Narrative Review

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New device for self-assisted breathing exercises in critical adult tracheostomized patients: protocol for a double blind randomized clinical trial

Novo dispositivo para exercício respiratório auto-assistido em pacientes críticos traqueostomizados: protocolo para um ensaio clínico randomizado duplo cego

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Abstract

Background: Tracheostomized patients have a higher chance of complications and mortality. The Quintero Lung Re-expansion Device (QLRD) was developed with the aim of preventing complications and reducing mortality, however, a clinical trial is needed to test its effectiveness. **Aim**: To evaluate the effectiveness of the QLRD, compared to incentive spirometry, on clinical outcomes, tracheostomy tube dwell time, length of hospital stay, comfort, and usability of the QLRD in tracheostomized inpatients. **Methods**: This clinical trial will involve 79 adult inpatients, allocated into two groups: intervention (IG) and control (CG). The IG will undergo daily respiratory exercise using the QLRD, twice a day, performing 2 to 4 sessions of 20 repetitions until the tracheostomy cannula is removed. The number of sessions will increase from 2 in the first four days to 4 after this period. The CG will perform incentive spirometry. The following outcomes; lung aeration (Lung Ultrasound Score), tracheostomy tube dwell time, length of hospital stay, adverse events, complications (bleeding, pneumothorax, subcutaneous emphysema, among others), need for supplemental oxygen support, peripheral oxygen saturation, lung function (spirometry), respiratory muscle strength (manovacuometer), comfort of therapy, return to invasive mechanical ventilation, ORLD usability, and implementation will be evaluated. Jamovi statistical software will be used. **Results**: The results of the trial will demonstrate whether the QLRD is easy and safe to use, and clinically beneficial. Furthermore, the findings can be used to determine whether the results of this study protocol can be implemented in clinical practice in the future. **Conclusion**: The QLRD may represent a new effective device for use in the recovery of tracheostomized patients.

Keywords: Tracheostomy; Medical Device; Controlled Clinical Trial.

Resumo

Introdução: Pacientes traqueostomizados têm uma chance maior de mortalidade e complicações. O Dispositivo de Reexpansão Pulmonar Quintero (DRPQ) foi desenvolvido na tentativa de prevenir complicações e reduzir a mortalidade. No entanto, é necessário ensaio clínico para testar a sua efetividade. **Objetivo**: avaliar a efetividade do DRPQ, em comparação à espirometria de incentivo, em desfechos clínicos, tempo de permanência do tubo de traqueostomia, tempo de internação hospitalar, conforto e usabilidade do DRPQ em pacientes hospitalizados traqueostomizados. **Métodos**: Este ensaio clínico irá envolver 68 pacientes adultos, alocados em dois grupos: intervenção (GI) e controle (GC). O GI será submetido a exercícios respiratórios com DRPQ diariamente, duas vezes ao dia, realizando 20 repetições em 2 a 4 sessões até a remoção da canulação da traqueostomia. As sessões aumentarão de 2 para 4, após os quatro primeiros dias de intervenção. O GC usará incentivador respiratório. Os desfechos aeração pulmonar (Ultrassom Pulmonar), tempo de permanência do tubo de traqueostomia, tempo de internação hospitalar, eventos adversos, complicações (sangramento, pneumotórax, enfisema subcutâneo, entre outros), necessidade de suporte de oxigênio suplementar, saturação periférica de oxigênio, função pulmonar (espirometria), força muscular respiratória (manovacuometria), conforto da terapia, retorno para ventilação mecânica invasiva, usabilidade do DRPQ, e implementação serão avaliados. O software estatístico Jamovi será usado. **Resultados:** será possível descobrir se o DRPQ é ou não fácil de usar, seguro e clinicamente benéfico. E, ainda, se os resultados deste estudo podem ser implementados na prática clínica no futuro. **Conclusão**: futuramente, podemos encontrar ou não um novo dispositivo efetivo para ser usado na recuperação dos pacientes traqueostomizados.

Palavras-chave: Traqueostomia; Dispositivo Médico; Ensaio Clínico Controlado.

INTRODUCTION

Tracheostomy is a necessary and frequently used procedure, that provides respiratory comfort to the patient, preventing orotracheal intubation and allowing ventilation with better airway care. This procedure can be surgical or percutaneous, elective or emergency, and is performed in intensive care units (ICU) and medical or surgical rooms[1,2]. In 2017, the United States of America reached the lowest number of cases since 2002, with 58,840 tracheostomies performed. However, this number is still worrying, reflecting an occurrence of approximately 28.4% in every 100,000 American adults[3].

The prevalence of this procedure is higher in men aged 60 to 69 with hydroelectrolytic disorders, arterial hypertension, and congestive heart failure, consecutively[3]. In Brazil, men are 1.8 times more likely to undergo tracheostomy than women[4], and in the last five years a total of 90,806 tracheostomies have been performed, with 2021 being the year with the highest rate of procedures[5].

Hospitalized patients who undergo tracheostomy are more likely to die when compared to those who do not undergo this procedure [6]. In addition, some complications are observed after tracheostomy, often within 7 days, including bleeding, pneumothorax, subcutaneous emphysema, airway burns, accidental decannulation, stoma infection, and aspiration. Other complications arise more frequently after the seventh day, such as tracheal stenosis, tracheomalacia, tracheoesophageal fistula, tracheoarterial fistula, delayed stoma closure, vocal cord paralysis, and respiratory symptoms (hoarseness, stridor, cough, dyspnea, or phonetic disorders)[7].

In an attempt to prevent or treat some of these complications and reduce the associated mortality rate, these patients are treated with breathing exercises, that aim to make breathing more comfortable, improve lung function, and optimize recovery[8,9]. However, it is challenging to perform respiratory maneuvers in tracheostomized patients, due to the presence of the tracheal cannula, which can impair and impede the physiological functioning of the glottis, possibly due to the direct pressure from the cannula[10]. The Quintero Lung Re-expansion Device (QLRD), that simulates the functioning of the glottis, was recently developed to perform respiratory exercises autonomously in tracheostomized patients who breathe spontaneously, enabling lung expansion[11]. However, methodologically robust randomized clinical trials are still needed to support the possible benefits of this device.

Therefore, the objective of the current study is to evaluate the effectiveness of the QLRD, used as a respiratory exercise, compared to incentive spirometry, on the following outcomes: lung aeration, tracheostomy cannula dwell time, length of hospital stay (LoS), adverse events, complications, need for supplemental oxygen (O_2) support, peripheral oxygen saturation (SpO_2), lung function, respiratory muscle strength, comfort of the therapy, and usability of the QLRD in hospitalized tracheostomized patients.

METHODS

Study design

This study design is a randomized, controlled, double-blind clinical trial, following the guidelines of the Consolidated Standards of Reporting Trials (CONSORT) statement[12]. The protocol used for this clinical trial will follow the Standardized Protocol Items and the Recommendations for Interventional Trials (SPIRIT)[13].

Ethical aspects and registration of the study protocol, population and setting

Patients will be invited to participate in the study and, after they accept and any possible doubts have been clarified, they will sign the free and informed consent form. This study was approved by the Research Ethics Committee of the Universidade Federal do Amapá (UNIFAP) under code CAAE-68556623.8.0000.0003) and prospectively registered on the website Brazilian Registry of Clinical Trials (ReBEC) (https://ensaiosclinicos.gov.br/welcome), under number RBR-4bxpkbb. The investigated population will be composed of patients who undergo the tracheostomy procedure in three public hospitals in the northern region of Brazil: Hospital de Emergências de Macapá, Hospital Estadual de Santana, and Hospital de Clínicas Doutor Alberto Lima. Data collection for this trial is planned to extend from 2025 to 2027.

Eligibility criteria

The study will include the following inpatients:

- Adults, aged 18 years or older, with tracheostomies, who are breathing in room air (spontaneous breathing).
- Without impairment in cognition or understanding, this will require the patient's collaboration and initiative.
- Within 72 hours after weaning off invasive mechanical ventilation (IMV).

Patients will be excluded if:

- After inclusion in the study, they develop neuromuscular diseases with involvement of respiratory muscles and upper spinal cord injury, because these patients typically remain with the tracheostomy cannula for a long time.
- They are without an indication for decannulation
- They withdraw from participating in the study for any reason

Randomization

Randomization will be performed using a computer-generated randomization sequence, conducted by an

independent investigator not involved in the study, with a 1:1 allocation ratio and using a swapped block method. A single randomization list will be created for all participants. Allocation will be performed using sequentially numbered sealed opaque envelopes that contain the patient's allocation to the intervention with QLRD[11] (Intervention Group) or incentive spirometry (Control Group) (Figure 1), with a unique identification code for each patient. Patients will be blinded to group allocation and if there are two or more patients on the same ward, they will be transferred to other wards to avoid contact between them, with only one included patient remaining in each ward.

Study procedures

The description of the procedures in the intervention and control groups will follow the Template for Intervention Description and Replication (TIDieR)[14], with the aim of facilitating the future implementation of this protocol in clinical practice (if the findings are suitable for implementation) and reproduction of this study by other researchers. To perform the intervention and evaluation, a sterile absorbent foam adhesive dressing for tracheostomy (PolarFix®, Winner Medical Co., Ltd, China) will initially be placed on the tracheostomy site for adequate sealing[15]. The assessment of patients' cognition and understanding will be performed based on their responses to five commands: "Open (or close) your eyes", "Look at me", "Open your mouth and stick out your tongue", "Nod your head", and "Raise your eyebrows when I count to 5". The patient will be considered not to have a cognitive or comprehension impairment if he/she complies with at least three of these requests[16].

All patients will undergo treatment for a period of eight days, starting from the first day of treatment. The proposed therapy will be performed twice a day, starting immediately after the patient signs the free and informed consent form and the initial evaluation, and will continue until either the 8th day of treatment, hospital discharge, or removal of the tracheostomy tube.

Before the intervention, if necessary, patients will undergo secretion removal therapy by tracheobronchial

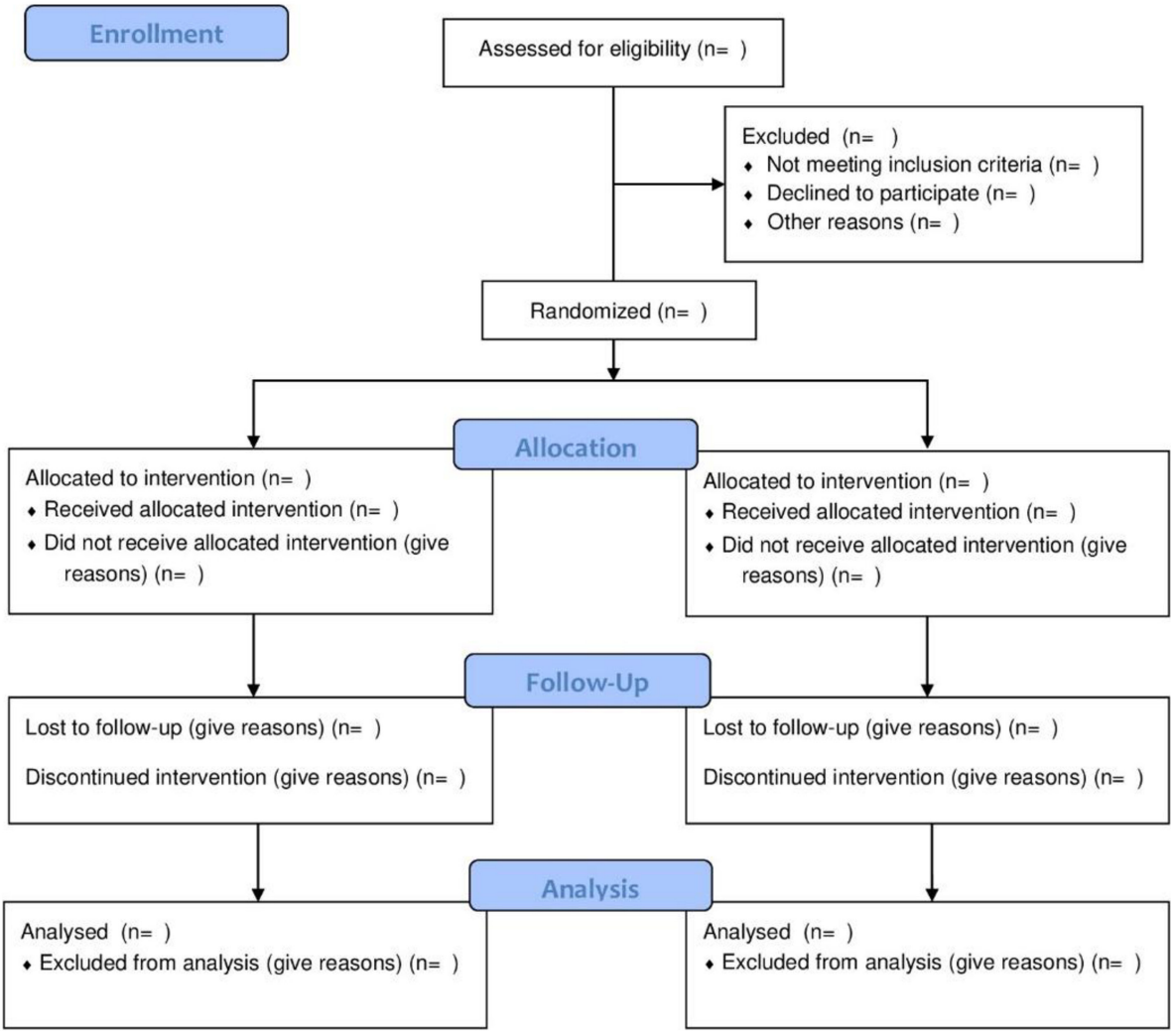

Figure 1. Flowchart of the future clinical trial.
Source: Prepared by the author based on the CONSORT 2010 Flow Diagram.

aspiration. The cuff pressure of the tracheostomy tube will be standardized to between 20 and 29 mmHg, to maintain the pressure below the perfusion pressure of the tracheal capillaries[17]. Cuff pressure monitoring will be continuous using the Accucuff™ device (MEDIS Medical Tiajin, China).

Intervention group

Participants in the intervention group will use the QLRD[11] to perform active assisted lung re-expansion breathing exercises, since even if the patient is breathing spontaneously, the interventionist will be the one handling the QLRD[11]. A preliminary study indicates that the use of the QLRD has yielded positive results in improving oxygenation and lung volumes through lung re-expansion therapy in tracheostomized patients[11]. The device allows an increase in transpulmonary pressure through fractional inspiration and a safe increase in total lung capacity with inspiratory pause[11]. The intervention will be performed in person and individually by a respiratory physiotherapist, previously trained in the use of the QLRD. The physiotherapists will receive training in the use of the QLRD.

Before the first session, the operation of the QLRD and its purpose will be carefully explained to the patient. This device allows a post-inspiratory pause of a few seconds by means of a one-way valve (Figure 2(1)) and an occlusion/flow release cap (Figure 2(2)), it is also equipped with a relief valve (Figure 2(3)) that opens at 60 cmH_2O (in adults) in cases where this threshold is reached. All devices used were purchased directly from the respective manufacturers after undergoing quality control (Biolife, Bioplast, Colombia). The intervention and measurements will be performed in an upright position, or with at least 60 to 70 degrees of trunk inclination. Before the initial care, blood pressure, respiratory rate, heart rate, and SpO_2 data will be collected.

During the breathing exercises with the QLRD[11], the patient will perform short, successive, and slow inspirations until reaching their maximum inspiratory capacity. Finally, the patient will be asked to perform a maximum sustained inspiration equivalent to a maximum inspiratory effort to reach total lung capacity, followed by a post-inspiratory pause of 5 seconds, finally performing a slow and controlled expiration, thus constituting 1 repetition. The sessions will be carried out daily, twice a day, and will consist of a protocol with 20 repetitions of 2 series on the first four days of intervention and 4 series on the last four days, with a two-minute interval between series. The protocol will be initiated after acceptance of the informed consent form and completed when the tracheostomy cannula of the participants is removed. The intervention will take place in the participants' hospitalization sector, such as the medical clinic, ICU, or similar unit of the hospitals where the recruitment will take place.

Control group

The patients in the control group will perform respiratory exercise using incentive spirometry. A flow-oriented incentive spirometer will be adapted for use by the tracheostomized patients. The adaptation will be performed by connecting the tracheostomy tube to a Heat and Moisture Exchange Filter (HMEF) or similar (Figure 3A) with its own corrugated tube (filter tube (Figure 3B), which in turn will be connected to the corrugated tube of the incentive spirometer (Figure 3C) and, finally, to the incentive spirometer (Figure 3D). With the help of the physiotherapist, patients will use the adapted device while sitting on a bed or chair, performing exercises of sustained maximum inspiration of 3 to 5 seconds in 2 sets, each containing 10 repetitions. A 2-minute rest interval will be allowed between sets[18]. Inspiratory incentive spirometry was chosen for use as a comparator because

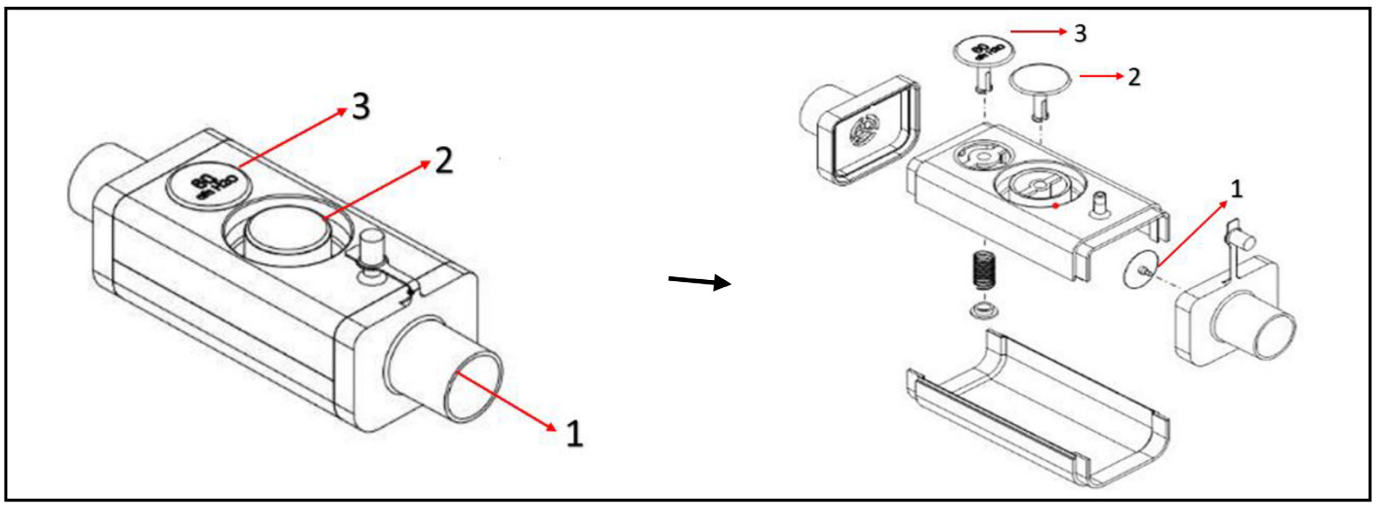

Figure 2. Quintero Lung Re-expansion Device and its components (1: One-way valve; 2: Occlusion/flow release cap; 3: Relief valve).
Source: Ofiicial Quintero Lung Re-expantion Device Manual.

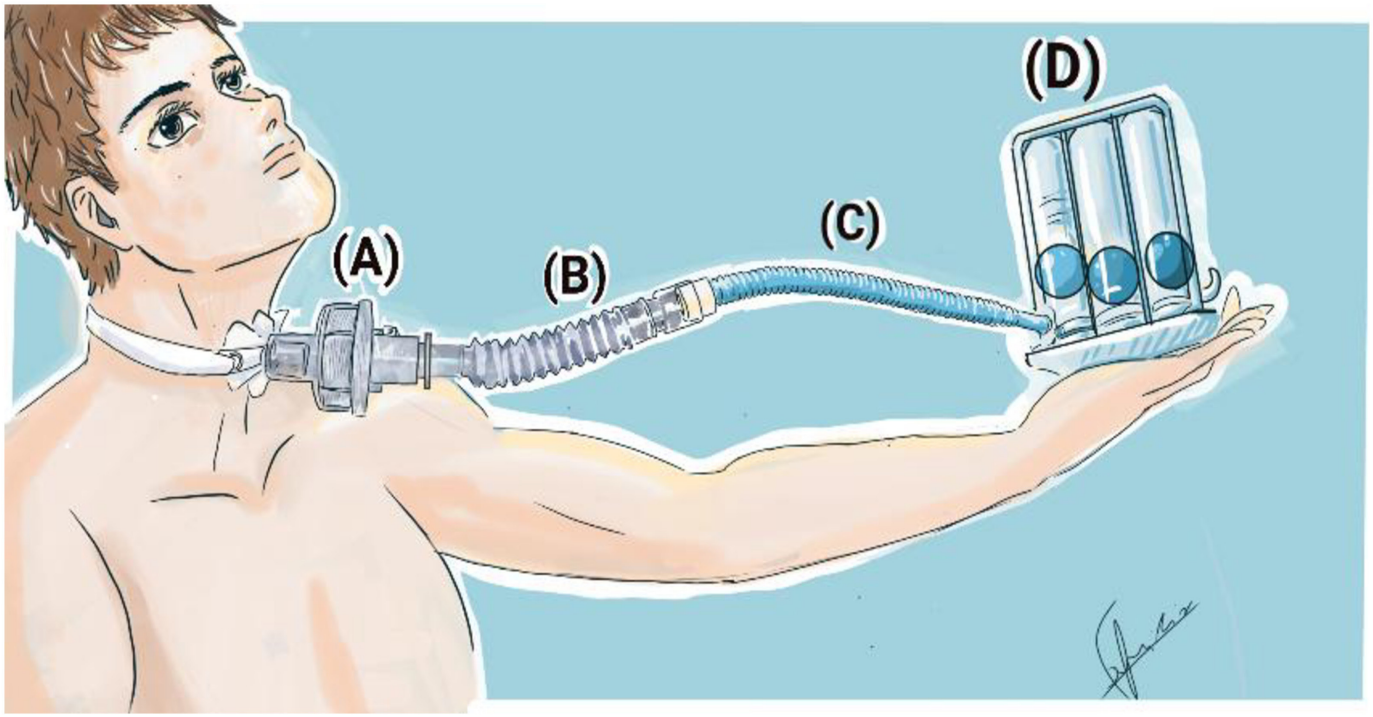

Figure 3. Incentive spirometer adapted for control group patient (A: Heat and Moisture Exchange Filter (HMEF); B: HMEF corrugated tube; C: Incentive spirometer corrugated tube; D: Incentive spirometer).
Source: Designed by the authors of the protocol.

this technique is equivalent to non-invasive ventilation (a technique well-established in the literature) and other techniques used to prevent pulmonary complications, reduce hospitalization time and ICU stay time, and improve pulmonary function[19].

Evaluation and blinding of evaluators

The evaluators will be blinded, that is, they will not know whether the patient is in the intervention or control group. To improve evaluator blinding, an QLRD[11] kit will be left in the ward of all included patients, where the evaluator can see it. Immediately after the patient is included in the study and before the first intervention, sociodemographic, clinical, hemodynamic, and surgical data will be recorded, as well as the size of the tracheostomy tube, all assessment data, and clinical outcomes. Assessments will be carried out daily and at hospital discharge, to record LoS outcomes, adverse events, and complications. The final reassessment will be performed on the eighth day after the final treatment session or on the day of removal of the tracheostomy tube if the patient is decannulated before the eighth day.

Outcomes assessed

Primary outcome

- Lung aeration: This will be evaluated by kinesiological lung ultrasonography, using the Lung Ultrasound Score (LUS) technique, which has similar accuracy to computed tomography[20]. The LUS will be performed by a trained evaluator, using a 2 to 4 MHz convex transducer (ClinicalTools C10-911, Beijing Konted Medical Technology Co., Ltd, China). Each intercostal space of the upper and lower parts of the anterior, lateral, and posterior regions of the left and right chest wall will be carefully examined. The videos of the evaluations will be stored for future use. Four ultrasound aeration patterns have been defined: 1) normal aeration: presence of lung sliding with A lines or less than two isolated B lines; 2) moderate loss of lung aeration: multiple well-defined B lines; 3) severe loss of lung aeration: multiple coalescent B lines; and 4) lung consolidation: presence of a tissue pattern characterized by dynamic air bronchograms. For each region of interest, the scores will be defined according to the worst ultrasound pattern observed. The added scores will be 0 (zero) in case of normal aeration, 1 (one) for moderate loss of lung aeration, 2 (two) for severe loss of lung aeration, and 3 (three) for lung consolidation. Therefore, considering that 12 thoracic regions or quadrants (6 in the right hemithorax and 6 in the left) will be evaluated, the overall LUS score can vary from 0 (zero) to 36 (thirty-six)[21].

Secondary outcomes

- Tracheostomy tube dwell time (in days): The number of days the tracheostomy tube remains in place will be recorded, from the day of placement until decannulation.

- LoS (in days): The total number of days the patient remains in the hospital will be recorded. In the case of studies that report the length of stay in the intensive care unit and in the wards, this will be recorded separately, and the days will then be added together to obtain the total length of hospital stay.
- Adverse events: All adverse events associated with the use of QLRD or tracheostomy will be recorded. Unexpected events arising from a proposed treatment will be categorized into two main types: adverse events and serious adverse events. Adverse events include any unfavorable event occurring in a patient receiving the proposed treatment, even if there is no direct causal relationship with the treatment. Serious adverse events will be considered as adverse medical occurrences that, at any dose, result in death, are life-threatening, require hospitalization or prolong an existing hospitalization, cause persistent or significant disability, or lead to birth defects[22]. The adverse events considered in the investigation of the current trial will be obstruction and displacement of the tracheostomy tube and persistent or severe pain[23].
- Complications: Complications, such as bleeding, pneumothorax, subcutaneous emphysema, accidental decannulation, stoma infection, aspiration, tracheal stenosis, tracheoesophageal fistula, delayed stoma closure, and vocal cord paralysis[7] will be considered and recorded.
- Need for supplemental O_2 support: The need for supplemental O_2 support will be recorded (if the overall SpO_2 is 92%, or less than 88% if the patient has chronic obstructive pulmonary disease and signs of respiratory distress)[24], including the time of supplementation and the level of O_2 offered in liters per minute.
- Peripheral oxygen saturation: Measured daily until the day of hospital discharge or on the day of removal of the tracheal tube. SpO_2 will be measured with the patient breathing room air for at least ten minutes.
- Lung function: Spirometry will be performed on the first day of patient inclusion in the study and on the day of removal of the tracheal cannula, following previously established performance and acceptability criteria[25]. The variables forced vital capacity (FVC) and forced expiratory volume in one second (FEV1) will be used according to the predicted values for the Brazilian population[26]. To perform this assessment, the portable spirometer Spirobank G® (MIR, Rome, Italy) will be used[27]. If, due to the need for decannulation, the reassessment occurs before the eighth day of treatment, lung function will be assessed before removal of the tube to avoid bronchoaspiration of fibers from the dressing.
- Respiratory muscle strength: Maximum inspiratory and expiratory pressures will be obtained using a Wika manovacuometer (WIKA, Ind, Iperó, SP, Brazil) and will be performed on the day the patient is included in the study and on the day the tracheal tube is removed or at hospital discharge. Maximum inspiratory pressure will be obtained from residual volume and maximum expiratory pressure from total lung capacity[28]. The tests will be performed according to the guidelines for spirometric testing[29]. The maneuvers will be performed three to five times, with the highest value being used for analysis. The evaluation will be considered valid if three acceptable and two reproducible measurements are obtained[28]. Considering that the patients will be tracheostomized, the measurement will be performed on the tracheostomy tube with an inflated cuff and without any internal tube[30]. If, due to the need for decannulation, the reassessment occurs before the eighth day of treatment, respiratory muscle strength will be assessed before removing the tube to avoid bronchoaspiration of fibers from the dressing.
- Comfort of therapy: Assessed using the adapted visual analogue comfort scale[31], with scores ranging from -2 to 2 ("−2 = very uncomfortable", "−1 = uncomfortable", "0 = indifferent", "1 = comfortable", and "2 = very comfortable") (Figure 4).
- Return to IMV: Whether the patient returns to IMV after the start of the intervention will be recorded.
- Usability of the QLRD: Evaluated using the System Usability Scale (SUS), a questionnaire that evaluates the level of usability of a product, including ten questions, answered on a scale ranging from 1 (I completely disagree) to 5 (I completely agree). The SUS will be applied to patients and all physiotherapists in the sector where the patient is hospitalized, on the last day of treatment. Before obtaining the final result, it is necessary to execute some commands, including: - in case of odd results (1, 3, or 5) it is necessary to subtract 1 from the patient's response score; - in the case of even results (2 or 4) it is necessary to subtract the answer from 5 (for example, if the patient answers 2, the number 3 will be counted (5 minus 2 equals 3); - then all the values of the ten questions are added and multiplied by 2.5. The result of this multiplication gives the final result, ranging from 0 to 100. Scores of 70 or more indicate that the device tested is above average (acceptable)[32].
- Implementation outcomes (acceptability, suitability, and feasibility): When the treatment protocol is completed, the outcomes will be assessed using the Weiner scale[33], translated and adapted to Brazilian Portuguese[34]. The response options for all questions are: I strongly disagree (1 point), I disagree (2 points), I neither agree nor disagree (3 points), I agree (4 points), and I strongly agree (5 points).

Acceptability represents the perception among stakeholders that a given treatment is pleasant or

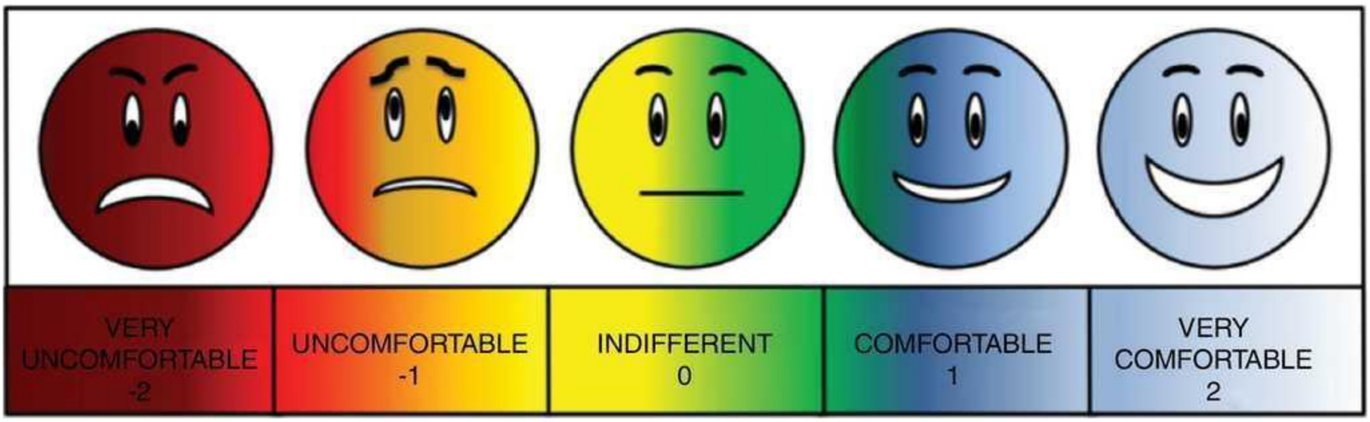

Figure 4. Adapted visual analogue comfort scale.
Source: Quintero et al.[11:356].

satisfactory. This will be assessed by the satisfaction reported by the patient allocated to the intervention group by answering the following questions: 1) "Breathing exercises with the QLRD have my approval"; 2) "Breathing exercises with the QLRD are attractive to me"; 3) "I liked the breathing exercises with the QLRD during hospitalization"; and 4) "I recommend the breathing exercises with the QLRD during hospitalization".

Suitability, is the relevance or compatibility of the proposed innovation (treatment) for a given clinical practice environment. It will be assessed by the following questions addressed to the health professionals who care for the patients included in this study, such as doctors, nurses, and physiotherapists: 1) "Breathing exercises with the QLRD during hospital admission seem to be accepted by the team"; 2) "Breathing exercises with the QLRD during hospital admission seem to be appropriate"; 3) "Breathing exercises with the QLRD during hospital admission seem to be applicable"; and 4) "Breathing exercises with the QLRD during treatment seem to be a good option".

Feasibility is defined as the extent to which a new treatment can be implemented within a given setting. It will be assessed by the following questions addressed to the physiotherapists and patients included in this study: 1) "Breathing exercises with the QLRD during hospital admission seem to be implementable"; 2) "Breathing exercises with the QLRD during hospital admission seem to be possible to perform"; 3) "Breathing exercises with the QLRD during hospital admission seem to be feasible"; and 4) "Breathing exercises with the QLRD during hospital admission seem to be easy to use".

Sample calculation and statistical analysis plan

Considering an α error of 5% (significance level of 95%), power (1 - β error) of 80%, and expected effect size of 0.7 on the outcome decannulation time[35], we calculated a sample size of 68 patients using GPower 3.1[36] software. To prevent loss to follow-up, 11 patients (15%) will be added. Therefore, the total sample will consist of 79 patients, with 40 in one group and 39 in the other.

All analyses will be conducted considering "intention-to-treat analysis", by an independent researcher not involved in the study. After checking the Gaussian distribution, continuous data will be presented as mean (standard deviation) or median (25th–75th (interquartile range)). Categorical data will be expressed as absolute values and percentages (n (%)). Continuous data, such as laboratory tests, will be compared between groups using the linear mixed model, which is a statistical test that already corrects for missing data and provides the size of the intervention effect for each outcome analyzed. Categorical data, such as adverse events and complications, will be analyzed by the z-test or chi-square test. Kaplan-Meier survival analysis will be considered to compare the LoS between groups. In case of doubt in the interpretation of the survival curves, we will use the Log Rank test to evaluate the differences between the curves. Jamovi software will be used in the statistical analysis.

RESULTS

We expect the results to show whether the QLRD is easy to use in the respiratory treatment of tracheostomized patients and healthcare professionals, providing clinical benefits, such as reduced LoS and decreased tracheostomy tube indwelling time, which can improve patients' quality of life and optimize hospital resources.

We hypothesize that the QLRD will be proven to be safe for use in tracheostomy patients, with a very low (or zero) rate of adverse events. Device safety is a priority, and we hope that its future implementation will contribute to the reduction in complications associated with tracheostomy management, ensuring more effective and safe treatment for patients. We also believe that in the future it will be possible to implement the scientific findings of the current trial in hospital settings.

DISCUSSION

Tracheostomy in adults is a worldwide problem, and at least one complication related to tracheostomy occurs within ninety days in a portion of this population[37]. Regardless of the type of complication, there is impairment in ventilatory function. Therefore, new treatments such as the QLRD, which are easy to apply and low cost, can help in the recovery of these patients, leading to a reduction in these complications and possibly enabling ventilatory improvement[37].

Previous studies have shown the importance of investigating new technologies that can be used as respiratory exercise options in treatment, or as an additional resource in other treatments in patients with changes in respiratory function[38-40]. Another point that has been observed over time is the relevance of investigating the supposed effectiveness of these new technologies. This will make it possible to offer clinicians a new technology that has been tested through robust studies.

A recent pilot study evaluated the impact of the QLRD on maximal inspiratory volumes and respiratory system compliance in ten spontaneously breathing tracheostomized patients. The authors observed that the QLRD improved oxygenation and lung volumes safely and comfortably[11]. Therefore, it seems prudent to clinically investigate these outcomes described in the current protocol for a future clinical trial.

CONCLUSION

The results of the current study are expected to provide valuable information on the effectiveness, or lack thereof, of the QLRD intervention in tracheostomized patients after weaning off IMV, especially regarding pulmonary aeration, which can significantly optimize recovery. In the future, QLRD may represent a new device for use in the recovery of tracheostomized patients.

FUNDING

Not applicable.

CONFLICT OF INTEREST

We declare that among the authors of this protocol is the Editor-in-Chief of BJR, Professor Adriana Cláudia Lunardi.

RESEARCH DATA AVAILABILITY

No research data was used.

ARTIFICIAL INTELLIGENCE USE STATEMENT

No AI was used at any stage of the manuscript production.

AUTHOR CONTRIBUTIONS

DOS: conceptualization, methodology, supervision, visualization, drafting – revision and editing; GMO: methodology, visualization; HVCS: methodology, visualization; JPRP: methodology, visualization; GMG: methodology, visualization; ACL: conceptualization, project management, methodology, visualization, drafting – original draft, drafting – revision and editing; ECS: conceptualization, project management, methodology, supervision, visualization, drafting – original draft, drafting – revision and editing.

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