Effects of Respiratory Therapy (bagging) on Respiratory Function, Swallowing Frequency and Vigilance in Tracheotomized Patients in Early Neurorehabilitation*

Effekte einer spezifischen Atemtherapie (Bagging) auf die Atemfunktion, Schluckfrequenz und Vigilanz bei tracheotomierten Patienten in der neurologischen Frührehabilitation

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Abstract

Objective: Tracheotomized patients often suffer from impairments in mucociliary clearance and limited capacities for active expectoration of secretions. We investigated the effects of a specific respiratory intervention method (bagging) for tracheotomized patients on respiratory parameters (pO_2, pCO_2, SpO_2, respiratory rates), swallowing frequency, vigilance and secretion viscosity. **Methods:** The bagging method supports enforced mobilization and expectoration of secretions by application of a series of manual hyperinflations with a resuscitation bag during active inspiration and manual cough support on the chest. 30 tracheotomized neurological patients participated in a multiple-baseline study including a three-weeks intervention period and a follow-up measurement three weeks after termination of the treatment. **Results:** Most outcome parameters improved significantly during the intervention period: pO_2 ($p<.01$), SpO_2 ($p<.01$), respiratory rates ($p<.01$), swallowing rates ($p<.01$), and vigilance scores ($p<.01$). The quality of bronchial secretions improved in all participants. All effects were sustained up to the follow-up measurements. **Conclusion:** This preliminary data indicates positive effects for a respiratory intervention method (bagging) on respiratory function and additional respiration-related functions in tracheotomized neurological patients. This easy-to-learn and inexpensive method might expand the range of treatment options for tracheotomized and non-responsive patients.

Zusammenfassung

Ziel: Bei tracheotomierten Patienten sind die mucociliäre Clearance und die Möglichkeiten zur aktiven Sekretexpektoration eingeschränkt. Wir untersuchten Effekte einer spezifischen atemtherapeutischen Methode (Bagging) für tracheotomierte Patienten auf respiratorische Funktionsparameter (PCO_2, PO_2, SPO_2, Atemfrequenz, bronchiale Sekretqualität), die Schluckfrequenz und die Vigilanz. **Methoden:** Die Bagging-Methode unterstützt die Mobilisation und Expektoration von Bronchialsekret durch Anwendung von manueller Hyperinflation und nachfolgender thorakaler Hustenunterstützung. In einer Multiple-Baseline-Studie mit Follow-up-Messung erhielten 30 tracheotomierte neurologische Patienten über einen Zeitraum von 3 Wochen täglich eine Bagging Anwendung. **Ergebnisse:** In fast allen Parametern zeigten sich nach der Intervention signifikante Verbesserungen: pO_2 ($p<.01$), SpO_2 ($p<.01$), Atemfrequenz ($p<.01$), Schluckfrequenz ($p<.01$) und Vigilanz ($p<.01$). Die Viskosität des Bronchialsekrets veränderte sich bei allen Patienten positiv. Alle Therapieeffekte waren zur Follow-up-Messung stabil. **Schlussfolgerung:** Diese ersten Daten zeigen positive Effekte einer spezifischen Atemtherapie für tracheotomierte neurologische Patienten auf Atemfunktion und weitere Funktionsbereiche. Durch diese kostengünstige und leicht zu erlernende Methode kann das Spektrum atemtherapeutischer Behandlungsmöglichkeiten für tracheotomierte Patienten effektiv ergänzt werden.

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Introduction

Clinical management of patients with tracheotomies and cuffed tracheotomy tubes presents a particular challenge in early neurorehabilitation. These patients often suffer from reduced mucociliary and tussive clearance of the bronchial system due to the transstomatal airway. Ineffective coughing and an insufficient peak cough flow have been described as the main reasons for mucus retention in neurological and neuromuscular patients [1]. As a consequence, bronchial secretions remain in the alveoli, leading to an increase in secretion viscosity and atelectasis, an aggravated risk of bronchopulmonary infections and a limited respiratory surface area [2,3].

Conventional chest physiotherapy methods to support bronchial secretion clearance have shown that active forced inspiration and expiration techniques are most effective in supporting the removal of excessive bronchial secretions [4–7]. Manual cough assist techniques have been recommended for patients with neuromuscular diseases [8] and positive effects regarding an increase in peak cough flow have been shown, especially in combination with inspiratory assist techniques [4,9,10].

Tracheotomized patients in early neurorehabilitation, however, are often unresponsive and unable to perform methods that involve active forced respiration or coughing. Thus, the range of functional treatment options for improving bronchial clearance is limited in this patient group. Manual hyperinflation techniques, such as 'bagging' and 'air stacking', can be considered treatment options for these individuals. These techniques have been applied in respiratory medicine and intensive care units for many decades [11–13]. The manual hyperinflation technique of 'bagging' involves squeezing a resuscitation bag with a series of larger-than-baseline tidal volumes during inspiration, adding approximately 1 litre of air to the inspiratory volume [13,14]. Previous studies have shown its positive effects on re-recruitment of atelectasis and alveolar ventilation [15], and on mobilisation of pulmonary secretions [16], especially when combined with a physiotherapy regimen of positioning and suctioning [17]. So far, however, the utility and effectiveness of the bagging method has not been investigated in tracheotomized patients in early neurorehabilitation.

In a pilot project, we adapted the bagging method to the needs of tracheotomized neurological patients with limited vigilance and low capacities for active participation. Specifically, a routine manual cough assist technique performed by the therapist was added after every bagging cycle, regardless of the patient's ability to generate an active cough to support expectoration of mobilized bronchial secretions. In a pilot study after the implementation of the method in a German hospital for early neurorehabilitation, we found a continuous increase in SpO_2 measurements in a group of 11 participants during an intervention period of 12 days [18]. Furthermore, the clinical team indicated that swallowing function and vigilance also improved during the modified bagging intervention trial. These incidental findings had not been systematically investigated during the pilot trial, thus, additional effects of this method on respiration-related functions could not be verified.

In previous studies, a close relationship between respiratory and swallowing function has been established [19–22] and positive effects of respiratory interventions on swallowing function have been suggested [22,23]. So far, only studies on the effects of CPAP (continuous positive airway pressure) intervention on swallowing function are available. Some studies report a facilitative effect of CPAP on swallowing, specifically a reduction of saliva aspiration in tracheotomized children [24], a positive regulation of breathing-swallowing coordination during sleep in patients with obstructive sleep apnea syndrome [25] and an increase in swallowing frequency in tracheotomized patients [26]. In contrast, another study found an inhibitory effect of CPAP on swallowing frequency and a reduced latency of swallowing reflex activity in humans [27].

The aim of the present study was to investigate the effects of the bagging method on respiratory function, swallowing frequency and vigilance in tracheostomized patients. Specifically, we addressed the following questions:

1. Does daily application of the bagging method over a period of three weeks lead to improvements in *respiratory function* (pO_2, pCO_2, SpO_2, respiratory rates) in tracheotomized patients?
2. Can we find additional improvements regarding *swallowing frequency*, *vigilance* and the *quality of bronchial secretions*?

Methods

The study obtained approval by the Ethics Committee of the University of Potsdam, Germany (Proposal No.21/2011, approval 14/31, November 11th, 2011). Written informed consent was obtained from all patients or their legal representatives. All data was collected at the Aatalklinik Wuennenberg, a center for early neurorehabilitation in Bad Wuennenberg, Germany.

Participants

The study was designed to include 30 patients consecutively admitted to a neurorehabilitation center in Germany from december 2011 – november 2012. Patients were included if they had a cuffed tracheotomy tube in situ, a pre-treatment swallowing rate of < 1/min and a history of at least one pneumonic infection post-onset. Patients with emphysema, COPD (chronic obstructive pulmonary disease), recent abdominal or thoracic surgery, vertebral or rib fractures, bone metastases and osteoporosis were excluded from participation.

Study design

The study was conducted in an ABA multiple baseline design with repeated baseline measurements and a follow-up measurement 3 weeks after treatment to confirm stability of patients' performance and to verify treatment effects. All experimental parameters (**Table 1**) were obtained in two pre-treatment baseline measurements (A1, A2) on two consecutive days. During the subsequent 3-week intervention period, all patients received a bagging treatment once every workday (a total of 15 interventions). After termination of the treatment interval, baseline measurements were obtained on the two following days (A3, A4) and 3 weeks after the last day of the intervention period (follow-up measurement).

Experimental procedures: bagging interventions

All bagging interventions were performed in upright sitting or lateral positions as the method (particularly the manual cough assistance) can be applied most effectively in these positions. The position chosen for each intervention day was dependent on the current daily fitness of the patient to ensure the optimum comfort. All interventions were performed by a physiotherapist and a respiratory therapist with more than 6 months experience in performing the bagging method with tracheotomized patients.

Table 1 Experimental parameters and measurements obtained at two pre-treatment baselines (A1, A2), two post-treatment baselines (A3, A4) and one follow-up baseline three weeks after termination of the treatment period.

	parameter	measurement
1	PaO_2/mmHG	capillary blood gas analysis[a]
2	$PaCO_2$/mmHG	capillary blood gas analysis[a]
3	SPO_2/%	pulse oximetry[a]
4	respiratory rate/min	respiratory cycles counted in 10 minutes[a]
5	swallowing rate/min	swallows (laryngeal elevations) counted in 10 minutes[b]
6	vigilance	Coma Remission Scale [35] (0: worst; 24: best)
7	quality of bronchial secretions	custom-made 5-point rating scale (1: thick; 2: ropey; 3: gel-like; 4: saliva-like; 5: watery)

[a] Normative values and ranges [28]

[b] Normative swallowing values calculated from data reported in the literature for non-nutritive swallows in healthy adults in the upright position (M = 1.17/min (SD = .53; 95 %CI [0.74 – 1.60]) [29 – 34].

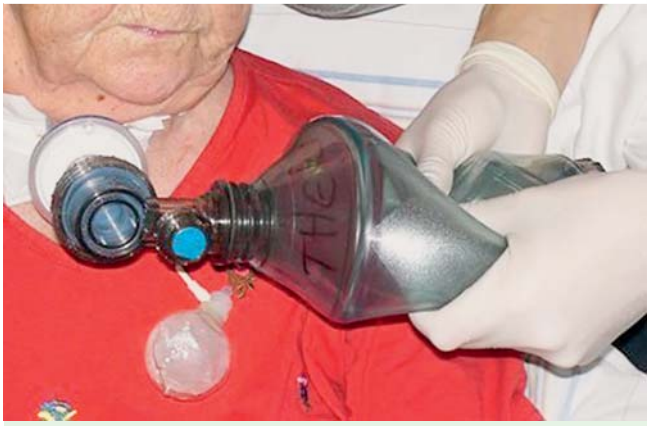

Fig. 1 Bagging: hyperinflation during active inspiration with a resuscitation bag attached to the tracheostomy tube.

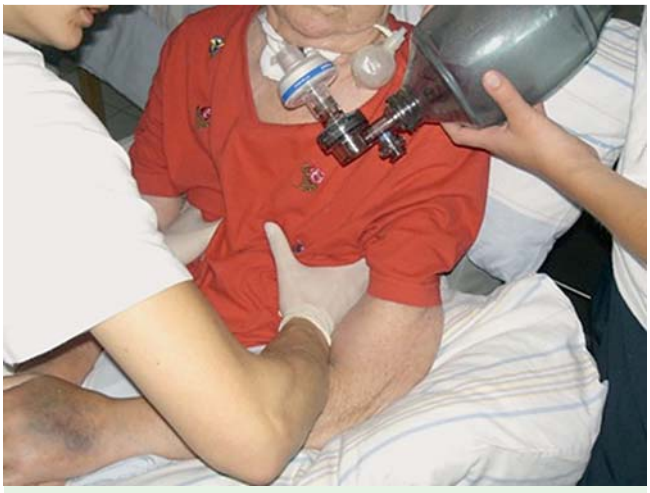

Fig. 2 Bagging: manual cough support on the chest during active coughing or (if not possible) during exhalation to enforce expectoration of mobilized bronchial secretions.

After providing information to the patient about the procedure, a standard adult single-patient resuscitation bag supplied with an HME-filter (heat moisture exchange filter) was attached to the tracheostomy tube (**Fig. 1**). The bagging was performed by applying one-hand or two-hand squeezes adding approximately 800 – 1000 ml of air to the active inspiration of the patient. Every patient was bagged according to an individualized bagging scheme (viz. series x insufflations; series = repetitions of one bagging cycle, insufflations = number of insufflations during one bagging cycle) depending on the patient's abilities and compliance. All patients received either 3 or 4 series of 10 insufflations (scheme 3 × 10; scheme 4 × 10). In case of spontaneous coughing attempts during the bagging cycle the bag was immediately detached and the reflexive coughing attempt was supported by a forced manual cough support on the chest by the therapist (**Fig. 2**). When no spontaneous cough occurred the maximum amount of 10 insufflations was applied, then the bag was detached and the patient was verbally instructed to cough. This voluntary cough was as well supported by forced manual cough support by the therapist. The manual cough support was supplied even if the patient was unresponsive or unable to cough spontaneously or actively, in order to support clearance of the mobilized secretions. All bagging interventions and all baseline measurements were performed with the cuff inflated. The patients received no other respiratory or swallowing therapy during the treatment period and up to the follow-up measurement.

Data collection

The experimental parameters collected are shown in **Table 1** (see [28] for an overview of normal values for parameters 1 – 4). Blood gases were obtained by capillary blood gas analysis and pulse oximetry. Respiratory rates were counted over 10 minutes in a resting period and analyzed as the mean per minute. Swallowing frequency was determined by visual observation of laryngeal elevations in a 10 minutes resting period and as well analyzed as the mean per minute. The normal values used as a reference for swallowing frequency were the calculated mean and 95 % confidence interval (CI) of data for non-nutritive swallows in awake healthy adults in the sitting position as reported in the literature (M = 1.17/min (SD = .53; 95 %CI [0.74 – 1.60]) [29 – 34]. The patients' vigilance was assessed using the "Koma Remissions Skala" (Coma Remission Scale), a rating scale ranging from 0 points (most severe impairment) to 24 points (no impairment) [35]. This tool assesses alertness, basic motor responses, reactions to acoustic, visual and tactile stimuli, and motor speech responses. The quality of bronchial secretions was assessed with a custom-made 5-point rating scale, as, to our knowledge, no similarly differentiated and validated secretion rating scale is reported in the literature. Secretions were rated according to their viscosity, as being thick (score 1), ropey (score 2), gel-like (score 3), saliva-like (4) or watery (score 5). Secretion qualities in the range of score 3 (gel-like) to score 4 (saliva-like) were clinically based interpreted as reflecting a more natural and physiological secretion quality than the other scores. Due to its lack of validation, the secretion score data was analysed descriptively only.

Statistical analysis

All data sets were checked for normality of distribution and variance homogeneity. Comparisons involving data sets that did not fulfil the requirements for parametric testing were conducted using the non-parametric Wilcoxon signed rank test. Other comparisons were conducted using a Student's t-test for paired samples. Significance levels were set at $p < .05$ for the comparison of baselines A1 vs. A2 and A3 vs. A4. Significance levels for the comparison of pre-treatment baseline (combined data sets A1 and

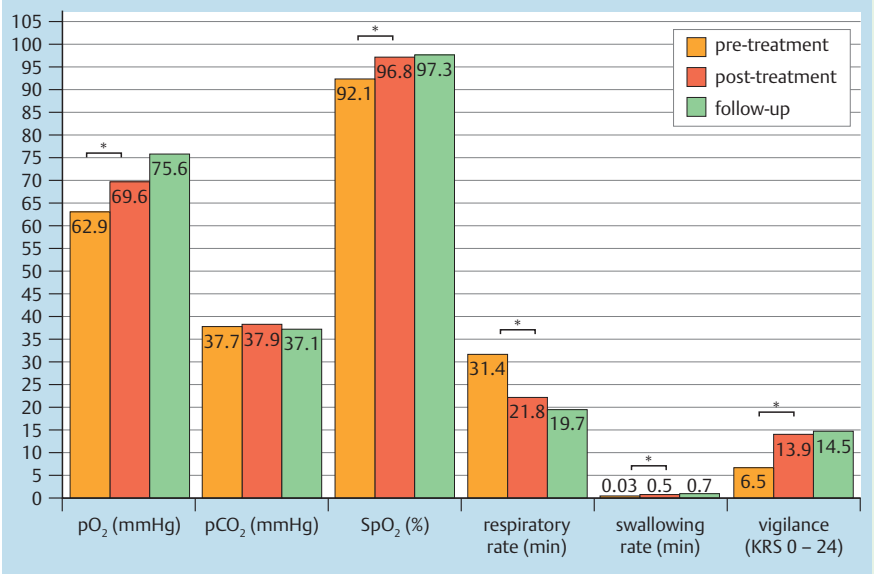

Fig. 3 Comparison of pre-treatment and post-treatment experimental baselines and a follow-up measurement after 3 weeks of bagging treatment in 30 neurological tracheotomized patients. Results stated as mean values: pre-treatment (A1, A2); post-treatment (A3, A4). * Significant difference: $p < .025$ (Bonferroni corrected p-level; Wilcoxon signed rank test, 2-tailed).

A2) vs. post-treatment baseline (combined data sets A3 and A4) and post–treatment baseline vs. follow-up baseline were adjusted to $p < .025$ (Bonferroni correction).

Results

Participants

The study included 15 male and 15 female tracheotomized patients within an age range of 25–84 years ($M = 61$ years, $SD = 16.1$). All patients completed the pre- and post- treatment baseline measurements (A1, A2, A3, A4) and the full intervention period (B). Unfortunately, only 16 patients (53.5%) could be included in the follow-up measurements, as 14 patients (46.6%) were discharged from the hospital earlier than expected. The study population included patients with various neurological diseases: cerebrovascular ischemic stroke ($n = 11$), haemorrhagic stroke ($n = 5$), traumatic brain injury ($n = 4$), hypoxic brain damage ($n = 5$), Parkinson's Disease (n = 1); critical illness polyneuropathy ($n = 1$), intracerebral tumor ($n = 1$), cervical disc herniation ($n = 1$), and myasthenia ($n = 1$). Most patients were early in their rehabilitation process with a mean latency of 57.3 days (4–200; $SD = 45.8$) between disease onset and first baseline assessment (A1). Some patients received medication with a potential effect on mucus production (Scopolamine, Gabapentin, Baclofen, Bromocriptine, Levodopa, Acetylcysteine [36]). The medication was not changed during the course of the study. All patients were exclusively tube-fed and did not receive any food or drink by mouth.

Pre- and post-treatment baselines: stability of performance on experimental parameters

We found no significant difference in the pre-treatment baseline measurements (A1 vs. A2) ($p > .05$, Wilcoxon, two-tailed), indicating the relative stability of patients' performance on the research parameters before treatment. Group performance before treatment on all parameters was outside normal ranges, except pCO_2, thus treatment effects on pCO_2 could not be expected. Also, the post-treatment baselines (A3 vs. A4) were not significantly different, except pCO_2 ($t(29) = -2.136$, $p = 0.041$) and vigilance ($t(29) = -2.504$, $p = 0.018$). All further analyses were conducted with the combined data sets of the pre-treatment (A1 and A2) and post-treatment (A3 and A4) baseline measurements.

Treatment outcomes

Comparing pre- and post-intervention baselines, we found significant improvements in the following parameters (**Fig. 3**): pO_2 ($U = -5.173$, $p = .000$, $r = 0.39$), SpO_2 ($U = -6.716$, $p = .000$, $r = 0.82$), respiratory rates ($U = -6.628$, $p = .000$, $r = -0.68$), swallowing rates ($U = -6.642$, $p = .000$, $r = 0.85$), and vigilance ($U = -6.631$, $p = .000$, $r = 0.66$). The parameter pCO_2 did not change significantly; however, it was already in normal range before treatment. All parameters sustained their improvements up to the follow-up baseline, and no further significant changes were observed (pO_2: $U = -1.708$, $p = .088$; pCO_2: $U = -.288$, $p = .820$; SpO_2: $U = -1.393$, $p = .164$, respiratory rates: $U = -1.289$, $p = .187$, swallowing rates: $U = -1.256$, $p = .209$, vigilance: $U = -.542$, $p = .588$).

Secretion viscosity changed to a more physiological quality after treatment in all participants (**Fig. 4**). Before the intervention, 28 patients suffered from thick or ropey secretion quality (scale categories 1 and 2); only 2 patients had gel-like or saliva-like bronchial secretions (scale categories 3 and 4). After the intervention period, 29 patients had gel-like or saliva-like secretions and 1 patient had a liquid secretion quality (scale category 5). This effect was maintained at the follow-up measurement, where still all remaining 16 patients had a gel-like or saliva-like quality of bronchial secretions.

Discussion

Effective respiratory treatment methods for tracheotomized patients in early neurorehabilitation are few, although this clinical population is particularly prone to reduced respiratory function due to the altered transstomatal airway. With a cuffed tracheostomy tube in situ, these patients cannot derive sufficient benefit from conventional physiotherapeutic approaches to support bronchial clearance, such as coughing and active expectoration techniques.

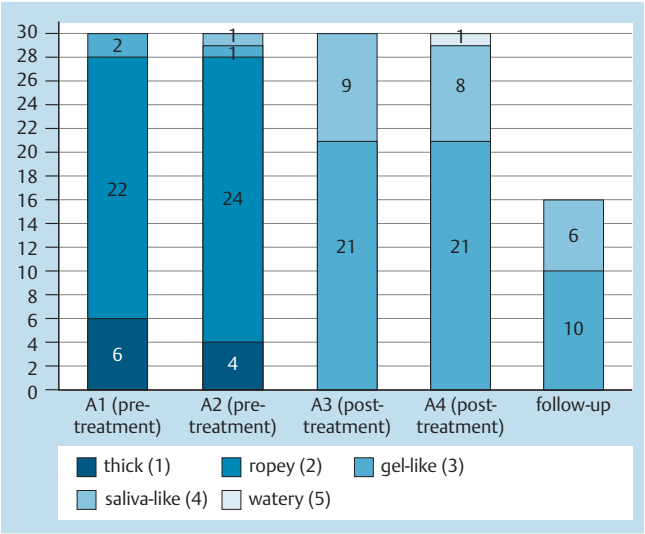

Fig. 4 Quality of bronchial secretions as measured on a 5-point rating scale at two pre-treatment baselines (A1, A2), two post-treatment baselines (A3, A4) and one follow-up baseline three weeks after termination of the treatment period.

The aim of this study was to investigate whether the 'bagging-method', a manual hyperinflation technique that can be performed with tracheotomized and minimally or non-responsive patients, has positive effects on respiratory parameters (pO_2, pCO_2 SpO_2, respiratory rates), swallowing frequency, vigilance and quality of bronchial secretions. After treatment of 30 tracheotomized patients over 3 weeks with a total of 15 individual bagging interventions, we found significant improvements in pO_2- and SpO_2-values, respiratory rates, swallowing frequency and vigilance as assessed by a coma remission scale [35]. A total of 13 patients were able to improve their pO_2-levels to normal limits and 29 of the 30 patients improved their SpO_2-levels during the treatment period to normal ranges, confirming our previous findings during the pilot study [18]. Furthermore, nine patients were within normal respiratory rate limits after the intervention. This seems to indicate that the method led to an improvement in mucociliary clearance and an increase in respiratory surface area, although this assumption would have to be confirmed by radiological assessments. Further evidence for a positive effect of the bagging method on bronchial mucus clearance comes from the descriptive analysis of bronchial secretion quality in the study sample. Whereas the majority of patients suffered from 'thick' or 'ropey' secretions before the intervention, this quality changed to predominantly gel-like or saliva-like secretion qualities. This finding reflects a change to a more physiological bronchial mucus quality that may have been supported by the hyperinflation and supported coughing technique used in this study. Obviously, patients will be able to manage and clear secretions of this quality much more easily than the more viscous varieties.

Significant improvements were also found regarding swallowing frequency and vigilance, although these functions are not directly related to the focus of the respiratory intervention technique that was applied in the study. Whereas the average swallowing rate before treatment was clearly beyond physiological limits in all patients, this parameter was improved after the intervention for seven individuals. Swallowing frequency alone is not a valid indicator for improved swallowing function and, certainly, these preliminary findings do not justify an assumption of a direct effect of the applied respiratory intervention on swallowing function. However, this result might emphasize the close interaction between respiratory and swallowing function, and indicate that an increase in respiratory effectiveness might facilitate improvements in swallowing function, as suggested in previous publications [22,23]. Another possible interpretation is that the increased swallowing frequency is the result of increased alertness, as a total of 14 participants were able to improve their vigilance scores from pre-treatment to post-treatment baseline by at least 8 points (1/3 of the total score). Five of the individuals who increased their swallowing rates to normal limits were among these patients.

Limitations

The study's outcome is limited by the following factors: pCO_2 measures were within normal ranges before the intervention started; thus, the effects of bagging on this important parameter of respiratory function could not be validated. A further limitation comes from the small sample size that was not determined from a power analysis, but rather based on pragmatic clinical concerns. Fourteen patients left the hospital and were not available for follow-up baseline measurements, so follow-up data could only be collected for 16 patients. This diminishes the validity of any interpretation of treatment effects as being sustainable. Furthermore, the follow-up period was rather short, thus the longer-term effect of the method cannot be predicted based on the results. Our study design did not include a control group or randomized assignment of the participants into treated or non-treated groups. Additionally, the patients were in an early stage of their rehabilitation process and expected to improve with time. To compensate for this limitation, we chose a multiple baseline design with repeated elicitation of experimental data before and after treatment to gain knowledge about the stability of the participants' performance. However, two consecutive baseline measures may not be enough to ascertain performance stability in a patient group with a very dynamic potential for improvements. Some of the medication involved during the study period might affect mucus production. Thus, a confounding effect on our results cannot be fully excluded. The study's results should be validated in a randomized controlled trial, including a larger group of participants to confirm the above stated results and interpretations.

Clinical implications

This study presents the first data set showing that respiratory intervention using a manual hyperinflation technique (the bagging method) has positive effects on respiratory function in tracheotomized neurological patients. Participants in our study showed improved oxygenation levels, respiratory rates, bronchial mucus quality, swallowing rates and vigilance scores after a 3-week intervention programme. These findings, together with a clear shift in bronchial secretions towards a more physiological quality, suggest that the method might have the potential to support mucociliary and tussive clearance in this patient group and contribute to improvements in respiratory function and in other respiration-related functions. In further studies, this respiratory treatment should be implemented into a swallowing rehabilitation programme to investigate whether specific intervention goals such as the regulation of breathing-swallowing coordination or tracheostomy weaning protocols can be supported by respiratory therapy. Although the specific physiological effect mechanisms of

the bagging-method cannot be clarified by this study, this easy-to-learn and inexpensive method might have the potential to expand the range of treatment options for tracheotomized and severely impaired non-responsive patients.

Conflict of Interest

The authors declare that they have no conflict of interests.

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