CoDAS
ISSN 2317-1782 (Online version)

Original Article
Artigo Original

Efficacy of speech therapy in post-intubation patients with oropharyngeal dysphagia: a randomized controlled trial

Eficácia da terapia fonoaudiológica em pacientes pós-intubação com disfagia orofaríngea: um ensaio clínico randomizado

Giovana Sasso Turra[1]
Ida Vanessa Doederlein Schwartz[1,2]
Sheila Tamanini de Almeida[3]
Chenia Caldeira Martinez[4]
Maristela Bridi[1]
Sérgio Saldanha Menna Barreto[1]

Keywords

Deglutition Disorders
Intubation Intratracheal
Intensive Care Units
Speech Therapy
Enteral Nutrition

ABSTRACT

Purpose: to verify the efficacy of speech therapy in the early return of oral intake in patients with post-orotracheal intubation dysphagia. **Methods:** It was a double-blinded randomized controlled trial for two years with patients of intensive care units of a hospital. Study inclusion criteria were orotracheal intubation>48hours, age≥18 years old, clinical stability, and dysphagia. Exclusion criteria were tracheotomy, score 4 to 7 in the Functional Oral Intake Scale (FOIS), neurological disorders. Patients were randomized into speech treatment or control group (ten days of follow-up). The treated group (TG) received guidance, therapeutic techniques, airway protection and maneuvers, orofacial myofunctional and vocal exercises, diet introduction; the control group (CG) received SHAM treatment. Primary outcomes were oral intake progression, dysphagia severity, and tube feeding permanence. **Results:** In the initial period of study, 240 patients were assessed and 40 (16.6%) had dysphagia. Of this, 32 patients met the inclusion criteria, and 17 (53%) received speech therapy. Tube feeding permanence was shorter in TG (median of 3 days) compared to CG (median of 10 days) (p=0.004). The size effect of the intervention on tube feeding permanence was statistically significant between groups (Cohen's d=1.21). TG showed progress on FOIS scores compared to CG (p=0.005). TG also had a progression in severity levels of Dysphagia protocol (from moderate to mild dysphagia) (p<0.001). **Conclusion:** Speech therapy favors an early progression of oral intake in post-intubation patients with dysphagia. Clinical Trial Registration: RBR-9829jk.

Descritores

Transtornos de Deglutição
Intubação Intratraqueal
Unidades de Terapia Intensiva
Fonoterapia
Nutrição Enteral

RESUMO

Objetivo: verificar a eficácia da fonoterapia no retorno precoce da via oral em pacientes com disfagia pós-intubação orotraqueal. Métodos: Ensaio clínico controlado, randomizado, duplo-cego, realizado por dois anos com pacientes de Unidades de Terapia Intensiva de um hospital. Os critérios de inclusão foram intubação orotraqueal>48 horas, idade ≥18 anos, estabilidade clínica e disfagia. Foram excluídos pacientes com traqueotomia, 4 a 7 pontos na Escala Funcional de Ingestão Oral (FOIS), distúrbios neurológicos. Os pacientes foram randomizados para grupo tratado (GT) ou grupo controle (GC) (dez dias de acompanhamento). O GT recebeu orientações, técnicas e manobras terapêuticas, exercícios vocais e miofuncionais orofaciais, introdução da dieta por via oral; o GC recebeu tratamento SHAM. Os desfechos foram progressão da ingestão oral, gravidade da disfagia e via alternativa de alimentação. Resultados: Inicialmente foram avaliados 240 pacientes, desses 40 (16,6%) apresentaram disfagia. Trinta e dois pacientes preencheram os critérios de inclusão e 17 (53%) receberam terapia fonoaudiológica. A permanência da alimentação por sonda foi menor no GT (mediana de 3 dias) em comparação ao GC (mediana de 10 dias) (p=0.004). O tamanho do efeito da intervenção sobre o tempo de permanência com sonda nasoentéroica foi estatisticametne significativo entre os grupos (Cohen's d=1.21). O GT apresentou progresso nos escores FOIS em comparação ao GC (p=0.005). O GT também teve uma progressão nos níveis de gravidade do PARD (de disfagia moderada a leve) (p<0.001). Conclusão: A terapia fonoaudiológica favorece uma progressão precoce da ingestão oral em pacientes pós-intubação com disfagia. Registro de Ensaio Clínico: RBR-9829jk.

Correspondence address:
Chenia Caldeira Martinez
Instituto de Psicologia, Universidade Federal do Rio Grande do Sul – UFRGS
Protásio Alves, 297, Protásio Alves, Porto Alegre (RS), Brasil, CEP: 90620-110.
E-mail: chenia.martinez@gmail.com

Received: October 31, 2019

Accepted: April 22, 2020

Study conducted at Faculdade de Medicina, Universidade Federal do Rio Grande do Sul – UFRGS - Porto Alegre (RS), Brasil.

[1] Programa de Pós-graduação em Ciências Médicas, Universidade Federal do Rio Grande do Sul – UFRGS - Porto Alegre (RS), Brasil.

[2] Serviço de Genética Médica, Hospital de Clínicas de Porto Alegre - Porto Alegre (RS), Brasil.

[3] Departamento de Fonoaudiologia, Universidade Federal de Ciências da Saúde de Porto Alegre – UFCSPA - Porto Alegre (RS), Brasil.

[4] Instituto de Psicologia, Universidade Federal do Rio Grande do Sul – UFRGS - Porto Alegre (RS), Brasil.

Financial support: Fundo de incentivo à pesquisa (FIPE) – projeto número 20090617.

Conflict of interests: nothing to declare.

INTRODUCTION

Prolonged orotracheal intubation is considered a risk factor for oropharyngeal dysphagia[1-7]. The incidence rate of dysphagia in Intensive Care Unit (ICU) ranges from 3 to 62%[2]. Deglutition disorders after extubation can persist until hospital discharge in the majority of affected patients, and can be considered an independent predictor of death[5].

Studies present that dysphagia is considered a variety of oropharyngeal compromises in post-intubation patients, and not only a specific type of disorder. These characteristics may be related to decrease in oral sensitivity, poor oral control of bolus, excess of oral or pharyngeal residues, and laryngeal penetration and aspiration[1,3,4,6,8,9]. Studies also suggest swallow-related muscle weakness[10], suppression of coughing reflex[11], reduced laryngeal sensitivity[11], and decreased proprioception[12].

Intubation patients usually use an enteral tube feeding for nutrition. Problems associated with the tube feeding include discomfort, nasal trauma/bleeding, sinusitis, erosions, tube misplacement displacement, tube blockage, dry mouth/parotitis, nausea, bloating, abdominal pain, loss of oral/social aspects of feeding, and others symptomps[6,12].

Patients submitted to prolonged intubation can present risk of aspiration and should be referred to an early Speech-Language Pathology assessment in order to receive appropriate and timely treatment[4], once therapeutic strategies aims to improve swallowing function, to protect the airways and to improve nutrition and hydration of patients[4,6]. The efficacy of swallowing treatment is usually defined as a and early return to oral intake, even in a small volume, improving general health and well-being of patients in ICU[8,11,13].

It is important to highlight that the body of evidence for dysphagia treatment is restricted, especially considering randomized controlled trials including Speech-Language Pathology interventions[2,6,9,11,14,15]. Nowadays, there are few evidences available about dysphagia following intubation and it is highlighted the need for high-quality prospective trials. The main purpose of this study was to verify the efficacy of speech therapy in the early return of oral intake in Intensive Care Unit (ICU) patients with post-orotracheal intubation dysphagia.

METHODS

Study design and selection criteria

A prospective, randomized, controlled, double-blind trial was conducted in post-intubation patients with oropharyngeal dysphagia recruited from the Intensive Care Unit of a Hospital, with data collection during two years. This study was approved by the Committee for Ethics in Research of the Institution (protocol 09-617) and all subjects signed an informed consent form before randomization process. The trial registration was registered in the Brazilian Registry of Clinical Trials – ReBEC - (protocol RBR-9829jk).

The inclusion criteria were patients being hospitalized, age≥18 years, being clinically stable, depending on alternative feeding methods, no neurological diseases, and receiving orotracheal intubation for at least 48 hours. Exclusion criteria were patients with a neurological disorder prior to the event that led to intubation, those whose event that led to the intubation was of neurological origin; those who showed neurological diseases in the period of extubation; tracheotomy; total oral diet with defined by Functional Oral Intake Scale (FOIS)[16], with scores between 4 to 7 in this scale.

The assessment

FOIS is an evaluation instrument that has adequate reliability, validity, and sensitivity to change in functional oral intake and comprises seven levels: From levels 1 to 3, patients are dependent on an alternative feeding method; from levels 4 to 7, patients have total oral intake. To score functional oral intake with this scale, clinicians may obtain information from a variety of sources including medical charts, dietary journals, and/or verified patient reports[16].

Dysphagia was evaluated by Protocolo de Avaliação do Risco para Disfagia (PARD)[17], a Brazilian protocol to risk identification of dysphagia. It includes the controlled offer of water and puree volumes. It characterizes clinical signs that are suggestive of laryngeal penetration or aspiration, the severity of dysphagia and it helps to determine how the case will be conducted. According to this protocol, the classification of dysphagia is based on seven levels to determine normal swallowing, functional swallowing and oropharyngeal dysphagia.

Outcomes

The primary outcomes of the study were oral intake progression, dysphagia severity, and enteral tube feeding permanence. FOIS was used in order to identify oral intake progression levels. A speech therapist, independent and blinded, assessed the Treated Group (TG) and the Control Group (CG) every other day for ten days (totaling 5 assessments) during the period of intervention. To measure this outcome, the number of days between study inclusion and removal of tube was also considered.

The dysphagia severity level was classified according to the PARD, in both TG and CG, before and after speech therapy program, including seven levels: In the first, patient has normal swallowing; in the second, functional swallowing; in the third, mild oropharyngeal dysphagia; in the fourth, mild to moderate dysphagia; in the fifth, moderate dysphagia; in the sixth, moderate to severe dysphagia, and in the seventh, severe dysphagia. In functional dysphagia is expected spontaneous compensations, with mild difficulties for at least one food consistency; absence of signs that are suggestive of aspiration. Oral feeding is recommended, but additional time may be necessary to complete this task.

Sample size and statistical analysis

Sample size was estimated at 44 patients, 22 treated and 22 untreated, by the software WinPepi. The sample was calculated to detect the difference in median tube feeding permanence between treated and untreated patients during hospitalization. In the literature, mean tube feeding permanence in patients

without oropharyngeal dysphagia was 7.2±4.3 days after 48 hours of extubation[6]. It was considered that a decrease by 50% (3.5 days) in this time could be attributed to the study intervention. The level of significance was 5%, and power was 80%. Losses were estimated at 10%.

Data were analyzed using descriptive statistics and by Mann-Whitney and Fisher's Exact tests to check for statistical significance. Normality was tested through the Kolmogorov-Smirnov test. For these tests, the significance level was set at a maximum of 5% ($p \leq 0.05$) and the software used for statistical analysis was SPSS version 18.0. For the comparison between TG and CG regarding FOIS and the level of oropharyngeal dysphagia, the generalized estimating equations (GEE) approach was used for multiple comparisons with Bonferroni adjustment, considering $p \leq 0.05$. The effect size for tube feeding permanence was assessed by the Cohen's d test.

Recruiting/sampling

Sampling was sequential. Patients were randomized into the following groups: treated group (TG="true speech intervention") and control group (CG="not true speech intervention"). There was no ethics restriction in establishing an untreated control group given that the institution where the study was conducted does not feature a speech therapy service that provides routine care to patients. For sample randomization, 44 random numbers were generated, using the function RV.UNIFORM(0.1) of the software SPSS version 18.0, in order to assign both the treated group and the control group.

Two hundred and forty patients were selected initially selected in ICUs, according the eligibility criteria. All patients were assessed by a speech-language pathologist, and 40 (16.6%) were classified with oropharyngeal dysphagia by PARD and FOIS protocols. Of these, 32 patients attended to inclusion criteria. Interim statistical analysis had already showed significance with this number of individuals; consequently, sample size was not increased. A flowchart of those included and excluded and the final number of participants is shown in Figure 1.

During the recruitment period of the study, speech therapist A made daily contacts with the medical team of the ICU in order to identify possible individuals for the study. All patients were evaluated 24 hours after extubation. After an authorization was given by the physician in charge, the patient was identified and research procedures were explained to his or her legal guardian. Upon agreement, the FOIS was first applied by speech therapist B, based on information collected from medical records or patient's interview. Next, a detailed assessment was done by speech therapist A in order to detect dysphagia and classify its severity level by PARD protocol[17,18]. If the presence of dysphagia was confirmed, and following the remaining inclusion and exclusion criteria, the patient was included in the study and randomized either into the TG or the CG (Figure 2). It must also be pointed out that the present study was based on intention-to-treat analysis.

During treatment, in some cases it was not possible to complete the length of intervention. In the TG, interruption happened in two cases (11.8%) due to death.

The intervention

Speech therapy program applied in the TG took place for 30 minutes once a day, for a maximum period of ten days, and was always administered by a speech pathologist (therapist A, not blinded). Patients were instructed to perform the exercises only with therapist A, during sessions.

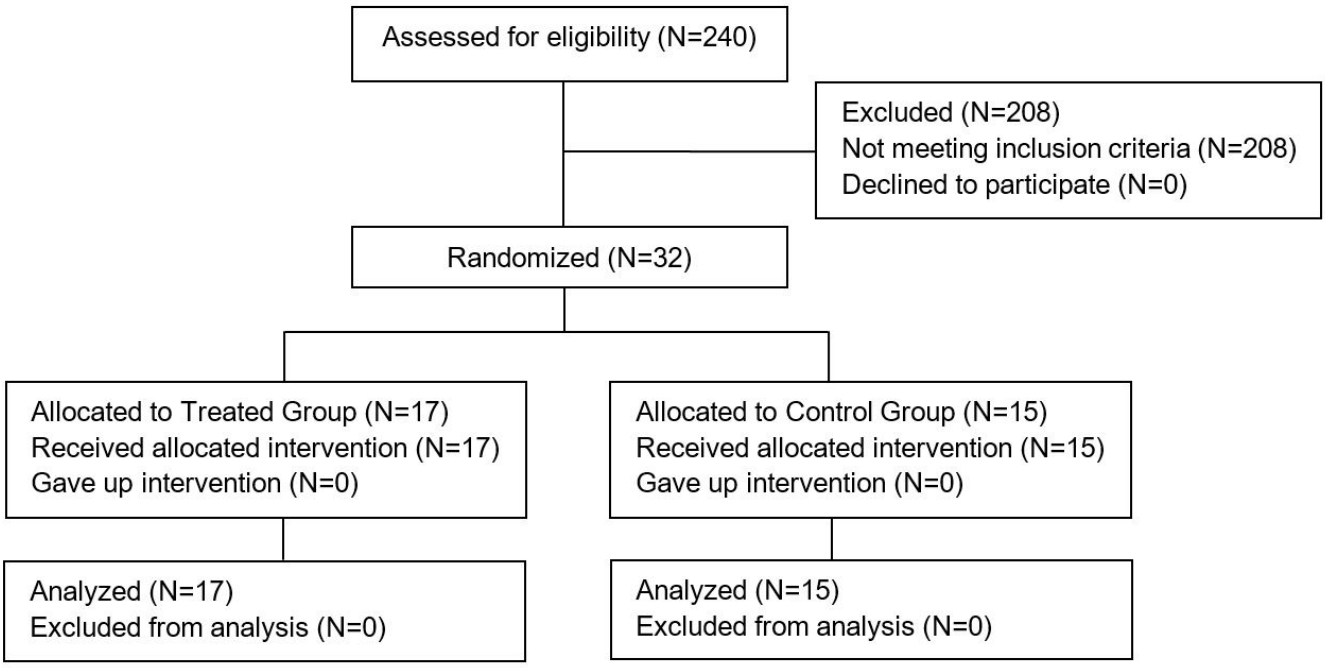

Figure 1. Flowchart of the recruitment process and allocation of the participants. N = number of patients

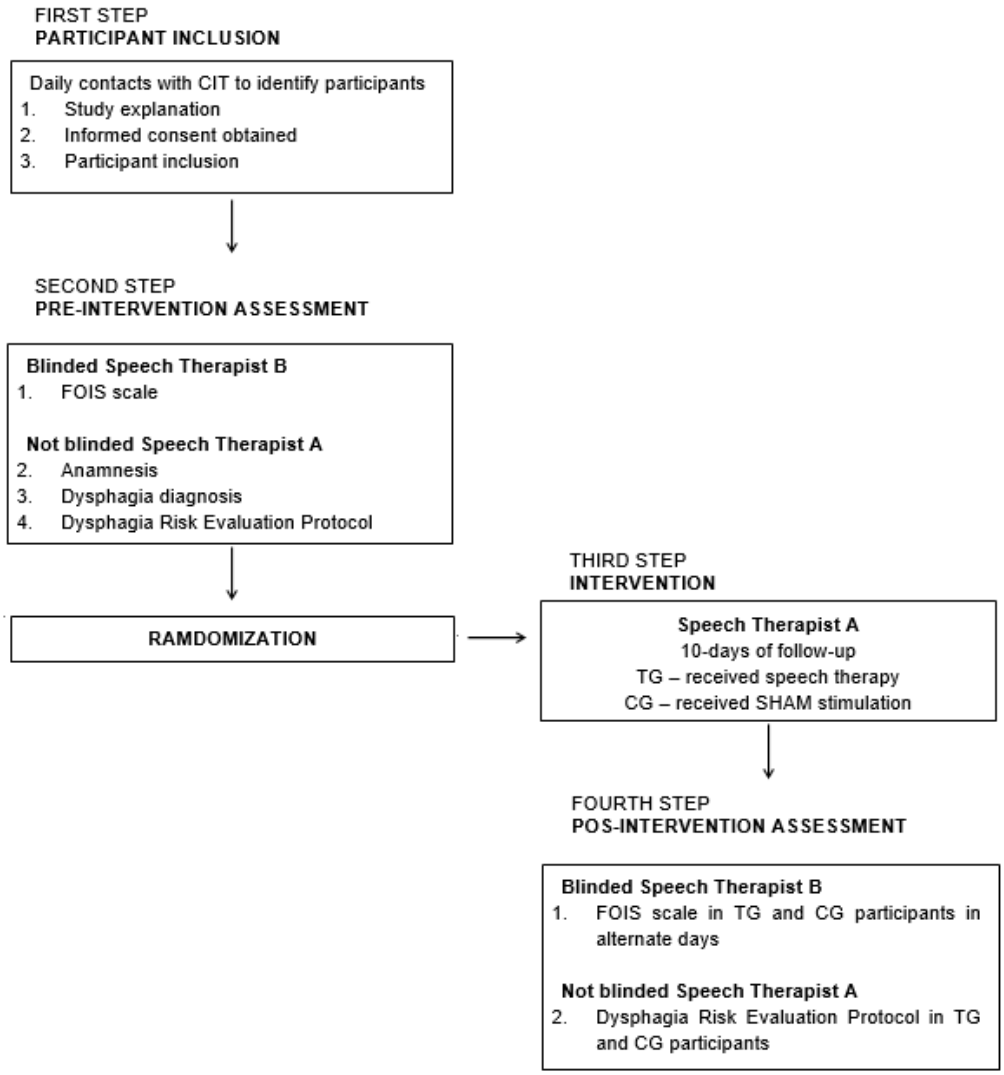

Figure 2. Flowchart of the study procedures

The intervention methods were adjusted to each patient's necessity, and comprised the following strategies: individual therapeutic planning; compensatory strategies (patient's postural changes; diet modification; alternative texture/temperature/flavor of meals; thickening liquids); adjust of environmental factors to improve deglutition/feeding abilities. Therapeutic strategies were also indicated, such as starting the swallowing response and the diet by mouth, strategies for airway protection and glottal cleaning maneuvers, motoric and coordination exercises to improve the range of motion of the lips, tongue, jaw, and to improve vocal fold adduction, laryngeal elevation, or tongue base retraction (three series of ten repetitions)[13,18].

The CG was followed in line with TG, but with SHAM stimulation program (placebo therapy). It means that they not received speech therapy procedures that was proposed for the TG. Patients were not required to practice the exercises outside speech therapy program sessions.

RESULTS

It is important to emphasize the prevalence of oropharyngeal dysphagia in this study sample. Two hundred and forty patients were assessed, and 40 (16.6%) were diagnosed with dysphagia after orotracheal intubation as demonstrated in Figure 1.

Clinical characteristics and baseline scores for both groups are shown in Table 1. Groups differed on inclusion regarding gender, age, presence of metabolic disorder, and PARD levels. The difference in tube feeding permanence between groups remained significant even after adjustment for age and PARD levels by Multiple Linear Regression (p=0.022).

In the beginning of the study, most patients showed clinical signs of dysphagia with liquid consistency (water), 10/17 (58.8%) in the TG and 8/15 (53.3%) in the CG (p=0.868). Deglutition of solid-consistency foods (french roll bread) were assessed only in patients with normal dentition, since patients who made use of dental prosthesis were not wearing them at the ICU (17/32,

Table 1. Sample characterization upon study inclusion

	Treated Group (n=17)	Control Group (n=15)	P value
Gender (M:F)	03:14	10:05	0.010†
Median age in years (IQ25-75)	59 (42-65)	74 (51-75)	0.008‡
Median length of intubation in days (IQ25-75)	8 (6-13.5)	9 (5-10)	0.834‡
Median length of extubation in days (IQ25-75)	2 (2-3.5)	2 (2-3)	0.581‡
Morbidities*			
Pulmonary Complications	16 (94.1%)	12 (80.0%)	0.319†
Heart Disease	6 (35.3%)	8 (53.3%)	0.476†
Renal Disorder	7 (41.2%)	4 (26.7%)	0.472†
Gastroenterological Disorder	5 (29.4%)	6 (40.0%)	0.712†
Infectious Disease	14 (82.4%)	13 (86.7%)	1.000†
Psychiatric Disorder	3 (17.6%)	1 (6.7%)	0.603†
Metabolic Disorder	9 (52.9%)	2 (13.3%)	0.028†
Use of medications that cause dysphagia	11 (64.7%)	9 (60.0%)	1.000†
Drug abuse**	5 (29.4%)	6 (40.0%)	0.712†
Normal Dentition	5 (29.4%)	5 (33.3%)	0.678†
Adequate Vocal Quality	2 (11.8%)	1 (6.7%)	1.000†
Presence of ability to cough	14 (82.4%)	15 (100%)	0.229†
Presence of laryngeal elevation	17 (100%)	15 (100%)	1.000

†Fisher's Exact Test; ‡Mann-Whitney Test; *The following were considered as: respiratory disorder (acute respiratory insufficiency – ARI; acute respiratory distress syndrome – ARDS; chronic obstructive pulmonary disease – COPD; tuberculosis), heart disease (mitral insufficiency; diastolic dysfunction; acute myocardial infarction), renal disorder (acute renal insufficiency – IRA; nephropathy), gastroenterological disorder (cirrhosis; hepatitis; pancreatitis; peritonitis), infectious disease (sepsis; HIV; pneumonia), psychiatric disorder (depression; schizophrenia), metabolic disorder (diabetes; hypothyroidism; hyperthyroidism); **crack cocaine, alcohol, tobacco

53.1%). Signs of dysphagia were identified in 2/17 (11.8%) TG patients and in 1/15 (6.7%) CG patients in this solid consistency. Regarding the swallowing difficulties with pudding consistency (mashed banana), no patient showed clinical signs of dysphagia. Two patients (11.8% of TG, and 13.4% of CG group) presented dysphagia with all consistencies.

The results and outcomes after speech intervention were presented in Table 2. The comparison between groups regarding the progression of oral intake and the severity of dysphagia, before and after intervention, presented a significant difference only in the TG group ($p<0.001$) by generalized estimating equations with Bonferroni Adjustment. After intervention, eight patients progressed to 4-7 FOIS levels in TG group, while two patients progressed to these levels in CG group.

It is important to highlight that the main reason for remaining the enteral tube feeding was unresolved dysphagia in this sample, with a significant difference between the groups. It was also observed that the size effect of the intervention on enteric tube feeding permanence was statistically significant between groups (Cohen's d=1.21). Similarly, after adjusting the results obtained for the FOIS with the same co-variables, statistical significance was maintained (p=0.023, GEE).

DISCUSSION

This is the first randomized controlled trial conducted with patients with post-intubation oropharyngeal dysphagia, in ICUs of a Hospital in Southern of Brazil. The comparisons between before and after periods of follow-up showed an improvement of dysphagia in both groups, more evidently in treated group, indicating the efficacy of a speech therapy program in the treatment of these patients. The high prevalence of oropharyngeal dysphagia identified in this study sample corroborate data presented in literature[2].

Swallowing assessment procedures applied were FOIS and PARD protocols. FOIS levels demonstrated a safe progression of oral intake in TG patients when compared to CG patients. FOIS is described as an important and reliable instrument to assess the progression of oral intake[13]. Although the gold standard assessment for dysphagia are fiberoptic endoscopic evaluation of swallowing and videofluoroscopy, not all hospitals and patients have access to such procedures. A recently study presented that non-invasive and non-instrumental assessment protocols, like FOIS, provide information about feeding aspects and can predict aspiration in oropharyngeal dysphagia mostly when they are associated with other assessment procedures[19]. There are studies in literature[9,20] that also assessed the efficacy of a speech therapy intervention using PARD protocol, indicating this instrument is also a good marker to assess the severity of oropharyngeal dysphagia.

Speech therapy rehabilitation in oropharyngeal dysphagia includes therapeutic procedures to produce benefic effects in swallowing dynamics, changing the neurophysiologic mechanisms responsible by the upper digestive system with orofacial myofunctional adjustment. This program can stabilize the nutritional aspect and eliminate laryngotracheal aspiration risks[13,20], reducing the length of enteral tube feeding and the severity of dysphagia as identified by the study outcomes.

In this context, tube feeding permanence in the CG can support the efficacy of speech therapy. This group had twice number

Table 2. Sample characterization and outcomes after speech intervention

	Treated Group (n= 17)	Control Group (n=15)	P value
Progression of Oral Intake Outcome			
Mean level on FOIS before intervention (SE)	2.11 (0.31)	1.83 (0.25)	0.489*
Mean level on FOIS after intervention (SE)	4.24 (0.58)	2.40 (0.28)	0.005*
Median length of intervention in days (IQ25-75)	8 (4.5-10)	10 (10-10)	0.053‡
Median length of ETF after study inclusion in days (IQ25-75)	3 (1-6)	10 (4-10)	0.004‡
Severity of Dysphagia Outcome			
Mean level on PARD protocol before intervention (SE)	5.71 (0.33)	6.67 (0.15)	0.008*
Mean level on PARD protocol after intervention (SE)	3.12 (0.64)	5.60 (0.54)	0.003*
Reasons for ETF permanence			
Unresolved dysphagia	6 (35.3%)	12 (80.0%)	0.039†
Maintenance of nutrition	3 (17.6%)	1 (6.7%)	
ETF did not stay in place	8 (47.1%)	2 (13.3%)	
Adverse Events			
Death	2 (11.8%)	-----	0.535†
Reintubation	3 (17.6%)	4 (26.7%)	
Clinical worsening	1 (5.9%)	-----	
Withdrawal	1 (5.9%)	-----	

*Generalized estimating equations with Bonferroni adjustment; †Fisher's Exact test; ‡Mann-Whitney test; **Caption**: ETF = enteral tube feeding; SE = standard error

of patients with tube feeding when compared to TG in the end of follow-up. According to Furkim and Sacco[13] the return to oral intake can be defined as an improvement of swallowing function. It is important to highlight that the presence of more severe signs of dysphagia was associated with a 50% increase in length of hospital stay[8].

As demonstrated in literature about dysphagia, pulmonary complications were the most frequent morbidity found in both groups. The main risk factor for oropharyngeal dysphagia in hospitalized patients was respiratory distress and pulmonary disorders[6,21]. It was also observed an elevated frequency of patients with infectious disease in this sample, corroborating the literature[7], once authors found sepsis like an independent predictor to dysphagia. Another study conducted in a Brazilian hospital highlighted that infectious diseases are one of the most prevalent morbidities in ICUs, especially in elderly patients. These health conditions can be related to a longer time and high cost of hospitalization, and higher morbidity and mortality rates[22].

In the baseline period, the groups were heterogeneous in some variables. The factors that could be potential biases in the present findings would be age and severity of dysphagia. Aging influences in swallowing mechanism and can be related to oropharyngeal dysphagia regardless of their use of orotracheal intubation[23], but differences between groups remained after adjusting for age and severity of oropharyngeal dysphagia in the post-intervention period.

It is important to highlight that the present results indicated the benefits of a daily speech therapy program for dysphagia during ICU hospitalization, once the study methods included a concept of intensive speech therapy in dysphagia, based on previous research focused on daily therapy sessions that showed an early progression of oral intake outcome[23].

This study had limitations. It was not included objective assessments for dysphagia. The treated and control groups were heterogeneous in the baseline period, but differences were also found between the groups in the post-intervention period after adjusting for age and severity of oropharyngeal dysphagia. It is also highlighted that, even with a small sample size, study data had a power of 95% to analyze the effects of speech therapy on the outcomes in both groups.

CONCLUSIONS

The present study identified an improvement of oropharyngeal dysphagia, with an early and safe return of oral intake, in ICU patients with post-orotracheal intubation dysphagia, comparing the before and after periods of speech therapy intervention. The results indicated the benefits of a daily speech therapy program during hospitalization, introducing relevant information about swallowing treatment in ICU patients.

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Author contributions

GST and STA participated in the data collection, analysis, writing, and review of the paper; CCM and MB participated in the data collection, analysis, and writing the paper; IVDS and SSMB had the project guidance, writing, and review of the paper.