related, research is preliminary and constantly updated. The role of the endothelial damage in COVID-19 pathogenesis remains unclear, but is still considered a potential future target for treatment. Here's an open access article that may be of interest: <https://pubmed.ncbi.nlm.nih.gov/32791568/>

Q: Cost of the Breather?

A: The Breather is currently available from pnmedical.com at \$47.95



Questions Answers

Q: How do you distinguish normal post-COVID recovery from myocarditis?

A: Myocarditis runs a spectrum from mild to severe, the biggest concern is that it may lead to cardiomyopathy and heart failure, and that is a concern in any viral infection, as they may cause more thrombotic events and arrhythmia. This may compromise organ perfusion elsewhere, etc. This is not as severe during COVID, but assessment and monitoring should be similar in association with COVID as without.



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com

CITED REFERENCES

1. Mello PR, Guerra GM, Borile S, Rondon MU, Alves MJ, Negrão CE, et al. Inspiratory muscle training reduces sympathetic nervous activity and improves inspiratory muscle weakness and quality of life in patients with chronic heart failure: a clinical trial. *J Cardiopulm Rehabil Prev.* 2012;32: 255–261.
2. Janssens L, Brumagne S, McConnell AK, Claeys K, Pijnenburg M, Burtin C, et al. Proprioceptive changes impair balance control in individuals with chronic obstructive pulmonary disease. *PLoS One.* 2013;8: e57949.
3. Ferraro FV, Gavin JP, Wainwright T, McConnell A. The effects of 8 weeks of inspiratory muscle training on the balance of healthy older adults: a randomized, double-blind, placebo-controlled study. *Physiological reports.* Wiley Online Library; 2019;7: e14076.
4. Eekhoff EMW, van Schoor NM, Biedermann JS, Oosterwerff MM, de Jongh R, Bravenboer N, et al. Relative importance of four functional measures as predictors of 15-year mortality in the older Dutch population. *BMC Geriatr.* 2019;19: 92.
5. Bausek N, Havenga L, Aldarondo S. Respiratory Muscle Training Improves Speech and Pulmonary Function in COPD Patients in a Home Health Setting - a Pilot Study [Internet]. *bioRxiv.* 2019. p. 523746. doi:10.1101/523746
6. Terzano C, Ceccarelli D, Conti V. Maximal respiratory static pressures in patients with different stages of COPD severity. *Respir Res.* 2008 Jan 21;9:8. doi: 10.1186/1465-9921-9-8.



KEY REFERENCES

1. Laghi F, Tobin MJ. Disorders of the respiratory muscles. *Am J Respir Crit Care Med*. 2003;168: 10–48.
2. Wu J, Kuang L, Fu L. Effects of inspiratory muscle training in chronic heart failure patients: A systematic review and meta-analysis. *Congenit Heart Dis*. 2018;13: 194–202.
3. Cipriano GF, Cipriano G Jr, Santos FV, Güntzel Chiappa AM, Pires L, Cahalin LP, et al. Current insights of inspiratory muscle training on the cardiovascular system: a systematic review with meta-analysis. *Integr Blood Press Control*. 2019;12: 1–11.
4. Hellebrandová L, Chlumský J, Vostatek P, Novák D, Rýznarová Z, Bunc V. Airflow limitation is accompanied by diaphragm dysfunction. *Physiol Res*. 2016;65: 469–479.
5. Petrovic M, Reiter M, Zipko H, Pohl W, Wanke T. Effects of inspiratory muscle training on dynamic hyperinflation in patients with COPD. *Int J Chron Obstruct Pulmon Dis*. 2012;7: 797–805.
6. McConnell AK. The role of inspiratory muscle function and training in the genesis of dyspnoea in asthma and COPD. *Prim Care Respir J*. 2005;14: 186–194.
7. Verissimo P, Casalasso TJA, Gonçalves LHR, Yang ASY, Eid RC, Timenetsky KT. High prevalence of respiratory muscle weakness in hospitalized acute heart failure elderly patients. *PLoS One*. 2015;10: e0118218.
8. Simões RP, Castello V, Auad MA, Dionísio J, Mazzonetto M. Prevalence of reduced respiratory muscle strength in institutionalized elderly people. *Sao Paulo Med J*. 2009;127: 78–83.
9. Adler D, Dupuis-Lozeron E, Richard J-C, Janssens J-P, Brochard L. Does inspiratory muscle dysfunction predict readmission after intensive care unit discharge? *Am J Respir Crit Care Med*. 2014;190: 347–350.
10. Jaber S, Petrof BJ, Jung B, Chanques G, Berthet J-P, Rabuel C, et al. Rapidly progressive diaphragmatic weakness and injury during mechanical ventilation in humans. *Am J Respir Crit Care Med*. 2011;183: 364–371.
11. Cahalin LP, Arena R, Guazzi M, Myers J, Cipriano G, Chiappa G, et al. Inspiratory muscle training in heart disease and heart failure: a review of the literature with a focus on method of training and outcomes. *Expert Rev Cardiovasc Ther*. 2013;11: 161–177.
12. Reyes A, Castillo A, Castillo J, Cornejo I, Cruickshank T. The Effects of Respiratory Muscle Training on Phonatory Measures in Individuals with Parkinson’s Disease. *J Voice*. 2019; doi:10.1016/j.jvoice.2019.05.001
13. Park JS, Oh DH, Chang MY, Kim KM. Effects of expiratory muscle strength training on oropharyngeal dysphagia in subacute stroke patients: a randomised controlled trial. *J Oral Rehabil*. 2016;43: 364–372



Sponsored By: Breather University, a subsidiary of www.PNMedical.com 877-414-4449 care@pnmedical.com