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Case Report

Respiratory support effect on pharyngeal area in patients with amyotrophic lateral sclerosis: A fluoroscopic comparison of NIV, helmet/CPAP, and high-flow nasal cannula

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ABSTRACT

The global use of noninvasive respiratory support provided by different supportive ventilation delivery methods (SVDMs) has increased, but the impact of these devices on the upper airway structures of patients with amyotrophic lateral sclerosis (ALS) is not known. We aimed to compare the pharyngeal cross-sectional area during spontaneous breathing with four different SVDMs: intranasal masks, oronasal masks, high-flow nasal cannula (HFNC), and helmet in patients with ALS. We compared measures of the pharyngeal area during spontaneous breathing and SVDM use. The greatest increase was observed with intranasal mask use, followed by HFNC, oronasal mask, and helmet respectively. In conclusion, upper airway opening in patients with ALS is enhanced by positive pressure with intranasal masks and HFNC, showing promise for increasing pharyngeal patency. Future studies should explore its applicability and effectiveness in maintaining long-term pharyngeal patency, especially in this population with bulbar weakness.

1. Introduction

Non-invasive ventilation (NIV) improves quality of life and survival for some people with amyotrophic lateral sclerosis (pwALS) [1,2]. Despite that, at least one-third of patients discontinue NIV therapy [3]. There are clear barriers and facilitators to NIV use in pwALS, many of which can be modifiable [3]. Potential barriers include the clinical features of ALS [2] as well as factors related to NIV including: unit type, effect on symptom amelioration, patient perceptions of (e.g. anxiety, fear, and trust) and acclimation to supportive ventilation, setting personalization [3], and mask interface choice [4,5].

In addition to respiratory and ventilation measures, some imaging techniques have been adapted in order to evaluate airway changes in the context of NIV. For example, video endoscopy [6] and ultrasound [7], have been used to predict supportive ventilation success following initiation and to provide guidance on ways to enhance NIV effectiveness. Videofluoroscopy has been suggested as

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an additional imaging technique for this purpose as it provides rapid, serial X-ray images, which can be used to assess and measure upper aerodigestive tract structures in both frame-by-frame and real-time contexts [4,8].

NIV eliminates the need for sedation and minimizes the risk of complications associated with invasive procedures such as tracheostomy or translaryngeal intubation in neuromuscular diseases [1,2]. However, the application of inspiratory pressure during NIV alters the upper airway configuration [5,9], which may result in treatment-induced airway obstruction [5,10]. While non-invasive ventilatory support can improve ventilation and respiratory comfort by reducing resistance and obstruction, the impact of devices for continuous pressure such as high-flow nasal cannula (HFNC) or helmet CPAP (continuous positive airway pressure) on the pharynx remains unknown. Therefore, further research is needed to understand how the pharynx responds to NIV and other ventilatory conditions.

The pharyngeal cross-sectional area measured through videofluoroscopy during swallowing was originally used to evaluate swallowing safety and/or post-swallow residue (a surrogate a marker of pharyngeal constriction) [11]. While it has been used to evaluate people with dysphagia, including those with ALS [12,13], recent studies have used it as an indirect measure of upper airway patency [4,8], a vital aspect of breathing physiology [14]. Assessing the pharyngeal cross-sectional area during NIV use [8] is crucial in determining its effectiveness and patient comfort, particularly in the case of bulbar ALS, where pharyngeal weakness is a common problem affecting ventilation [1].

Individuals with ALS on continuous NIV may face medical events that require orotracheal intubation, such as during hospitalization for acute illness or medical procedures (e.g., gastrostomy). Subsequently, weaning from mechanical ventilation can be difficult [15] and may lead to tracheostomies and dependence on invasive ventilation, which while life-saving, may drastically reduce their quality of life [16]. In a recent survey of pwALS, more than half with an advance healthcare directive chose a “do not resuscitate/do not intubate” code status [17]. Therefore, other supportive ventilation delivery methods (e.g. HFNC) could be a potential alternative in acute illness where patients with bulbar weakness or spasticity cannot use or tolerate NIV. For example, HFNC has been found to be a safe and effective option for elderly patients with respiratory failure who cannot tolerate NIV or CPAP and do not require intensive care [18]. HFNC has also been successfully used as an alternative ventilatory support for ALS patients [19,20] with outcomes comparable to those of “conventional” NIV delivery methods (e.g. oronasal mask). HFNC provides high oxygen flow (up to 60 l/min), and generates 1 cmH2O positive pressure for every 10 L/min of flow [21]; therefore, it is possible that the pressures generated during the use of HFNC, although low [19,22], improve the pharyngeal opening and may facilitate breathing in the context of bulbar weakness.

To date, there have been no studies using videofluoroscopy that compare the impact of different positive pressures on pharyngeal patency in people with ALS. We aimed to investigate the impact of four supportive ventilation delivery methods (SVDMs) on the upper airways of pwALS by measuring the pharyngeal cross-sectional area on videofluoroscopic images during SVDM use and spontaneous breathing.

2. Methods

This study was conducted as part of a larger cross-sectional study approved by the Ethics Committee of the Hospital das Clínicas of the Federal University of Goiás under protocol 3981050. We collected data from three participants diagnosed with probable-definite ALS (revised El Escorial criteria) [23] using NIV who volunteered to participate in the study while being followed at an ALS specialized center.

2.1. Pre-experiment pulmonary function testing

Before the experiment, experienced staff carried out pulmonary function tests. Spirometry was performed in the upright position using a Minispir (MIR, USA), in compliance with the European Respiratory Society (ERS) [24]. We measured the participants’ maximum inspiratory and expiratory pressures using a Micro RPM (CareFusion, USA) according to ERS guidelines [24]. We selected the highest value recorded from three consecutive attempts for analysis. Also, we recorded unassisted voluntary peak cough flow using a hand-held peak flow meter (Vitalograph, Ireland), according to ERS guidelines [24]. The participant was instructed to inhale deeply through the device and then cough as forcefully as possible. The peak cough expiratory flow was recorded as the highest value obtained after three consecutive attempts, with brief pauses (~30 s) between each attempt.

2.2. Supportive ventilation delivery methods and ventilatory conditions

We evaluated the participants in a single session while they were seated in an upright position, repositioning them as needed to achieve a chin angle of 90° (relative to the chest). We assessed the participants under conditions of spontaneous breathing and with four different devices: NIV (intranasal mask and oronasal mask), HFNC, and helmet during videofluoroscopy. Supportive ventilation delivery methods and ventilatory conditions are detailed as follows:

a) Intranasal mask: Synchrony II BiPAP (Philips Respironics, USA) (ET mode; IPAP 12 cmH2O; EPAP 6 cmH2O; Inspiratory time: 1.2s; Respiratory frequency: 12 bpm; Cycle: medium; Rise time: 3s; Fall time: 3s) using an intranasal mask (ResMed Airfit P10);
b) HFNC MyAirvo™ system (Fisher & Paykel Healthcare, USA) was used at a flow rate of 60 L/min at a fractional concentration of inspired oxygen (FiO2) of 30 % and air temperature of 34 °C;
c) Oronasal mask: Synchrony II BiPAP (Philips Respironics, USA) (ET mode; IPAP 12 cmH2O; EPAP 6 cmH2O; Inspiratory time: 1.2s; Respiratory frequency: 12 bpm; Cycle: medium; Rise time: 3s; Fall time: 3s) using an oronasal mask ResMed Airfit P20;
d) Helmet CPAP: Helmet 7lives (Agile Med, Brazil) connected to a Synchrony II BiPAP (Philips Respironics, USA) in CPAP mode set at 10 cmH2O with FiO2 of 21 %.

2.3. Videofluoroscopy

Standardized videofluoroscopy images were captured using the OEC-9900 Elite-Mobile-C-arm (GE-Healthcare, USA) – with a recording rate of 30 frames per second and processing in ImageJ (NIH, Bethesda, MD). To limit the risk of radiation exposure to both the operator and the participant, we controlled the radiation dose by setting a maximum duration of 3 minutes for the videofluoroscopic exams, following the recommended guidelines [25,26].

The images were reviewed frame by frame by two trained research assistants to identify two keyframes of interest: during spontaneous breathing and SVDM use. We selected the frames using the following criteria during spontaneous breathing: a neck angle closest to 90° relative to the chest during the inspiratory phase at the point of maximal airway opening. For frame selection during each different SVDM, we used these criteria following SVDM placement for at least 10 seconds. After indexing the frames of interest, we calculated the normalized pharyngeal area (nPA) [11]. The nPA is a measure of the unobliterated pharyngeal area, based on pixel values, using the procedure described by Stokely et al. and our experience with this method [4,8]. Fig. 1 depicts the boundaries for tracing the unobliterated pharyngeal area. All measurements were normalized using an anatomical scalar (squared C2–C4 vertebral distance) to correct for differences in pharyngeal size across participants. The nPA was then calculated using the following formula nPA = (pharyngeal area/C2–C4^2)*100 [11]. Therefore, the nPA measurements represent a percentage of a scaled area, indicated by the dashed-line square in the image on the right side of Fig. 1.

To assess the effects of the SVDM on the unobliterated pharyngeal area, the difference in nPA (nPAΔ) between SVDM and spontaneous breathing (SB) was calculated using the formula nPAΔ = (nPA SVDM - nPA SB)/nPA SB*100(%).

3. Results

Sample demographics, baseline pulmonary function tests, and pharyngeal area results are shown in Table 1. We observed an increase in the pharyngeal area comparing all SVDMs with spontaneous breathing. For the intranasal mask, HFNC, oronasal mask, and helmet, the results are as follows (nPAΔ): Patient 1 (+89.9 %; +84.9 %; +48.2 %; +29.9 %); Patient 2 (+57.2 %; +55.6 %; +10.9 %; +10.4 %); Patient 3 (+92.0 %; +38.7; +39.9 %, helmet not assessed). Differences across patients and interfaces and the parameters used on each interface are available in Fig. 2 and Video 1 (supplementary material).

Supplementary video related to this article can be found at https://doi.org/10.1016/j.rmcr.2023.101958

4. Discussion

All devices in our study produced a positive nPAΔ value, denoting an increase in the pharyngeal area compared to spontaneous breathing. The greatest increase among the patients was observed during the intranasal mask use, followed by HFNC, oronasal mask, and helmet respectively. When compared to other interfaces, the oronasal mask is frequently used in clinical practice [4,5,10]; however, our findings suggest that an intranasal mask or HFNC may be more effective at pharyngeal opening for some patients.

Our small case series suggests that both disease stage and SVDM delivery methods may influence upper airway opening. While the intranasal mask offered larger pharyngeal opening during ventilation, individuals with less pronounced functional decline, as mea-

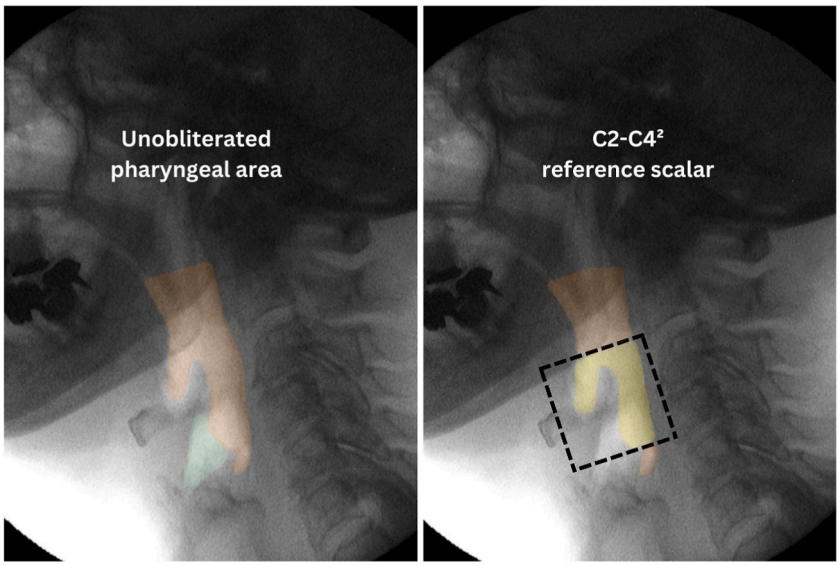

Fig. 1. Squared-C2-C4 reference scalar and normalized pharyngeal area calculations. The image on the left (patient 2) shows an anatomical reference scheme, which is used for normalizing measures of the pharyngeal area. The unobliterated pharyngeal area is represented by the color orange and the laryngeal vestibule (not considered for the analyses) is highlighted in green. The image on the right shows the anatomical reference scalar, which is used to calculate the normalized pharyngeal area, represented by the color yellow. Normalized area measures can be interpreted as a percentage of this reference scalar area (C2–C4^2). (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Table 1
Baseline pulmonary function tests and normalized pharyngeal area across delivery methods and ventilatory conditions.

Patient	Gender	Age	ALS onset type	TSSO (years)	ALSFRS-R	ALSFRS-R bulbar subscore	seated FVC (% predicted)	seated FEV1 (% predicted)	MIP (cmH_2O)	MEP (cmH_2O)	PCF (L/min)	nPA SB (%)	nPA Intranasal mask (%)	nPA HFNC (%)	nPA Oronasal mask (%)	nPA Helmet (%)
1	f	70	bulbar	1.5	33	3	74	75	40	40	180	33.1	62.9	61.3	49.1	43.1
2	f	76	spinal	1.5	39	10	69	74	62	59	190	36.9	58.1	57.5	41.0	40.8
3	m	64	spinal	3.0	6	1	9	6	5	15	0	25.9	49.7	35.9	36.2	NA

ALS - Amyotrophic Lateral Sclerosis; ALSFRS-R - Amyotrophic Lateral Sclerosis Rating Scale-revised; FEV1 - forced expiratory volume over 1 second; FVC - Forced vital capacity; HFNC - High-flow nasal cannula; nPA - Normalized pharyngeal area = pharyngeal area/($C2–C4^2$ length) X 100 (%); MIP - Maximal inspiratory pressure; MEP - Maximal expiratory pressure; PCF - Peak cough flow; SB - Spontaneous breathing; TSSO - time since symptom onset; NA-Not Assessed.

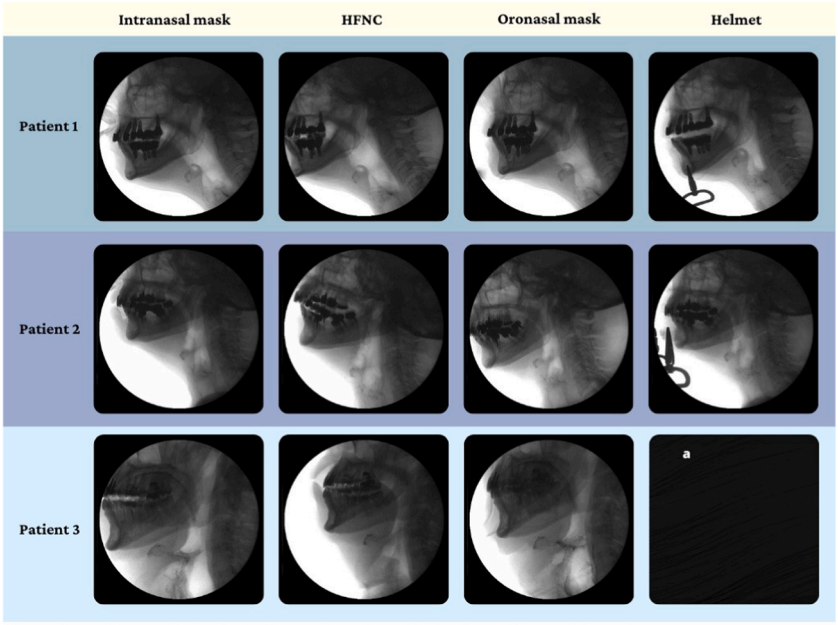

Fig. 2. Patient videofluoroscopy across supportive ventilation delivery methods. [a] Patient 3 was unable to use the helmet interface due to a continuous NIV dependency and advanced bulbar weakness.

sured by the ALSFRS-R scale (patients 1 and 2), had a higher increase in their pharyngeal area. We observed that the pharyngeal cross-sectional area was smaller in patients with longer disease duration, which suggests it could serve as a biomarker for disease progression and a predictor of NIV tolerance. However, further research is needed to confirm these findings.

The smallest changes in pharyngeal area were observed with helmet CPAP, a delivery method not recommended for patients with neuromuscular diseases with concomitant diaphragm weakness and/or hypoventilation because it does not provide inspiratory support [27]. This may explain why patient 3, who had the greatest functional decline, was unable to tolerate this method. Furthermore, previous studies reported that positive inspiratory pressure can cause obstruction by collapsing weakened upper airway structures [4,5,10]. As a result, bilevel ventilatory support is indicated for such patients [27].

Assessing the effectiveness of NIV is a key part of measuring efficacy for treatment of those with ALS. We propose that for this patient group and following a larger study, pharyngeal cross-sectional area obtained from videofluoroscopy, when combined with other respiratory parameters and measures, may be used as additional information to help guide NIV delivery method and/or settings. Optimal mask selection could improve adherence to NIV, leading to a better quality of life and survival outcomes [1].

Several authors have cited mask-related skin abrasions or necrosis as one of the primary factors linked to NIV intolerance, in general [20,28–30]. Patients with neuromuscular disease may not tolerate NIV due to gastric and/or colonic distension, claustrophobic feelings, or the accumulation of bronchial secretions caused by their inability to cough forcefully [20,31]. In patients with acute hypoxemic respiratory failure after extubation, HFNC has been shown to be more comfortable and better tolerated than other forms of NIV [28–30]. Neuromuscular patients can well tolerate daily use of HFNC, as it does not need to be removed for oral hygiene care, talking, eating, or drinking [20]. Due to its simplicity, cost-effectiveness, and greater patient tolerance than other NIV delivery methods, HFNC warrants adequately resourced clinical trials to evaluate its efficacy and conditions for use in patients with progressive neuromuscular disease [20].

HFNC has been also proposed as an important alternative to other forms of NIV in patients who cannot tolerate certain SVDMs or who are at high risk of requiring endotracheal intubation [20]. This may suggest that combining daytime HFNC with other forms of nocturnal NIV is a safe and effective treatment strategy for patients with neuromuscular disease complicated by acute respiratory failure and/or other medical complications [20].

Bulbar weakness severity along with ventilation needs should be considered when deciding on the preferred SDVMs. In the future, studies should correlate measures of bulbar function (e.g. pharyngeal manometry, lingual pressure) with upper airway opening during supportive ventilation. Additional outcomes should also be included in study design not limited to respiratory parameters, speech, voice, and swallowing. Our findings on pharyngeal area do not necessarily predict functional outcomes; however, they have highlighted the need for ongoing research on SDVMs. Our work suggests potential benefit from HFNC use, particularly with the maintenance of upper airway patency in patients with ALS, specifically those with bulbar onset who cannot tolerate support via face mask [19,32]. The cross-sectional pharyngeal area is a simple, fast, and reliable method to assess upper airway displacement during different ventilatory conditions. However, this approach relies on videofluoroscopy - an expensive imaging method that provides a two-dimensional assessment (cross-sectional area) of a three-dimensional airway (volume). This may limit its availability in some health-

care settings. It should also be noted that there is currently no established normative data for pharyngeal cross-sectional area during breathing in both the healthy and ALS populations.

In conclusion, upper airway opening in patients with ALS is enhanced by positive pressure, with intranasal masks and HFNC appearing to be promising interfaces for increasing pharyngeal patency. Future work is necessary to define upper airway mechanisms and clinical outcomes under supportive ventilation via several delivery methods. Through continued prospective data collection and analysis, evidence-based best practices can be defined.

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CRediT authorship contribution statement

Alessandra Dorça: Conceptualization, Investigation, Resources, Writing – review & editing. **José Vergara:** Validation, Writing – original draft, Writing – review & editing. **Stacey A. Skoretz:** Supervision, Writing – original draft, Writing – review & editing. **Michael J. Brenner:** Supervision, Writing – original draft, Writing – review & editing. **Denise Sisterolli Diniz:** Supervision, Writing – original draft, Writing – review & editing. **Jorge L. Zeredo:** Supervision, Writing – original draft, Writing – review & editing. **Max Sarmet:** Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The authors have declared that no competing interests existed at the time of publication.

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We would like to thank all our patients living with ALS. You are not alone in this fight. Know that all our efforts will always be directed towards seeking a better quality of life during your difficult journey.

Quick look

Current knowledge

Pharyngeal weakness is a hallmark of bulbar amyotrophic lateral sclerosis (ALS), and assessment of the pharyngeal area is a critical parameter for gauging the efficacy of respiratory support in enhancing upper airway patency. However, to date, no studies have compared the effects of different supportive ventilation delivery methods on upper airway opening in the ALS population.

What this paper contributes to our knowledge

Upper airway opening in patients with ALS was enhanced by all respiratory support methods. Intranasal masks and high-flow nasal cannula appeared as particularly promising interfaces for increasing pharyngeal patency during medical procedures (e.g., percutaneous endoscopic gastrostomy). HFNC is a potential alternative for ALS patients who are intolerant to NIV in the acute care setting.

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