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FULL PAPER

Does the total dysphagia risk score correlate with swallowing function examined by videofluoroscopy?

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Objective: The purpose of this study was to correlate the total dysphagia risk score (TDRS) with swallowing function as measured by videofluoroscopy of swallowing using the swallowing performance scale (SPS) and the penetration aspiration scale (PAS).

Methods: 63 patients from two different centres treated with radiotherapy for head and neck cancer were evaluated in the current study. Swallowing videofluoroscopies at baseline, 6 and 12 months following radiotherapy were evaluated by two observers. The TDRS of all patients was calculated and correlated with the consensus PAS and SPS scores of the two observers.

Results: Regarding the PAS scale, we did not observe a significant correlation with the TDRS. Regarding SPS, we found a significant correlation at 6 months ($p = 0.01$) and a borderline significant correlation at 12 months ($p = 0.05$). We observed statistically lower SPS scores for patients in the intermediate-risk category when compared to the high-risk category. When we compared low vs high TDRS risk patients, we did not observe a significant difference regarding SPS scores. When comparing

low- vs intermediate-risk patients, we observed higher SPS scores in the low-risk group ($p = 0.01$). When the low- and intermediate-risk patients were grouped together, we observed less swallowing problems as measured by SPS in the low and intermediate group when compared to the high-risk group ($p = 0.05$) at 6 months.

Conclusion: Patients with high-risk TDRS scores have higher SPS scores when compared to the intermediate group and the intermediate- and low-risk group together. However, low-risk patients in our patient cohort could not be distinguished from high or intermediate-risk patients.

Advances in knowledge: TDRS was never correlated with videofluoroscopies in past studies. The hypothesis of this paper was to see if the TDRS could guide us to see which patients are at risk for high scores on SPS and PAS and might need a videofluoroscopic examination in the follow up. Given the poor correlations in our study, however, we cannot recommend the use of the TDRS to select patients who might benefit from the additional information provided by videofluoroscopies.

INTRODUCTION

Head and neck squamous cell carcinoma (HNSCC) encompasses a large number of tumour entities originating from different subsites. It is the sixth most common cancer worldwide. The main treatment options for loco-regionally advanced HNSCC are (chemo-) radiotherapy (RT) and surgery. The intensification of the RT treatment, by adding concomitant chemotherapy and by using altered RT fractionation schedules, resulted in better outcome, but also in an increase in both acute and late toxicity.¹⁻⁶ Especially, late dysphagia is a major

concern and has a strong negative impact on quality of life.^{3,5}

The total dysphagia risk score (TDRS), a risk model for predicting the risk to develop physician scored dysphagia 6 months following RT for HNSCC, was created in 2009.³ The following prognostic factors for swallowing dysfunction at 6 months were included into this model: (1) T_3 - T_4 , (2) bilateral neck irradiation, (3) weight loss prior to radiation, (4) oropharyngeal and nasopharyngeal tumours, (5) treatment modality: accelerated RT and concomitant chemoradiation

therapy (CRT) ([Supplementary Material 1](#), Supplementary material available online). Three risk groups could be defined: low- (TDRS 0–9), intermediate- (TDRS 10–18) and high-risk patients (TDRS > 18). This risk model was validated retrospectively by one research group for acute dysphagia⁷ and for acute and late dysphagia (1, 3, 6 and 9 months following CRT) by our research group in a prospective manner.⁸

The aim of this study was to correlate the TDRS with swallowing function as measured by videofluoroscopies [using the swallowing performance scale (SPS) and the penetration aspiration scale (PAS)—scales can be found in the [Supplementary Material 1](#)]. The TDRS is known to correlate with physician-scored dysphagia but the relation to objective measurements like videofluoroscopy is unknown.

METHODS AND MATERIALS

Patient data

The current paper is a secondary analysis of a prospective randomized controlled trial on dose de-escalation to the elective nodal volume in head and neck cancer.^{9,10} The initial trial was a randomized multicentre study that was initiated in six centres, including 200 patients with previously untreated, squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, larynx or cervical lymph node metastases with unknown primary cancer (CUP).⁹ Patients were randomized to two treatment arms. A total of 200 patients were included in the study (100 for each arm).

All macroscopically affected tumour sites were treated up to a normalized iso-effective dose in 2 Gy fractions (NID2 Gy) of 70 Gy. For the elective lymph nodes, patients randomized in the experimental arm were treated up to a NID2 Gy of 40 Gy. For arm B (control arm) the elective nodal volumes were treated up to a NID2 Gy of 50 Gy.⁹

In two centres of this study, patients received a videofluoroscopy at baseline and at 6 and 12 months following the end of treatment. The endpoint of the current study is swallowing problems evaluated on PAS and SPS at 6 and 12 months of follow up in this patient population. Patients from the original trial lacking pre-treatment videofluoroscopy and videofluoroscopy at 6 or 12 months following the end of RT were excluded from the current analysis. After exclusion of patients who did not meet the inclusion criteria, 63 patients could be further analysed.

Scoring and videofluoroscopy protocol

Videofluoroscopies were done at baseline and at 6 and/or 12 months following the end of therapy. These time points were chosen according to the endpoints of the initial trial in which these patients were included.⁹ The TDRS was built to predict dysphagia at 6 months following treatment.³ Comparing the TDRS with videofluoroscopies should, thus, ideally be done at 6 months of follow up. The videofluoroscopies were digitalized and scored blindly by two trained supervisors with at least 20 years of experience in the evaluation of videofluoroscopy (AG and ED). Afterwards, we calculated the inter-rater agreement between the two observers and made a consensus scoring for the

PAS and SPS based on the highest score of the two observers for every patient at every time point (baseline, 6 and 12 months). The PAS is an 8-point interval scale to describe penetration and aspiration events. Scores are determined primarily by the depth to which material passes in the airway and by whether or not material entering the airway is expelled.¹⁰ The SPS provides an accurate assessment of the presence and severity of dysphagia and aspiration risk by combining clinical and radiographic data.¹¹

During videofluoroscopy, patients were given firstly a 5 cc liquid bolus, subsequently a 10 cc liquid bolus and a more concentrated 10 cc bolus. When feasible, a piece of bread with a contrast agent was administered as well. This bolus consisted of a contrast agent (Micropaque® Bariï Sulfas Guebert, France). When there was risk for aspiration, a low osmotic iodine agent was used (Ultravist®). The pulse and frame rate were both 15 s.

Statistics

As a first step, we retrospectively calculated the TDRS for every patient. We defined the weight loss as the percentage of total body weight lost during the 6 months prior to RT, as we did in a previous paper.⁸ The TDRS was scored as described in the original paper.³

To determine the inter-rater agreement between both observers, the intraclass correlation coefficient (ICC) was calculated. The ICC takes values between 0 and 1 with higher values indicating higher levels of agreement.

Proportional odds models were used to look at the link between TDRS and videofluoroscopies. The interaction with time was tested. A significant interaction with time means that the association between the variables is different between the three time points (baseline, 6 and 12 months). In such case, results are reported per time point. In absence of an interaction effect, the main effect is presented. All tests are two-sided, a 5% significance level is assumed for all tests. Analyses have been performed using SAS software (v. 9.4 of the SAS System for Windows).

RESULTS

Patient characteristics of the 63 patients who were included in this study are listed in [Table 1](#). All patients ($n = 63$) received a baseline videofluoroscopy, 54 patients received an additional videofluoroscopy at 6 months of follow up, 39 patients received an additional videofluoroscopy at 12 months of follow up.

The ICC values for the agreement regarding the PAS and SPS scoring between both observers demonstrated a fair level of inter-rater agreement for SPS (range 0.56–0.75) and a good level of agreement for PAS (range 0.64–0.94). Agreement seemed to be better for pre-measurements than at 6 or 12 months ([Table 2](#)).

The different TDRS groups were rather unbalanced in our patient population. 49% of the study population belonged to the high-risk group according to the TDRS. 38% belonged to the intermediate-risk group and only 12.70% to the low-risk group ([Table 3](#)).

Table 1. Patient and treatment characteristics

Patient and treatment characteristics	
Sex	
Female	12/63 (19.05%)
Male	51/63 (80.95%)
Age	
Mean	61.4
Median	61.0
IQR	(55.0; 68.0)
Range	(38.0; 80.0)
Dose to the elective neck	
40	46/63 (73.02%)
50	17/63 (26.98%)
Neck dissection	
No	42/63 (66.67%)
Yes	21/63 (33.33%)
Location	
CUP	4/63 (6.35%)
Hypopharynx	15/63 (23.81%)
Larynx	11/63 (17.46%)
Oropharynx	33/63 (52.38%)
T	
CUP	4/63 (6.35%)
1	4/63 (6.35%)
2	24/63 (38.10%)
3	19/63 (30.16%)
4	12/63 (19.05%)
N	
0	10/63 (15.87%)
1	10/63 (15.87%)
2a	3/63 (4.76%)
2b	22/63 (34.92%)
2c	18/63 (28.57%)
Chemotherapy	
No	25/63 (39.68%)
Yes	38/63 (60.32%)

CUP, unknown primary cancer; IQR, interquartile range.

Table 3. The TDRS groups in our patient population

TDRS	n/N
High-risk group	31/63 (49.21%)
Intermediate-risk group	24/63 (38.10%)
Low-risk group	8/63 (12.70%)

Regarding the PAS scale, we did not observe a significant p -value regarding interaction ($p = 0.14$), meaning that the interaction was the same at all time points (baseline, 6 and 12 months). This interaction was not significant ($p = 0.15$) when we removed interaction from the model, meaning that we did not observe a significant correlation between TDRS and PAS scored at baseline, 6 and 12 months of follow up.

Regarding SPS, we found a p -value of $p < 0.01$ for interaction, indicating that the interaction was different at all time points. We observed no correlation between the TDRS and baseline SPS values; a significant correlation was, however, observed between the TDRS and SPS score at 6 months ($p = 0.01$) and a borderline significant effect at 12 months ($p = 0.05$) (Table 4).

We observed a statistically significant lower SPS scores for patients in the intermediate-risk category when compared to the high-risk category at 6 months of follow up [$p = 0.02$; OR -0.804 (-1.506 to -0.103)]. When we compared patients with a low vs high TDRS score we did not observe a significant difference regarding SPS scores [$p = 0.08$; OR 0.981 (-0.107 to 2.069)]. When comparing low vs intermediate TDRS patients, we observed significantly higher SPS scores in the low-risk group [$p = 0.01$; OR 1.786 (0.670 to 2.902)] (Table 5).

Since we only had 8 patients in the low-risk group, we repeated the analysis where we combined the low ($n = 8$) and intermediate TDRS risk patients ($n = 24$) together in one group to compare to the high-risk group ($n = 31$). Regarding PAS scores, we did not observe statistically significant differences. We found a significant p -value for interaction $p < 0.01$ regarding the SPS. We found again no correlation at baseline and a significant correlation at 6 months ($p = 0.01$) but not at 12 months ($p = 0.08$). When we looked at 6 months to the low + intermediate TDRS risk group vs the high-risk TDRS group, we observed a borderline significant correlation [$p = 0.05$; OR -0.406 (-1.207 to -0.082)], where the low and intermediate-risk group together have lower SPS scores when compared to the high-risk group (Table 5).

Table 2. The intraclass correlation coefficient values for the agreement regarding the PAS and SPS scoring between both observers

Intraclass correlation coefficient (95% CI)				
Score	pre	6 m	12 m	Overall
PAS	0.937 (0.899 to 0.962)	0.763 (0.625; 0.855)	0.639 (0.411 to 0.792)	0.803 (0.740; 0.853)
SPS	0.747 (0.614; 0.838)	0.555 (0.341; 0.715)	0.577 (0.326; 0.753)	0.648 (0.547; 0.730)

CI, confidence interval; PAS, penetration aspiration scale; SPS, swallowing performance scale.

Table 4. Correlation of the TDRS with the SPS at all time points

TDRS (global test)	<0.01
Baseline: TDRS (global test)	0.76
6 months: TDRS (global test)	<0.01
12 months: TDRS (global test)	0.05

SPS, swallowing performance scale; TDRS, total dysphagia risk score.

DISCUSSION

Dysphagia remains a major problem for patients treated with (C) RT for locally advanced HNSCC.¹² Dysphagia leads to longer eating times, inability to eat different types of food, and fear or inability to eat in public which in turn results in social isolation and depression. The TDRS is a way to predict physician scored dysphagia at 6 months.³ This risk model was validated retrospectively⁷ and in a prospective manner.⁸ The purpose of this study was to correlate TDRS with videofluoroscopy evaluation. This is the first paper to correlate this model with videofluoroscopies. We chose to use the PAS and SPS, since these scales have been used extensively and have been validated^{10–16} and were recommended in a recent review.¹² The hypothesis of this paper was to see if the TDRS could guide us to see which patients are at risk for high scores on SPS and PAS and might need a videofluoroscopic examination in the follow up.

Since our population consists of only 63 patients, and not all patients received a videofluoroscopy at all time points, it is important to say that these results are only exploratory.

We did not observe a correlation between the TDRS and PAS. Regarding the SPS, we observed a better correlation with the TDRS. However, we could not distinguish the low-risk group from the high-risk group and more importantly, it seemed that the low-risk group was more at risk when compared to the intermediate-risk group. This might be partially explained by the imbalances in our patient population when we look at the division in the different TDRS risk categories. 50% of the patients were T_3 – T_4 , all patients received a bilateral neck irradiation, 52% of the patients had an oropharyngeal tumour, and 60% received concomitant chemoradiation. These factors are highly scored in the TDRS, leaving almost no patients with low scores in our patient population ($n = 8$).

Therefore, we repeated the analysis combining the low- and intermediate-risk group. This way, we obtained more balanced groups ($n = 31$ in the high-risk group and $n = 32$ in the low-/

Table 5. Comparison of the different risk groups with SPS at all time points

Comparison	Estimate (95% CI)	<i>p</i> -value
Low vs intermediate	1.786 (0.670 to 2.902)	<0.01
Low vs high	0.981 (–0.107 to 2.069)	0.08
Intermediate vs high	–0.804 (–1.506 to –0.103)	0.03
Low + intermediate vs high	–0.406 (–1.207 to –0.082)	0.05

Estimate >(<) 0 means higher (lower) SPS score for first level.

CI, confidence interval; SPS, swallowing performance scale.

intermediate-risk group). We found significant higher SPS scores in the high-risk group when compared to the low-risk group.

Therefore, based on our study we cannot recommend the use of the TDRS to select patients who might benefit from the additional information provided by videofluoroscopies following RT for head and neck cancer. Nonetheless, the TDRS has been validated in the past to predict acute and late physician scored dysphagia. Therefore, it can have its use in selecting suitable candidates for preventive strategies for dysphagia.³ However, the best intervention method to lower dysphagia is currently unknown.⁸ Recently, however, the relationship between early and late toxicity following radiotherapy has been demonstrated.^{17,18} This insight might lead the way for more individualized treatments, resulting in less acute and late dysphagia.^{17,18}

The strength of this paper is that this paper is the first to correlate TDRS with videofluoroscopies, the fact that all data were prospectively gathered and that the scoring was done by two experienced, blinded observers. Furthermore, our research group has experience with research concerning the TDRS.⁸ Limitations of the current study are the relatively small patient population, the imbalances between the different risk groups of the TDRS and the fact that we only used PAS and SPS for the videofluoroscopy scoring. Furthermore, we had a relatively large proportion of dropouts. This might be partly explained due to the fact that videofluoroscopies are stressful procedures.

CONCLUSIONS

High-risk TDRS patients had higher SPS scores when compared to the intermediate group and the intermediate- and low-risk group together. However, low-risk patients in our patient cohort could not be distinguished from high or intermediate-risk patients.

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