Dysphagia Risk Score two (DRS2): Development and validation of a rapid screening card for dysphagia in patients with stroke

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Abstract

Background- Each year approximately 15 million people around the world are affected by stroke, about six million die, while five million suffer from severe disabilities. Oropharyngeal dysphagia (OD) is a frequent comorbidity, affecting between 37% and 78% of stroke patients. The early assessment of dysphagia has a significant influence on the patient's health, on hospitalization times and ultimately on the costs of care for the stroke patient. Nonetheless, there is a gap between recommendations and clinical reality. The objective of this study is the validation of a screening tool, Dysphagia Risk Score 2 (DRS2), consisting of 8 items, whose administration takes about 120 seconds. Methods- The study involved 1006 patients (499 female and 507 male), aged between 15 and 101 years (mean age 70), evaluated with the DRS2 within 24/48 hours of admission to the Stroke Unit of the A.O. San Camillo-Forlanini in Rome and the San Giovanni Battista Hospital. Patients were enrolled in order of admission. To validate the scale, out of those 1006 patients, a random sample of 168 subjects (100 male and 68 female, mean age 71) also underwent an examination with a fiberoptic endoscopic evaluation of swallowing (FEES) during the same diagnostic session. To evaluate the reproducibility of the DRS2 score, a random sample of 35 of the total 1006 patients was evaluated simultaneously by an experienced observer and two inexperienced ones by blinded administration of DRS2. Results -The bivariate correlation between risk classification and risk index calculated as a parametric correlation r of Pearson (Pearson's Correlation Coefficient), and non-parametric correlation Spearman rho (Rank Correlation Coefficient) highlights a significance of r = 0.777 p = 0.01: ρ = 0.790 p = 0.01. The analysis of the Roc curve shows the levels of sensitivity and specificity with an area under the curve of 0.90 and a p value = 0.001, with a confidence interval (CI) between 0.822 and 0.952. The concordance of the two scales, the screening test and the endoscopic evaluation of swallowing, is equal to 0.93 or 93% (with P-value = 0.0001). The data analysis on the inter-observer reproducibility of the DRS2 score shows the agreement is perfect as the Cohen's Kappa value is between 0.81 and 1.00. Conclusion - Statistical analysis demonstrated the validity of DRS2, which proved to be a reliable and sensitive tool for detecting the risk of dysphagia in a population of patients suffering from acute stroke. DRS2 assessments are reproducible, also in case of administration by operators without a specific experience, if they undergo a specific training. The tool has also been well accepted by operators for its simplicity and execution rate.

Keywords: Swallowing disorders, Dysphagia, Stroke

Introduction

Each year approximately 15 million people around the world are affected by stroke, about six million die, while five million suffer from severe disabilities, according to World Health Organization data. Oropharyngeal dysphagia (OD) is a frequent comorbidity, affecting between 37% and 78% of stroke patients. The incidence of swallowing difficulties is higher in the acute phase of stroke and decreases in the first following days, with percentages ranging from 51% on day zero to 27% on day seven (Martino, 2005). OD leads to the risk of malnutrition and to a threefold risk of developing aspiration pneumonia compared to patients without swallowing disorders (Katzan, 2003; Foley 2009). Furthermore, the onset of aspiration pneumonia entails a triple risk of mortality for dysphagic patients. It is important to notice that half of patients with post-stroke dysphagia are unaware of their swallowing problems (Parker, 2004). For this reason, according to all the guidelines, it is highly recommended in stroke patients the swallowing evaluation within the first 24 hours (Jauch, 2013). The early assessment of dysphagia has a significant influence on the patient's health, on hospitalization times and ultimately on the costs of care for the stroke patient. Nonetheless, there is a gap between recommendations and clinical reality (Titsworth, 2013).

In the last few years, many screening tests with good psychometric features have been made available to the clinical environment. These include GUSS (Trapl, 2007), TOR-BSST (Martino, 2009) and V-VST (Clavé, 2008), just to name the most recent ones. Nevertheless, the use of screening tests is not yet satisfactory enough and, in our opinion, this is due to the time of administration of the tests. The Dysphagia Risk Score 2 (DRS2), a screening test which has a shorter time of administration than those currently in use, can facilitate the nursing activity, which is often overloaded with many tasks.

The objective of this study is the validation of a screening tool consisting of 8 items.

Materials and methods

The authors drew up a research project following the COSMIN (Mokkink, 2010) guidelines.

Population

For the study, there was a recruitment of a sample of individuals admitted to two hospitals in Rome: San Camillo-Forlanini and San Giovanni Battista from 01.01.2014 to 01.07.2019. To be included in the study, the participants had to meet the following criteria for inclusion:

- age > 18
- diagnosis of stroke made through clinical and radiological assessment
- not having any associated neurological disorder

All the individuals were informed on the purpose of the study, and they were asked to sign the informed consent.

Screening tool

The DRS2 comes from Amitrano and Pezzella's Dysphagia Risk Score (DRS) (Amitrano, 2009), a test designed to identify at an early stage the risk of developing complications associated with dysphagia.

The DRS2 comes from a simplification of the items and aims at the identification of patients to refer to in-depth diagnostic study of swallowing disorders. The simplification of the version 2 of the DRS led to a further decrease in administration times. DRS2 consists of eight items, which are proposed, in a different order than the first version. In the second version, the item concerning the understanding of simple orders has been abolished.

DRS2 comprises eight items:

1. *Age of the patient*. A score of 1 is assigned to patients aged 80 or more.
2. *Level of consciousness.* A score of 1 is assigned if the patient is unconscious. In this case the administration of the scale is interrupted, attributing the maximum risk value to the patient.
3. *Voluntary cough.* A score of 3 is assigned if the patient fails to cough upon verbal request or imitation.

4. *Glass of water.* The patient is requested to drink a glass of water of 90cc. A score of 3 is assigned if a cough occurs during the test or within one minute of administering the test. The test is interrupted if the patient starts coughing.
5. *Voice quality.* A score of 3 is assigned if the vocal quality changes after the glass of water test.
6. *Sialorrhea.* A score of 0.5 is assigned in the presence of sialorrhea.
7. *Spitting.* A score of 3 is assigned if the patient can independently spit saliva.
8. *Dyspnoea.* A score of 2 is assigned if the patient has clear difficulty in breathing.

The sum of the scores obtained in the individual items determines the risk class:

- No risk   total score = 0
- Low risk 0.5 <= total score <= 2.5
- Average risk 3 <= total score <= 5
- High risk total score >= 5.5

Any total score higher than zero triggers further swallowing evaluation procedures and leads to the precautionary suspension of oral feeding. In other words, the screening is a *pass* with a zero total score, a *fail* in all other cases.

The DRS2 test administrators were specifically trained through a 70-minute video and were supported by an expert administrator during the first 10 tests.

As a reference test the Fiberoptic Endoscopic Examination of Swallowing (FEES) was used (Langmore, 2017). The phoniatrician who performed the FEES was blind to the results of the DRS2 tests.

FEES evaluation included:

- The morpho-functional examination of the oral-pharyngeal-laryngeal tract and the analysis of the effectiveness of cough reflex;
- The evaluation of the swallowing of a bolus of liquid consistency (coloured water) and a bolus of semi-solid consistency (a 25g jar of cherry jam).

Once examined, the patients were classified within one of the following four classes:

1. *No risk.* The morpho-functional examination was negative and the swallowing activity was normal;
2. *Low risk.* Morpho-functional anomalies, but reflexes and swallowing activity are normal;
3. *Medium risk.* There are severe morpho-functional anomalies and/or alterations of the defence reflexes and/or presence of discrete residues after one or more swallowing acts;
4. *High risk.* There are abundant residues after several swallowing acts or pre/post swallowing falls or presence of aspiration.

Data Analysis

Statistical Analysis

The descriptive analysis of the sample was carried out with means and standard deviation of the scores. The inferential analysis involves the evaluation of the Cronbach' alpha for the evaluation of the internal consistency. For the assessment of reliability, a subpopulation was assessed twice at 24 hours

Patients in the random sample were evaluated with DRS2 by a speech therapist within 24 hours of admission. Within 24 hours, the same patient was evaluated with a FEES instrumental survey by a phoniatrics. This evaluation also took place blindly. Furthermore, to evaluate the reproducibility of the DRS2 score, a random sample of 35 of the total 1006 patients was evaluated simultaneously by an experienced observer and two inexperienced ones by blinded administration of DRS2.

Cronbach's alpha was used to quantify the internal reliability of the total questionnaire. Content validity was addressed through the process employed to develop the instrument. The process included basing the items on the prior instrument. Stability (test-retest) reliability was determined with Pearson's correlation coefficient between the first time (time1=test) and the second (time 2= retest) responses to the scale's test. Concurrent validity was performed through Pearson's correlation coef-

ficient and was also determined with Spearman's and Kendall's correlation coefficients on the two scales considered the gold standard for the evaluation of FEES.

We carried out an analysis of the ROC curve by choosing the FEES as the state variable. Statistical analyses were performed using the SPSS26 Italian version and MedCalc statistical software.

To test the sensitivity and specificity of the scale, we carried out an analysis by choosing the FEES as dichotomic variable with the DRSG.

The following was calculated

- the correlation between the risk classification obtained from the FEES examination and the risk index resulting from the administration of the DRS2;
- the ROC curve, by inserting the FEES as an independent variable and the result of the risk index as a dependent variable;
- the evaluation of the diagnostic test, to identify the validity of the screening test from which the sensitivity and specificity values were derived, as well as the Positive Predictive Value and the Negative Predictive Value;
- the positive and negative likelihood ratio;
- the concordance correlation coefficient between the risk classification obtained from the FEES examination and the global risk index of the screening test;
- the reproducibility of blinded screening by experienced and inexperienced operators.

Results

Population

The study involved 1006 patients (499 female and 507 male), aged between 15 and 101 years (mean age 70), evaluated with the DRS2 within 24/48 hours of admission to the Stroke Unit of the A.O. San Camillo-Forlanini in Rome and the San Giovanni Battista Hospital. Patients were enrolled in order of admission.

Only subjects who suffered an acute cerebrovascular event, which could be evaluated with FEES and DRS2 in the same diagnostic session, within 24/48 hours of admission, were included in the sample for validation. The presence of cerebral stroke was documented by radiological reports and by the medical diagnosis reported in the hospital medical record.

To validate the scale, out of those 1006 patients, a random sample of 168 subjects (100 male and 68 females, mean age 71) also underwent an examination with a fiberoptic endoscopic evaluation of swallowing (FEES) during the same diagnostic session.

Reliability
Internal consistency

The Internal consistency (IC) test of the DRS2 was performed on the data obtained before the first administration to determine the size of the sample. It was calculated that N=30 subjects. The alpha reliability of the scale was found to be equal to 0,8534 with a 95% lower confidence limit to 0,7767

Stability
Test-retest reliability

To see if the test itself would provide the same results after repeated assessments by the same operator, the test-retest reliability was conducted to estimate the stability of individual measures over time, after which we calculated the intraclass correlation coefficient (ICC) between the two assessments by Pearson's r. The scale was stable from a statistical point of view regarding the ICC values0,8479 p= .0001 with 95% Confidence interval for r 0,7021 to 0,9255

Construct validity
Correlation

About the bivariate correlation between risk classification and risk index, given by the test carried out, calculated as a parametric correlation *r of Pearson* (Pearson's Correlation Coefficient), and non-parametric correlation with *Kendall tau* (Rank Correlation Coefficient) and *Spearman rho* (Rank Correlation Coefficient) highlights a significance of r = 0.777 p = 0.01: ρ = 0.790 p = 0.01.

ROC Curve
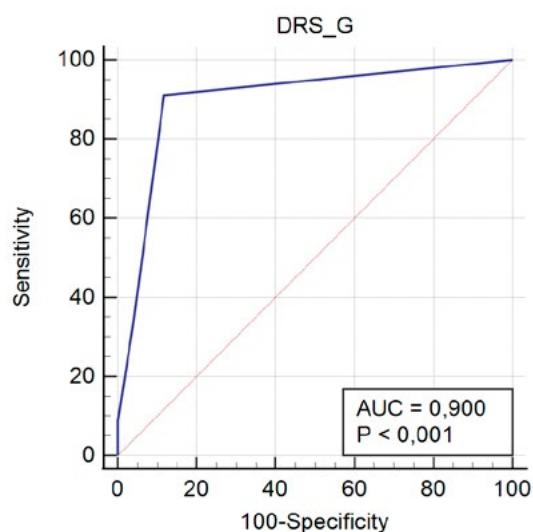
The analysis of the Roc curve shows the levels of sensitivity and specificity with an area under the curve of 0.90 and a p value = 0.001, with a confidence interval (CI) between 0.822 and 0.952.

The Positive Likelihood Ratio, RV + = 8.14, which means the screening test has a high impact in detecting the pathology, and the Negative Likelihood Ratio RV- = 0.05 is the margin of error in identifying the non-pathology, plausible and acceptable.

To ascertain the validity of the DRS2 screening test, the sensitivity of the test was assessed, i.e., its ability to correctly identify subjects at risk for swallowing problems. It was calculated the test has a sensitivity of 95%. Such a high rate meets the established criteria to consider the test reliable; above all it allows to correctly classify the subjects with dysphagia. The confidence interval (CI) was also calculated, which is between 90% and 98%. The specificity of the test was found to be 88%, with a confidence interval between 76% and 95%.

From the statistical analysis of the data reported in the following table, it was possible to derive the sensitivity and specificity values:

Inter-rater reliability

The next table shows the data analysis on the inter-observer reproducibility of the DRS2 score. According to the qualitative interpretation (Landis and Koch) of the Kappa index (equal to 0.97) as a function of the degree of global agreement, the agreement is perfect as the Cohen's Kappa value is between 0.81 and 1.00.

DRS Score	K
1	1
2	0,94
3	0,94
4	1
Globale	0,97 P < 0.0001

Discussion

Data from our study show a good correlation between the risk classification obtained from the FEES examination and the risk index resulting from the administration of the DRS2, due to the presence of a two-tailed significance, both in a parametric and non-parametric correlation. The concordance between the risk assessed with DRS2 and FEES is furthermore confirmed by the agreement determined with the Cohen's Kappa coefficient.

The DRS2 shows a high sensitivity and can detect the presence of a risk in oral feeding, even if slight. The specificity of the test is not high, but ranges within the standards, set for a specificity >= 50.

The DRS2 specificity is particularly affected by the inclusion of an item related to the age of the patient. On the other hand, age is the major risk factor for stroke, most strokes occurring after age 65 (Feigin 2019; Kim 2020). Therefore, it was considered useful an additional level of investigation for patients over eighty, with suspected presbyphagia, which could miss screening tests. The inclusion of age parameter in calculating the test score could make DRS2 suitable for use even outside the stroke departments. Further studies are needed to confirm this.

It also was considered useful to evaluate the effect of language difficulties, due to the high number of aphasic patients in the stroke

units, and the growing number of foreign patients availing of health services in Italy. Otherwise in our clinical practice linguistic deficits did not affect the administration of the test, therefore, to avoid increasing the complexity of the test, it was decided not to add an additional specific element.

As regards the repeatability and reproducibility of the test between different operators, the high value of Cohen's Kappa coefficient and of the P Value indicates a remarkably high degree of agreement between the rankings provided by the different administrators.

The administration rate of the test and its good acceptability, make the DRS2 easily applicable to very large populations. In case of "fail" patients can be cautiously placed in a "nothing by mouth" regime and referred to a further in-depth evaluation process. This way meets in full the basic parameters in terms of cost/benefit for the implementation of a screening test (public health Reviews) (13).

Conclusions

Statistical analysis demonstrated the validity of DRS2, which proved to be a reliable and sensitive tool for detecting the risk of dysphagia in a population of patients suffering from acute stroke. DRS2 assessments are reproducible, also in case of administration by operators without a specific experience, provided that they undergo a specific training. The tool has also been well accepted by operators for its simplicity and execution rate. Further studies may validate the DRS2 for other neurological diseases.

Conflict of interest declaration

The authors declare the absence of a conflict of interest.

Disphagia Risk Score 2 (DRS2)

(Amitrano, Rossi, Pezzella)

Patient's details:

Last Name _____ First Name _____

Place of birth _____ Date of birth __/__/____ Sex M ☐ F ☐ NIHSS Rate ___

Please check the box that applies			Score	comments
Age: *Is the patient's age ≥ 80?*	yes ☐		1	
	no ☐		0	
Level of consciousness *Is the patient alert?*	yes ☐		0	
	no ☐		1	
Cough test *Can the patient cough voluntarily?*	yes ☐		0	
	no ☐		3	
Drinking test *Can the patient drink a glass of water without coughing?*	yes ☐		0	
	no ☐		3	
After drinking, did his/her voice change?	yes ☐		3	
	no ☐		0	
Is sialorrhea present?	yes ☐		0.5	
	no ☐		0	
Is the patient spitting saliva?	yes ☐		3	
	no ☐		0	
Is there dyspnoea?	yes ☐		2	
	no ☐		0	
TOTAL SCORE				

Risk ranking	No risk Total = 0	Low risk 0.5 ≤ Total = 3	Medium risk 3.5 ≤ Total = 5	High risk Total ≥ 5.5

Test administrator:		Date:	
Request SLT evaluation	Fail YES ☐	Pass NO	

Dysphagia Risk Score 2 (DRS2)

(Amitrano, Rossi, Pezzella)

Cognome _____ _____   Nome _____

Nato a _____ il _____   Sesso M ☐ F ☐   ScalaNIHSS _____

Barrare il quadratino corrispondente alla risposta			commento
Età del paziente *Paziente ≥80 anni ?*	SI ☐ NO ☐	1 0	
Livello di coscienza *Paziente vigile?*	SI ☐ NO ☐	0 1	
Test della tosse *Paziente in grado di tossire volontariamente?*	SI ☐ NO ☐	0 3	
Test dell'acqua *Paziente in grado di bere un bicchiere d'acqua senza tossire?*	SI ☐ NO ☐	0 3	
Dopo aver bevuto il bicchiere di acqua è cambiata la voce?	SI ☐ NO ☐	3 0	
E' presente scialorrea?	SI ☐ NO ☐	0,5 0	
Autonomamente sputa la saliva?	SI ☐ NO ☐	3 0	
E' presente dispnea ?	SI ☐ NO ☐	2 0	
TOTALE			

Classificazione del rischio	Assente Totale = 0	Basso 0,5 ≤ Totale = 3	Medio 3,5 ≤ Totale = 5	Alto Totale ≥ 5,5

Somministratore:			Data:	
Richiedere valutazione Logopedica?	Fail	SI ☐	Pass	NO ☐

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