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Full title: Risk Factors for Laryngeal Penetration-Aspiration in Patients with Acute Traumatic Cervical Spinal Cord Injury

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Abstract

Background Context: Laryngeal penetration-aspiration, entry of material into the airways, is considered the most severe subtype of dysphagia and common among patients with acute cervical spinal cord injury.

Purpose: The aim of this study was to investigate risk factors for penetration-aspiration in patients with acute traumatic cervical spinal cord injury (TCSCI).

Study design: A prospective cohort study.

Patient sample: Thirty-seven patients with TCSCI.

Outcome measures: The highest Rosenbek's penetration-aspiration scale (PAS; range 1-8) score of each patient was the primary outcome measure. The risk factors consisted of patient characteristics, demographics and clinical signs observed during a clinical swallowing trial.

Methods: A clinical swallowing trial and videofluoroscopic swallowing study (VFSS) was performed to all patients within 28 days post-injury. For group comparisons, the patients were divided into two groups: (i) penetrator/aspirators (PAS score ≥3) and (ii) non-penetrator/aspirators (PAS score ≤2). This study was self-funded with no conflict of interest.

Results: Of the 37 patients, 83.8% were male. The mean age at the time of the injury was 61.2 years. Most patients had an incomplete TCSCI (78.4%) due to a fall (75.7%). In the VFSS, 51.4% of the patients were penetrator/aspirators, and 71.4% had silent aspiration. The risk factors for predicting penetration-aspiration were: (i) necessity of bronchoscopies, (ii) lower level of anterior cervical operation, (iii) coughing, throat clearing, choking related to swallowing, and (iv) changes in voice quality related to swallowing. Binary logistic regression identified coughing, throat

clearing, choking and changes in voice quality related to swallowing as independent risk factors for penetration-aspiration.

Conclusions: The necessity of bronchoscopies, post-injury lower cervical spine anterior surgery, coughing, throat clearing, choking and changes in voice quality related to swallowing were marked risk factors for aspiration and penetration following a cervical spinal cord injury. These factors and signs should be used to suspect injury-related pharyngeal dysfunction and initiate preventive measures to avoid complications. The clinical swallowing evaluation is a relevant adjunct in the management of these patients and can improve the detection of penetration and aspiration.

Keywords: trauma, spinal cord injuries, dysphagia, deglutition, respiratory aspiration

INTRODUCTION

At the acute phase of a traumatic cervical spinal cord injury (TCSCI) normal swallowing function is often compromised. Early detection of possible dysphagia, especially laryngeal penetration-aspiration, is critical to secure safe nutrition and optimal pulmonary function. In TCSCI, the loss of innervation in respiratory muscles increases the risk of hypoventilation, atelectasis and poor secretion management due to reduced ability to cough.[1] Protection of the lungs is also influenced by the ability to swallow safely and the ability to cough up an aspirated swallow. Generally, aspiration of food, liquids or saliva is considered to be a risk factor for pneumonia.[2, 3] Pneumonia can be a life-threatening complication in the acute phase of a spinal cord injury (SCI) [4, 5] and the treatment of respiratory complications is also an economic burden.[6] In acute phase of TCSCI, one important aspect is to detect and prevent these respiratory complications in order to optimize rehabilitation.

Improved understanding of the risk factors of laryngeal penetration-aspiration in this clinically demanding patient group could help minimize the possible negative consequences i.e. aspiration pneumonia, dehydration and malnutrition. Furthermore, these actions could lower treatment costs and facilitate better recovery. The purpose of this study was to investigate a wide range of potential pre-, peri- and post-injury risk factors (including clinical signs assessed by a speech therapist) of laryngeal penetration-aspiration on videofluoroscopic swallowing study (VFSS). This generalizable study utilized a prospective sample of acute TCSCI patients.

MATERIAL AND METHODS

Patients and demographic data

The study population consists of a prospective cohort of 37 applicable patients with acute TCSCI admitted to the xxx xxx xxx from February 2013 to April 2015. Permission to conduct this study

was obtained from the Ethics Committee of xxx, xxx, xxx. All patients provided a written informed consent according to the Declaration of Helsinki. A flowchart displaying the study process is presented in figure 1.

The variables used in this study consisted of demographics, injury- and treatment-related variables, computed tomography (CT) findings, and observations of a speech therapist (T.I.) during a clinical swallowing trial. The primary outcome variable was the incidence of laryngeal penetration or aspiration as per the validated 8-point Rosenbek's Penetration-Aspiration Scale (PAS)[7] assessed during a videofluoroscopic swallowing study (VFSS). In detail, the demographic and injury-related variables included gender, age at the time of injury and injury mechanism (as per the International Spinal Cord Injury Core Data Set [8]). The completeness of the injury was defined according to the American Spinal Injury Association impairment scale (AIS). [9] The mean time from the injury to the first AIS classification was 16.4 days (SD=23.7, median=5.0, min=1, max=114).

The treatment-related variables consisted of necessity of bronchoscopy/-ies, necessity of tracheostomy, acute post-injury surgical procedures prior to the VFSS, specific levels and number of cervical levels operated and whether an anterior fixation plate was used or not. The first available posttraumatic preoperative CT images were evaluated for the incidence and level of fracture(s) in the cervical vertebrae (X.X).

The clinical swallowing trial

The clinical swallowing trial was performed to all enrolled patients (n=37) by a speech therapist as soon as practically possible after injury. The trial included the voluntary swallowing of different consistencies (thin liquid, thick liquid and puree). At the beginning of the trial, the boluses were given with a teaspoon and at the end of the trial a 100ml water swallow test was performed if possible. The trial was discontinued if signs of penetration-aspiration occurred. The swallowing trial

variable set was adapted from Logemann et al.[10] The mean time from the injury to the clinical swallowing trial was 6.9 days (SD=5.7, median=4.0, min=1, max=23).

VFSS

The VFSS (Siemens Axiom Luminos DRF, Erlangen, Germany) was conducted within 28 days post-injury to all 37 patients. The VFSS protocol included 5 ml, 10 ml and 20 ml boluses of a thin, water-soluble contrast agent (Omnipaque 350 mgI/ml, GE Healthcare, Oslo, Norway). A metal coin (diameter 3 cm) was taped to the chin or neck of the patient for measurement calibration. The VFSSs were evaluated for the following: the incidence of laryngeal penetration or aspiration as per the validated 8-point Rosenbek's PAS (X.X. and X.X.), and the thickness of the pharyngeal wall at the level of cervical vertebrae 3 and 6 to identify possible prevertebral oedema (X.X). Given that normal adults are known to score 1-2 on the PAS, patients were considered to be penetrator/aspirators if they scored ≥3 on one or more swallow(s) on the PAS.[11-13] The patient's worst (i.e. highest) PAS score was used as the primary outcome measure. In regard to the normal pharyngeal wall thickness, the upper limits were set according to Rojas et al.[14] The mean time from the injury to the VFSS was 12.4 days (SD=7.5, median=11.0, min=2, max=28). The mean time from the clinical swallowing trial to VFSS was 5.5 days (SD=4.4, median=4.0, min=1, max=16).

Statistical Analysis

The normality of the variable distributions was tested using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Group comparisons were tested with the Fisher's exact test, the Pearson's Chi Square test and the Mann-Whitney U-test. Correlations were tested with the Spearman's rank correlation coefficient. Variables with clinical interest and relevance [age (continuous), AIS grade

(complete/incomplete), anterior cervical surgery (yes/no), and coughing related to swallowing (yes/no)] were placed into a binary logistic regression model to determine eventual independent risk factors for penetration-aspiration. Odds ratios were calculated with 95% confidence intervals. Among some variables there were missing data. We did not model or impute missing data. Statistical significance was set at 5% for all analyses. The Statistical Package for Social Sciences software program (IBM SPSS Statistics for Windows, Version 23.0, Armonk, NY, USA) was used to perform all the statistical analyses.

RESULTS

Patients

In the VFSS 51.4% of the patients showed laryngeal penetration-aspiration (PAS score ≥3 on one or more swallows) and the rest 48.6% showed high penetration (PAS score 2) or no penetration-aspiration (PAS score 1). The distribution of the PAS scores is presented in figure 2.

As shown in Table 1, the only statistically significant difference between the penetrator/aspirators (n=19) and the non-penetrator/aspirators (n=18 patients) was the necessity for bronchoscopy (p=0.042, OR=9.9, 95% CI=1.1-91.5); there were no other significant differences for the other variables. Note that the penetrator/aspirators had more often cervical spine fracture and higher number of fractured vertebrates.

Post-injury Cervical Spine Surgery

Surgery was performed on 28 (75.7%) patients before the VFSS: duration from the injury to the first surgery was mean 1.9 days (SD=1.3, median=2.0, min=0, max=6), while duration to the secondary surgery was mean 4.3 days (SD=1.7, median=4.5, min=2, max=6). Table 2 shows the

detailed summary of the surgical procedures. The lower level of anterior operation was the single factor that differed statistically significantly between these groups (p=0.050, OR=6.1, 95% CI=1.1-33.2).

Clinical Swallowing Trial

As shown in Table 3, coughing (p=0.007, OR=9.1, 95% CI=2.0-41.4) and changes in voice quality (p=0.004, OR=13.0, 95% CI=2.2-77.3) related to swallowing differed statistically significantly between the groups.

Independent Risk Factors of Penetration/Aspiration

To determine independent risk factors for penetration-aspiration we placed independent variables with clinical interest and relevance [age (continuous), AIS grade (complete/incomplete), anterior cervical surgery (yes/no), coughing and changes in voice quality related to swallowing (yes/no)] into a binary logistic regression model. The results of the three different models are summarized in Table 4. Coughing and changes in voice quality were independently associated with penetration-aspiration.

DISCUSSION

To our knowledge, the current study is the first that focuses on the risk factors and the clinical signs of laryngeal penetration-aspiration at the acute phase in patients with TCSCI. Two risk factors and two clinical signs for penetration-aspiration were identified in our acute TCSCI cohort: the necessity of bronchoscopies and the lower level of anterior operation. The clinical signs were coughing, throat clearing, choking and changes in voice quality related to swallowing.

Previous studies focusing on SCI have presented some risk factors for dysphagia, e.g., age [15-19], tracheostomy [15-24], mechanical ventilation [15, 18, 19, 22, 24], the completeness of SCI [15, 21], the level of injury [15, 21-23, 25], and cervical surgery [15, 20]. In contrast, some studies found no association between dysphagia and age [20, 21, 23, 25], dysphagia and mechanical ventilation [17], dysphagia and the level of completeness of the injury [16-19, 24], and dysphagia and cervical surgery.[16, 17, 19, 21-23] The prior literature is contradictory possibly because of the heterogeneity in diagnostic criteria of dysphagia, data collection methodology, and enrolled patient populations. In addition, many studies have focused on only a subgroup of potential risk factors. Therefore, it is difficult to draw firm and generalizable conclusions based on these studies. However, it seems that tracheostomy is the most agreed upon dysphagia risk factor among SCI patients.[15-24]

Risk factors

No association between age and penetration-aspiration was found in this study. Nevertheless, the relation between higher age and increased incidence of swallowing problems in general is well described in the literature.[26, 27] Furthermore, cervical injury epidemiology is changing, and currently both injury rate and age are increasing.[28-30] Thus, it would be premature to exclude an association between age and penetration-aspiration based on our findings.

It is somewhat surprising that we found no association between the completeness or level of SCI and penetration-aspiration. Although these results differ from some published studies,[15, 21, 23, 25] they are consistent with some others.[16-19, 24] These controversies can be at least partly explained by differences in study design and methodology (e.g., delays between injury and different assessments, the method of injury ascertainment).

Contrary to earlier studies,[15-24] we did not find a tracheostomy to be a statistically significant risk factor for penetration-aspiration. Interestingly, we found an association between the necessity of bronchoscopies and penetration-aspiration. However, this finding is not supported by former literature.[17, 18, 24] Again, this discrepancy can be related to variability in study methodology. In general, it is reasonable to hypothesize that patients with penetration-aspiration require more often bronchoscopies for therapeutic management of aspiration and excess bronchial secretion.

Post-injury cervical surgery has been consistently documented as a risk factor for swallowing problems.[31-34] We found that only C5 to Th1 level anterior operation increased the risk of penetration-aspiration. Statistically, the same association was not evident as all cervical operations were examined in relation to penetration-aspiration.

Clinical signs

Coughing, throat clearing, choking and changes in voice quality related to swallowing were statistically significant clinical signs for penetration-aspiration. Nevertheless, it is important to bear in mind that patients with TCSCI often have reduced ability to cough. In our study, the clinical swallowing evaluation was performed by one speech therapist (X.X.) experienced in patients with TCSCI. A cervical auscultation was used to detect every effort to cough, to clear the throat, or to choke and to detect changes in voice quality related to swallowing in patients with a tracheostomy or reduced ability to cough voluntarily. Some of the clinical signs could have been missed without the cervical auscultation. The association between the clinical signs and penetration-aspiration has not been established in prior studies of this patient group. In general, coughing, throat clearing, choking and changes in voice quality related to swallowing are well-accepted indicators of penetration-aspiration.[10, 35, 36]

The limitations of the study

The major limitation of this study is the small sample size. Considering the overall incidence of TCSCI in XXX, the number of recruited patients can still be seen as better than satisfactory. Furthermore, our sample is representative of the xxx population.[30] The age, gender and injury mechanism distributions of our study are comparable with the ones published by XXX and colleagues.

Secondly, the time frame between the clinical swallowing trial and the VFSS was delayed in some cases. As a note for future studies, fiberoptic endoscopic evaluation of swallowing would be a more suitable method for the first acute instrumental evaluation of this patient group.

CONCLUSIONS

The necessity of bronchoscopies, post-injury lower cervical spine anterior surgery, coughing, throat clearing, choking and changes in voice quality related to swallowing are marked risk factors for aspiration and penetration following a cervical spinal cord injury. These factors and signs should be used to suspect injury-related pharyngeal dysfunction and initiate preventive measures to avoid complications. The clinical swallowing evaluation is a relevant adjunct in the management of these patients and can improve the detection of penetration and aspiration.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Figure legends:

Figure 1. Study process.

Figure 2. The distribution of the Rosenbek's penetration-aspiration scores.

Table 1. Group comparisons between penetrator/aspirators (n=19) and non-penetrator/aspirators (n=18) on demographics, injury- and treatment-related and radiological variables.

Variable	Penetrator/aspirators	Non-penetrator/aspirators	p-value
Patient (n)	19	18	
Gender			**0.090**
Male	18 (94.7%)	13 (72.2%)	
Female	1 (5.3%)	5 (27.8%)	
Age at the time of injury (years)			**0.940**
Mean (SD)	59.3 (15.7)	63.2 (13.1)	
Median (min–max)	64.7 (25.7–87.7)	61.9 (35.1–91.6)	
Injury mechanism			**1.000**
Sport	1 (5.3%)	1 (5.6%)	
Assault	0 (0%)	0 (0%)	
Transport	3 (15.8%)	3 (16.7%)	
Fall	14 (73.7%)	14 (77.8%)	
Unknown	1 (5.3%)	0 (0%)	
AIS impairment scale			**0.331**
AIS A	3 (15.8%)	5 (27.8%)	
AIS B	3 (15.8%)	0 (0%)	
AIS C	3 (15.8%)	2 (11.1%)	
AIS D	10 (52.6%)	11 (61.1%)	
The AIS level of injury			**1.000**
Upper (C1–C4)	16 (84.2%)	16 (88.9%)	

Lower (C5–C8)	2 (10.5%)	2 (11.1%)	
Unknown	1 (5.3%)	0 (0%)	
Tracheostomy	4 (21.1%)	1 (5.6%)	**0.340**
Bronchoscopie(s) ≥ 1	7 (36.8%)	1 (5.6%)	**0.042***
Prevertebral oedema at the time of VFSS			
C3 > 7 mm	17 (89.5%)	15 (83.3%)	**0.660**
C6 > 18 mm	3 (15.8%)	2 (11.1%)	**1.000**
Unknown (C6)	1 (5.3%)	1 (5.6%)	
Cervical spine fracture	15 (79.0%)	10 (55.6%)	**0.170**
The level of cervical fracture			
Upper (C0-C2)	2 (10.5%)	1 (5.6%)	**1.000**
Lower (C3-C7)	14 (73.7%)	9 (50.0%)	**0.184**
The number of fractured vertebrae			**0.428**
1 vertebrae	6 (31.6%)	6 (33.3%)	
> 1 vertebrates	9 (47.4%)	4 (22.2%)	

Abbreviations: AIS = ASIA Impairment Scale; AIS A = complete injury, AIS B–D = incomplete injury; VFSS= videofluoroscopic swallowing study

Table 2. Group comparisons between operated penetrator/aspirators (n=16) and non-penetrator/aspirators (n=12) on surgical details.

Variable	Penetrator/aspirators	Non-penetrator/aspirators	p-value
Cervical spine operation			
Yes	16 (84.2%)	12 (66.7%)	**0.269**
No	3 (15.8%)	6 (33.3%)	
The number of operations			**0.428**
1	13 (81.3%)	9 (75.0%)	
≥ 2	3 (18.8%)	3 (25.0%)	
The number of operated levels			**1.000**
≤ 2	14 (87.5%)	10 (83.3%)	
> 2	2 (12.5%)	2 (16.7%)	
The number of anterior operations	15 (93.8%)	8 (66.7%)	**0.104**
The level of anterior operation			
Upper (C1-C4)	7 (43.8%)	3 (25.0%)	**0.434**
Lower (C5-Th1)	13 (81.3%)	5 (41.7%)	**0.050***
Anterior fixation plate	14 (87.5%)	7 (58.3%)	**0.103**

Table 3. Group comparisons between penetrator/aspirators (n=19) and non-penetrator/aspirators (n=18) on the clinical swallowing trial variables.

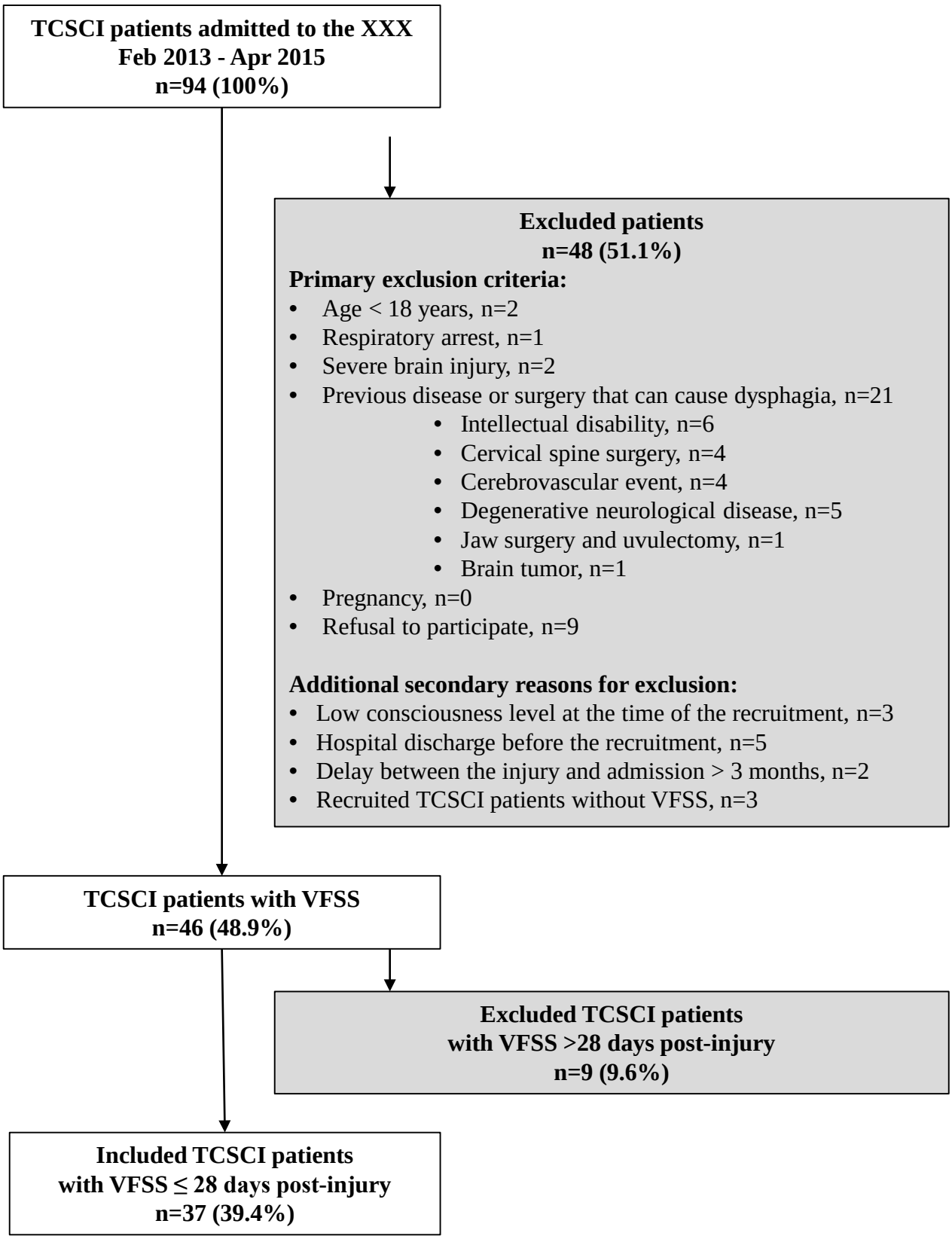
Variable	Penetrator/aspirators	Non-penetrator/aspirators	p-value
Patient (n)	19	18	
Coughing, throat clearing, and choking	14 (73.7%)	5 (27.8%)	**0.007****
Unknown (tracheostomy)	1 (5.3%)	0 (0%)	
Changes in voice quality	13 (68.4%)	6 (33.3%)	**0.004****
Unknown (tracheostomy)	4 (21.1%)	0 (0%)	
Delayed pharyngeal swallow	0 (0%)	2 (11.1%)	**0.230**
Reduced or inconsistent laryngeal elevation	10 (52.6%)	12 (66.7%)	**0.737**
Unknown	1 (5.3%)	0 (0%)	
Multiple (≥ 3) swallows per bolus	8 (42.1%)	2 (11.1%)	**0.060**
Unknown	1 (5.3%)	0 (0%)	

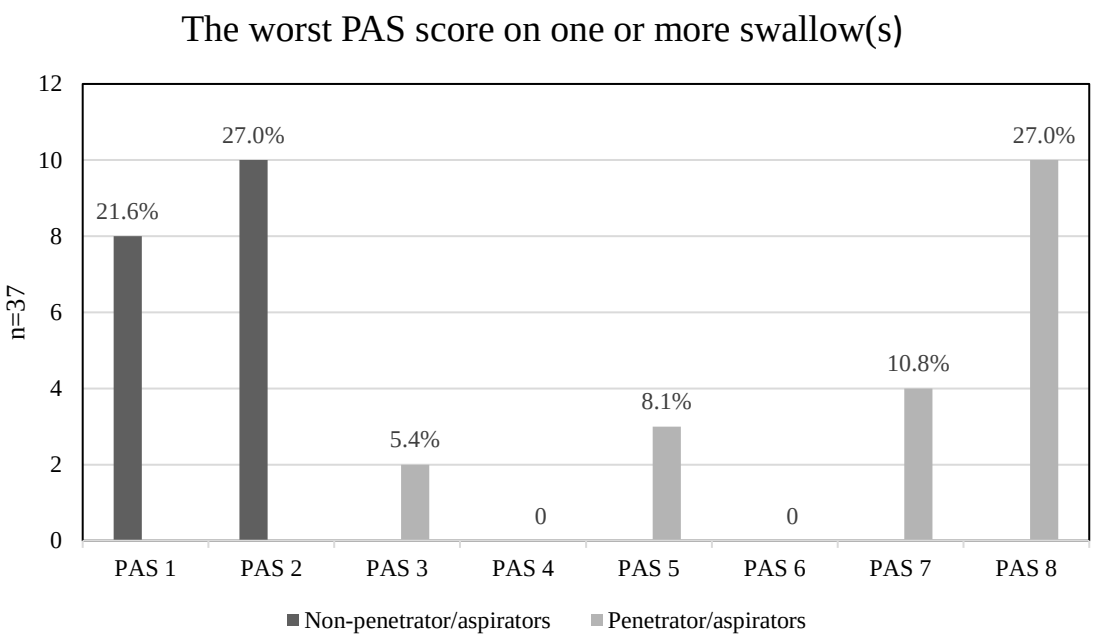
Table 4. Three binary regression model summaries assessing risk factors for penetration-aspiration.

Variable	**Bivariate analysis**	
	OR (95% CI)	**p-value**
Model 1.		
Nagelkerke R^2 0.450		
Age (years)	0.99 (0.93-1.05)	**0.680**
AIS grade (complete/incomplete)	0.29 (0.03-3.07)	**0.306**
Anterior cervical operation	4.73 (0.63-35.46)	**0.131**
Coughing	14.20 (2.21-91.22)	**0.005***
Model 2.		
Nagelkerke R^2 0.486		
Age (years)	0.97 (0.90-1.05)	**0.492**
AIS grade (complete/incomplete)	0.60 (0.06-5.69)	**0.659**
Anterior cervical operation	4.01 (0.48-33.80)	**0.202**
Changes in voice quality	20.93 (2.53-173.01)	**0.005***
Model 3.		
Nagelkerke R^2 0.673		
Age (years)	0.95 (0.86-1.05)	**0.329**
AIS grade (complete/incomplete)	2.50 (0.21-29.89)	**0.470**
Anterior cervical operation	10.67 (0.59-193.10)	**0.109**
Coughing	26.63 (1.48-477.12)	**0.026***

Changes in voice quality	47.30 (2.29-975.18)	**0.012***

Abbreviations: CI=confidence interval; OR=odds ratio


TCSCI patients admitted to the XXX
Feb 2013 - Apr 2015
n=94 (100%)
Excluded patients
n=48 (51.1%)
Primary exclusion criteria:
Age < 18 years, n=2
Respiratory arrest, n=1
Severe brain injury, n=2
Previous disease or surgery that can cause dysphagia, n=21
Intellectual disability, n=6
Cervical spine surgery, n=4
Cerebrovascular event, n=4
Degenerative neurological disease, n=5
Jaw surgery and uvulectomy, n=1
Brain tumor, n=1
Pregnancy, n=0
Refusal to participate, n=9
Additional secondary reasons for exclusion:
Low consciousness level at the time of the recruitment, n=3
Hospital discharge before the recruitment, n=5
Delay between the injury and admission > 3 months, n=2
Recruited TCSCI patients without VFSS, n=3
TCSCI patients with VFSS
n=46 (48.9%)
Excluded TCSCI patients
with VFSS >28 days post-injury
n=9 (9.6%)
Included TCSCI patients
with VFSS ≤ 28 days post-injury
n=37 (39.4%)


The worst PAS score on one or more swallow(s)
n=37
12
10
8
6
4
2
0
21.6%
27.0%
5.4%
0
8.1%
0
10.8%
27.0%
PAS 1
PAS 2
PAS 3
PAS 4
PAS 5
PAS 6
PAS 7
PAS 8
Non-penetrator/aspirators
Penetrator/aspirators