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Swallowing rehabilitation of dysphagic tracheostomized patients under mechanical ventilation in intensive care units: a feasibility study

Reabilitação da deglutição em pacientes traqueostomizados disfágicos sob ventilação mecânica em unidades de terapia intensiva: um estudo de factibilidade

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ABSTRACT

Objective: The aim of the present study was to assess the feasibility of the early implementation of a swallowing rehabilitation program in tracheostomized patients under mechanical ventilation with dysphagia.

Methods: This prospective study was conducted in the intensive care units of a university hospital. We included hemodynamically stable patients under mechanical ventilation for at least 48 hours following 48 hours of tracheostomy and with an appropriate level of consciousness. The exclusion criteria were previous surgery in the oral cavity, pharynx, larynx and/or esophagus, the presence of degenerative diseases or a past history of oropharyngeal dysphagia. All patients were submitted to a swallowing rehabilitation program.

An oropharyngeal structural score, a swallowing functional score and an otorhinolaryngological structural and functional score were determined before and after swallowing therapy.

Results: We included 14 patients. The mean duration of the rehabilitation program was 12.4 ± 9.4 days, with 5.0 ± 5.2 days under mechanical ventilation. Eleven patients could receive oral feeding while still in the intensive care unit after 4 (2 - 13) days of therapy. All scores significantly improved after therapy.

Conclusions: In this small group of patients, we demonstrated that the early implementation of a swallowing rehabilitation program is feasible even in patients under mechanical ventilation.

Keywords: Tracheostomy; Respiration, artificial; Deglutition disorders/rehabilitation; Dysphagia; Intensive care units

INTRODUCTION

In the intensive care unit (ICU), pulmonary protection mechanisms are usually abnormal,⁽¹⁾ and dysphagia is a common finding.⁽²⁾ Some researchers have investigated an association between oropharyngeal dysphagia and the presence of an endotracheal tube and cuffed tracheostomy⁽³⁻⁶⁾ because these patients may present silent tracheal aspiration.⁽⁵⁻⁷⁾ Additionally, during the tracheostomy weaning process, patients may experience difficulty in swallowing saliva, and the likelihood of developing aspiration pneumonia is considerably high.⁽⁶⁻⁹⁾

It has been clearly demonstrated that swallowing can be rehabilitated using some therapeutic strategies.⁽¹⁰⁾ Compensatory maneuvers are designed to minimize the signs and symptoms of dysphagia and include changes in posture, enhancement of oral sensitivity⁽¹¹⁾ and changes in food characteristics such as

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volume, viscosity, temperature and taste.^(12,13) The aim of these therapeutic strategies is to restore physiological swallowing; these strategies include mobility exercises, sensory motor integration and swallowing maneuvers.^(14,15)

Thus, there is a reasonable rationale for the early diagnosis and treatment of oropharyngeal dysphagia in critically ill patients. A rehabilitation program can contribute to minimize the negative aspects of food restriction, including patient discomfort, muscular atrophy, decreased oropharyngeal structure sensitivity and nutritional deficiencies. It can also contribute to reducing the risks related to the presence of a feeding tube and bronchial aspiration. It is very likely that the early return of swallowing ability in the setting of mechanical ventilation, even in a small volume, may contribute to better recovery of the health and general well-being of inpatients in the ICU setting.

Early speech therapy in the ICU has received growing attention by researchers and clinicians.^(16,17) A recent study showed that among the 222 patients submitted to a rehabilitation program in an Italian acute care hospital, 14% were referred from the intensive care unit.⁽¹⁸⁾ However, rehabilitation interventions remain uncommon in the management of tracheostomized patients under mechanical ventilation, and studies in this subject are scarce. An Australian retrospective observational study analyzed 140 critically ill patients and reported a 78% incidence of speech-language pathology. The first assessment was performed on average only 14 days after tracheostomy insertion, and the median time to oral intake was 15 days.⁽¹⁹⁾ Some commentaries regarding the relevance of this intervention⁽²⁰⁻³²⁾ and some case reports have been published.⁽³³⁻³⁶⁾ However, there is a lack of information on swallowing rehabilitation outcomes in prospective studies that address the effectiveness of swallowing function or the feasibility of reintroducing an oral diet during mechanical ventilation.

Thus, the aim of this study was to assess, in a small number of patients, the feasibility of implementing an early swallowing rehabilitation program in tracheostomized patients under mechanical ventilation with dysphagia.

METHODS

Patients

This is a prospective, non-controlled, intervention study including patients admitted in 7 intensive care units

of a university public hospital, each one with a particular population. They comprised a general (24 beds), a medical (6 beds), a respiratory (8 beds), a cardiology (10 beds), an emergency department (10 beds) and a nephrology (9 beds) intensive care unit. We included patients under mechanical ventilation with a tracheostomy for at least 48 hours and a diagnosis of dysphagia. They needed to have an appropriate level of consciousness, defined by spontaneous eye opening and the ability to obey commands, hemodynamic stability without a need for vasoactive drugs, and minimum mechanical ventilation parameters, characterized as follows: pressure support ventilation $\leq 20\text{cmH}_2\text{O}$, positive end-expiratory pressure (PEEP) $\leq 8\text{cmH}_2\text{O}$, fraction of inspired oxygen (FiO_2) ≤ 50 and respiratory rate ≤ 30 inspirations per minute. The exclusion criteria included recent surgery involving the resection of oral cavity, pharyngeal, laryngeal and/or esophageal structures, the presence of a nasal or skull base fracture preventing otorhinolaryngological examination, the presence of degenerative diseases characterized by outbreaks and remissions, the lack of upper airway patency, grade III dysphagia, otorhinolaryngological exam intolerance, low survival expectancy or the absence of dysphagia (Table S1 in the electronic supplementary materials). After inclusion, we excluded patients in whom the assessment could not be adequately made as described below.

This study was approved by the Research Ethics Committee of the *Universidade Federal de São Paulo* (UNIFESP) under the protocol number 1802/06, and all participants or legal representatives signed an informed consent form.

Procedure

The study comprised three phases: (1) initial assessment for patient selection, with evaluations by a speech pathologist and an otorhinolaryngologist; (2) swallowing rehabilitation program; and (3) post-treatment reassessments.

The initial assessment included the evaluation of upper airway patency using a Passy-Muir[®] speaking valve. We used a ventilometer to assess the patient's ability to direct an appropriate volume of expired air to the mouth and nostrils while using this device. Spontaneous tidal volume through tracheostomy with an inflated cuff was compared with that measured with a totally deflated cuff and the speaking valve. In this phase, secondary exclusion criteria

included intolerance to remain with a deflated cuff and impossibility of inserting and adjusting a speaking valve due to intolerance or a lack of upper airway patency.

Subsequently, patients underwent initial otorhinolaryngological and speech therapy assessments. In this phase, the exclusion criteria included intolerance to the fiberoptic endoscopic evaluation of swallowing, grade III oropharyngeal dysphagia, defined as massive tracheal aspiration of food at the video nasal endoscopic examination, a tracheostomy tube size that would not allowed the passage of expired air, the presence of bilateral vocal fold paralysis in the adduction position, severe laryngeal and tracheal stenosis, severe laryngo-tracheomalacia, granuloma or tumor and the occurrence of death before the end of evaluations. The speech pathologist's assessment of oropharyngeal structures took into account tonus of the lips and tongue as well as mobility of the lips, tongue, jaw and larynx. The functional evaluation of swallowing was based on lip sealing, food and/or saliva stasis in the oral cavity, the swallowing trigger time, laryngeal elevation and synchronism between swallowing and breathing. At this time point, patients also underwent the modified blue dye test as a complementary test for the evaluation of dysphagia.⁽³³⁾

The otorhinolaryngological assessment was carried out using a bedside video nasal endoscopic examination of swallowing and included evaluation of the following aspects: mobility of vocal folds, swallowing trigger time, food stasis in pharyngeal recesses, laryngeal penetration, tracheal aspiration (according to the Rosenbek scale),⁽³⁷⁾ pharyngeal clearance after swallowing, laryngeal sensitivity and cough reflex. Laryngeal sensitivity was tested by lightly touching the epiglottis with the tip of the scope. This assessment was performed both by the otorhinolaryngologist and the speech-language pathologist in patients using the speaking valve. A value between zero and three was assigned by the examiner, where zero corresponded to an absence of alteration (normal), one corresponded to mild alteration, two corresponded to moderate alteration and three indicated severe alteration. We used these variables to assess the degree of dysphagia from 0 to III, with grade 0 corresponding to a score from 0 - 2 (absence of dysphagia), grade I (mild) corresponding to a score from 3 to 6, grade II (moderate) corresponding to a score from 7 to 18 and grade III (severe) corresponding to a score from 19 to 29.

Based on these results, the research team also developed an oropharyngeal structural score (OSS), a swallowing functional score (SFS) and an otorhinolaryngological structural and functional score (OSFS), which are described in detail in the electronic supplementary materials (Tables S2 to S4). We graded each item of these scores according to the severity from 0 to 3, and a pre-established weight was given according to its functional relevance in swallowing. Thus, a higher score denoted a greater compromise of the swallowing functions, with the OSS score varying from 0 to 27, the SFS score varying from 0 to 17, and the OSFS score varying from 0 to 29.

After the baseline assessment, the rehabilitation program was initiated. A single oral-motor technique was selected for each observed deficit, aiming to standardize the intervention and to reduce muscular fatigue. Every day, each technique was initially performed 10 times in a series intercalated with rest, and the amount of work was reevaluated in each session. Swallowing training techniques comprised indirect therapy (swallowing of saliva) and direct therapy (swallowing of food). The techniques used were as follows: strengthening and motility exercises of the lips, tongue and cheeks; thermal-tactile stimulation; chin down posture; sustained /i/ vowel and melodic curves maneuvers; vocal fold adduction exercises; and coughing and effortful swallowing exercises. We used paste consistency and thin liquids. If disorders of oropharyngeal structures, swallowing delay or reduced laryngeal elevation were detected in the baseline assessment, we began with paste consistency. We used the Passy-Muir[®] speaking valve in each of the rehabilitation sessions.

We defined the treatment duration as the period between the first and the last day of the effective therapy; thus, we included days of interruptions secondary to changes in ventilation parameters or in the level of consciousness. At the end of the treatment period or at the time of ICU discharge, whichever came first, the assessments by the speech pathologist and otorhinolaryngologist were repeated to enable the evaluation of treatment outcomes.

Statistical analysis

The swallowing treatment efficacy was assessed by comparing the scores before and after treatment. The results were expressed as the mean \pm SD for variables with normal distribution. Upon rejection of the normality hypothesis (by the Wilk-Shapiro test), we used the

median and minimum/maximum values. Paired *Student's t* test was applied to data with a normal distribution. When normality was rejected, the Wilcoxon test was used. Categorical variables were expressed as the number and percentage and analyzed by the McNemar test. All p-values were two-sided, and a p-value < 0.05 was considered statistically significant. Statistical analysis was conducted using Statistical Package for the Social Science (SPSS) software, version 15.0 for Windows.

RESULTS

A total of 97 tracheostomized patients receiving mechanical ventilation who were admitted to ICUs from October 2006 to October 2007 were screened. Of those, 81 patients did not participate in the study for various reasons. Sixteen dysphagic patients matched all of the inclusion criteria; 8 were neurological patients, and 8 were non-neurological patients. The mean age was 56.6 ± 25.4 , and a total of 11 males and 5 females were included. The mean hospital stay was 46.9 ± 17.0 days, the mean duration of mechanical ventilation was 32.4 ± 11.6 days, and the mean duration of tracheostomy was 16.5 ± 11.2 days. The demographic and individual characteristics of these patients are described in table 1.

All patients underwent the rehabilitation program; two died during the course of therapy. There was 100% agreement between the assessments conducted by the speech-language pathologist and the otorhinolaryngologist in the diagnosis of oropharyngeal dysphagia. The rehabilitation program characteristics are described in table 2.

Data collected pre and post swallowing therapy for the 14 surviving patients were compared. Analysis of the scores showed a significant improvement on all scales (OSS: pre - 9.0 (3.0 - 15.0), post - 2.5 (0.0 - 8.0), $p = 0.0007$; SFS: pre - 4.5 (3.0 - 6.0), post - 1.0 (0.0 - 3.0), $p = 0.001$ and OSFS: pre - 8.0 (6.0 - 10.0), post - 3.0 (0.0 - 6.0), $p = 0.0004$), as shown in figure 1.

Before speech therapy, four patients presented grade 1 dysphagia, and 10 patients presented grade 2 dysphagia. In the group with grade 1 dysphagia, two patients (50.0%) achieved full improvement; however, in those patients with grade 2 dysphagia, four (40.0%) achieved full improvement, and two (20.0%) patients achieved partial improvement characterized by grade 1 dysphagia. All 14 patients were receiving tube feeding before the onset of therapy. After the rehabilitation program, it was possible for 10 of these patients to receive oral intake associated with enteral feeding; one patient could receive

Table 1 - Demographic data and characterization of individuals in the sample

	Classification	Age	Gender	Baseline disease	Length of hospital stay (days)	Length of tracheostomy (days)	Length of MV (days)
1	Non neurological	21	F	Uncontrolled diabetes	75	38	59
2	Non neurological	26	M	ARDS	41	26	35
3	Non neurological	86	M	Pleural effusion	41	15	35
4	Non neurological	81	M	Chronic renal failure	55	30	43
5	Non neurological	78	M	Renal transplant	63	19	35
6	Non neurological	34	M	Firearm wound	47	29	36
7	Non neurological	51	F	Renal transplant	88	20	48
8	Non neurological	81	F	Femur fracture	49	10	31
9	Neurological	62	M	Hydrocephalus	37	18	27
10	Neurological	82	F	Parkinson's disease	55	16	32
11	Neurological	14	M	Spinal cord injury	25	3	14
12	Neurological	75	F	Alzheimer's disease	36	3	18
13	Neurological	60	M	Stroke	31	6	21
14	Neurological	21	M	Brain injury	26	2	22
15	Neurological	75	M	Parkinson's disease	42	4	24
16	Neurological	59	M	Botulism	39	25	38

MV - mechanical ventilation; F - female; M - male; ARDS - acute respiratory distress syndrome.

Table 2 - Overall features of the speech rehabilitation program

Item	N (%)	Results
Duration of treatment (days)*	16 (100.0)	12.44 ± 9.40 10 (1 - 38)
Sessions performed (N)	16 (100.0)	7.50 ± 5.34 7 (1 - 22)
Mechanical ventilation therapy (days)	15 (93.8)	5.00 ± 5.22 3 (1 - 20)
Spontaneous breathing therapy (days)	13 (81.3)	3.46 ± 1.76 3 (2 - 8)
Indirect therapy (days)	16 (100.0)	4.06 ± 3.70 3 (1 - 12)
Direct therapy (days)	11 (68.8)	5.00 ± 2.79 5 (1 - 10)
Starting day of oral route (days)	11 (68.8)	4.91 ± 3.70 4 (2 - 13)

* Includes the days of treatment interruption. The results are expressed as the mean ± standard deviation, median (minimum - maximum).

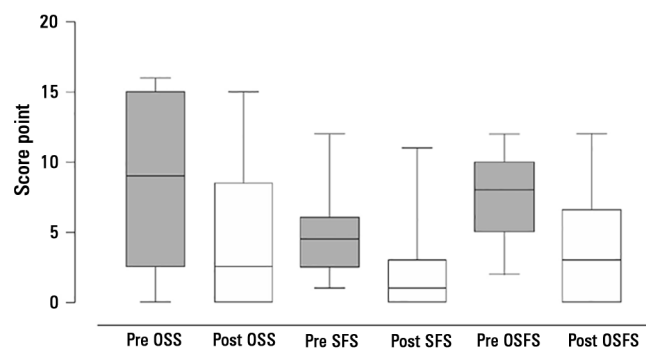


Figure 1 - Comparison between the oropharyngeal structural score, swallowing functional score and otorhinolaryngological structural and functional score pre and post treatment. OSS - oropharyngeal structural score; SFS - swallowing functional score; OSFS - otorhinolaryngological structural and functional score. Results show the significant reduction of all scores; OSS, $p = 0.007$, SFS, $p = 0.001$ and OSFS, $p = 0.004$. (OSS and OSFS - paired t test, SFS - Wilcoxon paired test).

an exclusively oral diet, and 3 patients could not receive an oral diet. The average amount of oral intake was 180ml (11 patients) for the paste consistency diet and 87.5ml (4 patients) for the thick liquid diet.

DISCUSSION

This study showed that a speech therapy intervention on ICU patients under mechanical ventilation is feasible and might help to improve the swallowing function and oropharyngeal dysphagia severity. We did not find any studies in the literature analyzing the impact of swallowing

rehabilitation on dysphagia in patients on mechanical ventilation except for case reports⁽³³⁻³⁶⁾ and the opinions of specialists in the field.⁽²⁰⁻³²⁾ Thus, this feasibility study in a small number of patients suggests that a clinical trial with an adequate sample size and clinical outcomes should be conducted.

Through the assessment of oropharyngeal structures, we observed that the most evident pre-program abnormalities, i.e., lip and tongue tonus and larynx mobility, showed improvement, although without statistical significance, after the treatment. Even the less frequent abnormalities (lip, tongue and jaw mobility) also showed non-significant improvement. This finding suggests that the proposed isolated exercises were able to improve the range of movement and the tonus of each oropharyngeal structure, which may have led to better swallowing.⁽³⁸⁾ We found similar results in the functional parameters (swallowing trigger time and laryngeal elevation). Although none of these parameters significantly improved after treatment, likely because of our small sample size, this finding is in accordance with the significant improvement found in the scores. As for the structural and functional analysis of swallowing based on the OSFS score, a significant improvement was observed in the laryngeal sensitivity and the cough reflex.⁽⁵⁾ Tracheal penetration, food stasis in pharyngeal recesses and the swallowing trigger time showed non-significant improvements.

One of the contributions of our study is the score analysis, as no score was previously available. We did not use the Functional Oral Intake Scale (FOIS) proposed by Crary et al., as this scale only accounts for improvement in the consistencies of oral intake after a speech therapist rehabilitation program.⁽³⁹⁾ In our study, we needed to evaluate and compare structural and functional alterations related to the presence of dysphagia. The Toronto Bedside Swallowing Screening Test (TOR-BSSST), described by Martino et al, is a screening tool used to assess the risk of dysphagia and is thus not suitable to assess the impact of our rehabilitation program.⁽⁴⁰⁾ The criteria to select our score parameters and to determine their weights were based on the relevance of each parameter in the swallowing process. From the structural point of view, the tongue is responsible for propelling the food bolus towards the pharynx, whereas the larynx is part of the protective mechanism of the airways. From a functional point of view, laryngeal elevation and synchronism between

breathing and swallowing are essential mechanisms to prevent tracheal aspiration. For this reason, a weight of 2 was assigned to these variables. In the OSFS, a weight of 2 was assigned to the cough reflex, laryngeal penetration and tracheal aspiration.

According to Cowley et al. and Moraes et al., daily assistance is necessary, especially during the transition from tube feeding to oral feeding.^(23,41) In our study, although we predefined a daily follow-up, this was not possible due to limitations inherent to the patients themselves such as changes in ventilation parameters and in the level of consciousness. In this study, the mean number of sessions per patient was 7.5, with a mean treatment duration of 12 days, including both the swallowing sessions and the days of interruption. It is possible that our results would have been more relevant if the daily assistance approach had been feasible.

Our swallowing therapy was based on data from the baseline swallowing assessment. All patients in this study initially received indirect therapy over a mean period of 4 days. The indication of indirect therapy as the initial approach was based on the presence of a significant number of swallowing deficits related to the range of movement and tonus of the lips, tongue, mandible and larynx. The objective of indirect therapy was to prepare the oropharyngeal muscles using swallowing and voice maneuvers and techniques, with the final goal of reintroducing oral feeding. Additionally, a period of one to two days was necessary to adjust the speaking valve. Direct therapy was implemented according to the patient's progression. Specific swallowing training was initiated with 3 to 5ml of paste consistency diet, administered orally. Although several authors have advocated that direct therapy could be given to these patients,^(25,27,35,42-44) the safety of this procedure has never been studied. In this study, the initial use of indirect therapy followed by direct therapy may have contributed to our positive outcomes. Three patients were unable to manage food in the oral cavity and were not able to progress to direct therapy during their stay at the ICU. Although oral feeding could not be attained in these patients, the general improvement in the aspects related to the oropharyngeal structures has allowed for better communication regarding speech - voice and articulation, at least in a subjective analysis.⁽⁴⁵⁾ In addition, because the rehabilitation treatment continued after discharge from the ICU, indirect therapy may still

have contributed to improving the swallowing function throughout the patient's stay at the hospital ward.

This study has both strengths and limitations. For the strengths, first, we compared the results of clinical and otorhinolaryngological assessments before and after swallowing therapy. Additionally, the evaluation of swallowing was complete and included clinical and objective aspects using detailed scores. However, there were some limitations. First, the scores used had not been previously validated; thus, it is not possible to assure that they truly express the severity of dysphagia. However, the negative impact of the lack of validation was minimized by the fact that the same scores were used both before and after the intervention. Second, the number of patients evaluated was small, which certainly compromises the generalizability of the results. As mentioned previously, this is a case series and should be thus considered as a feasibility study. Third, we did not have a randomized control group. The lack of a control group hindered the analysis of potential spontaneous improvement during the swallowing rehabilitation program. Fourth, we analyzed a specific subset of critically ill patients, all of whom had a tracheostomy, were ventilated with minimal parameters, and were clinically stable, awake and cooperative at the time of the procedure. Consequently, other populations with different features should be further investigated. As this was the first feasibility study, as a safety measure, we decided not to include hemodynamically unstable patients or patients with high levels of PEEP or pressure support. However, based on our promising initial results, a future study could certainly include those patients. Finally, in most of the ICUs, a speech therapist is not available; this might hamper the applicability of our scores as well as the use of the rehabilitation program.

CONCLUSION

In this study, we demonstrated that an early rehabilitation program is feasible in a small group of patients still under mechanical ventilation. Our results should help to design a clinical trial with an adequate sample size and clinically applicable outcomes.

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RESUMO

Objetivo: Avaliar a factibilidade da implantação precoce de um programa de reabilitação da deglutição em pacientes traqueostomizados com disfagia e sob ventilação mecânica.

Métodos: Estudo prospectivo realizado em unidades de terapia intensiva de um hospital universitário. Incluímos pacientes hemodinamicamente estáveis e submetidos à ventilação mecânica por pelo menos 48 horas e há no mínimo 48 horas com traqueostomia e nível adequado de consciência. Os critérios de exclusão foram cirurgia prévia na cavidade oral, faringe, laringe e/ou esôfago, presença de doenças degenerativas ou história pregressa de disfagia orofaríngea. Todos os pacientes foram submetidos a um programa de reabilitação da deglutição. Antes e após o tratamento de reabilitação da deglutição, foram determinados

um escore estrutural orofaríngeo, um escore funcional de deglutição, e um escore otorrinolaringológico estrutural e funcional.

Resultados: Foram incluídos 14 pacientes. A duração média do programa de reabilitação foi de $12,4 \pm 9,4$ dias, com média de $5,0 \pm 5,2$ dias sob ventilação mecânica. Onze pacientes puderam receber alimentação por via oral enquanto ainda permaneciam na unidade de terapia intensiva após 4 (2 - 13) dias de tratamento. Todos os escores apresentaram melhora significativa após o tratamento.

Conclusões: Neste pequeno grupo de pacientes, a implantação de um programa precoce de reabilitação da deglutição foi factível, mesmo em pacientes sob ventilação mecânica.

Descritores: Traqueostomia; Respiração artificial; Transtornos de deglutição/reabilitação; Disfagia; Unidades de terapia intensiva

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