

Impact of Transoral Robotic Surgery vs. Radiation on Swallowing Function in Oropharyngeal Cancer Patients: A Sub-study from a Randomized Trial

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BACKGROUND

Attempts to reduce long term treatment-related toxicities and increase quality of life (QOL) in patients treated for oropharyngeal cancer (OPSCC) have included transoral robotic surgery (TORS) as an alternative to radiation therapy (RT).

The ORATOR trial¹ (NCT01590355) provided the first randomized comparison of swallowing following primary RT (± chemotherapy) versus primary TORS (± ND), with reported results based on patient QOL questionnaires alone. Several studies have described swallowing physiology post-TORS using instrumental assessment,²⁻⁵ however, no prior physiologic swallowing comparisons in the context of a randomized trial have been reported.

The **purpose** of this ORATOR sub-study was to prospectively investigate the impact of RT versus TORS on physiologic swallowing outcomes in patients with early-stage OPSCC.

MEASUREMENT

Modified Barium Swallow (MBS) studies were obtained at baseline, and at 6- and 12-months. The M.D. Anderson Dysphagia Inventory⁵ (MDADI) was collected at each of these time points as the primary outcome of the main ORATOR trial.

MBS studies were analyzed using:

- Modified Barium Swallow Impairment Profile⁶ (MBSImP[®]™), and
- Penetration-Aspiration Scale⁷ (PAS)

Statistical analyses:

- Between group differences – Chi-square, Fisher's Exact and Wilcoxon rank sum tests as appropriate, and linear mixed modeling
- Correlation between MBSImP[®]™ Oral and Pharyngeal total scores and MDADI across all time points - Pearson correlation coefficients (PCCs)
- Descriptive: frequencies of normal/abnormal PAS scores

RESULTS

Swallowing Physiology (Figure 1)

- No significant differences in mean MBSImP oral and pharyngeal total scores between groups and across time
- Trend toward greater pharyngeal impairment in Arm 2 (TORS) vs. Arm 1 (RT) at 6M and 12M

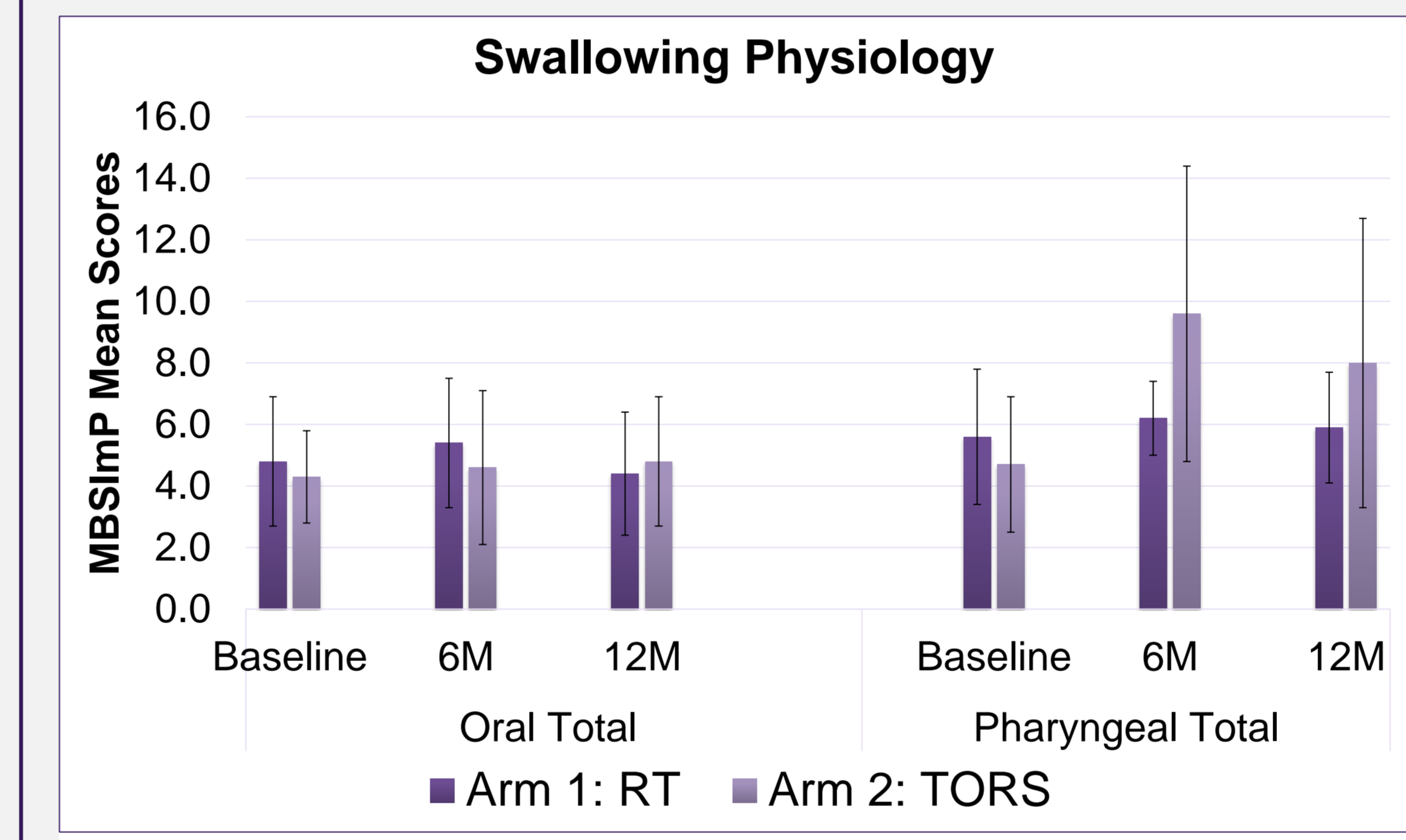


Figure 1. Mean MBSImP Oral and Pharyngeal Total Scores by group and time point

Penetration/Aspiration Scale (Figure 2)

- Comparison of median PAS scores did not demonstrate significant differences between groups or across time
- Frequency of normal (1-2) vs. abnormal PAS scores changed over time for both treatment groups

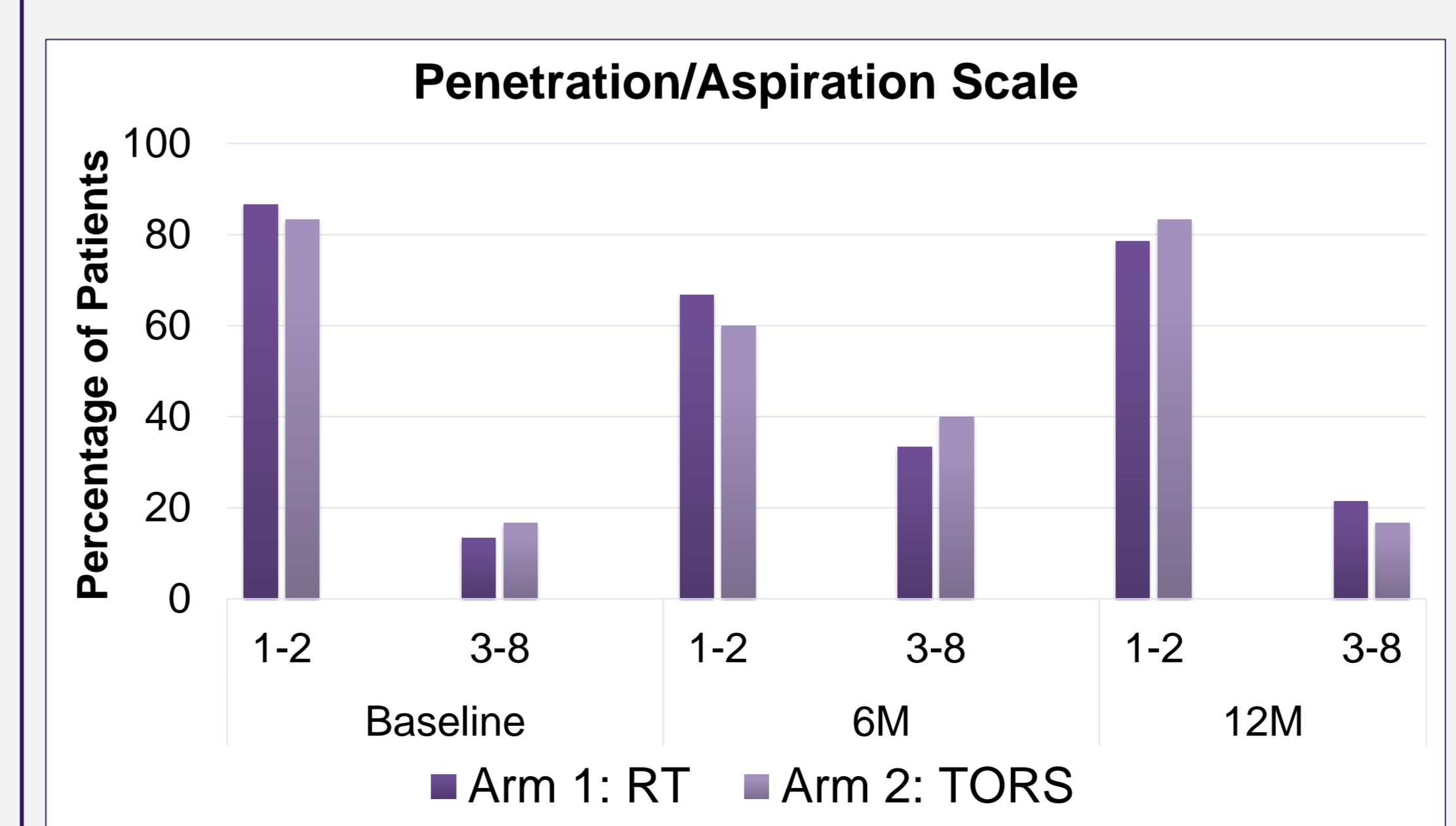


Figure 2. Frequency of Penetration-Aspiration Scores: Normal (1-2) vs. Abnormal (3-8)

RESULTS

Swallowing-Related Quality of Life (Figure 3)

Using pooled data MBSImP data:

- Oral total scores: no significant correlations with any MDADI scale scores
- Pharyngeal total scores: weak negative correlations with MDADI *composite* ($r=-0.257$, $p=0.049$), *emotional* ($r=-0.283$, $p=0.028$), and *physical* ($r=-0.288$, $p=0.027$) subscales

When MBSImP data grouped by 12M MDADI pattern of response (Figure 3):

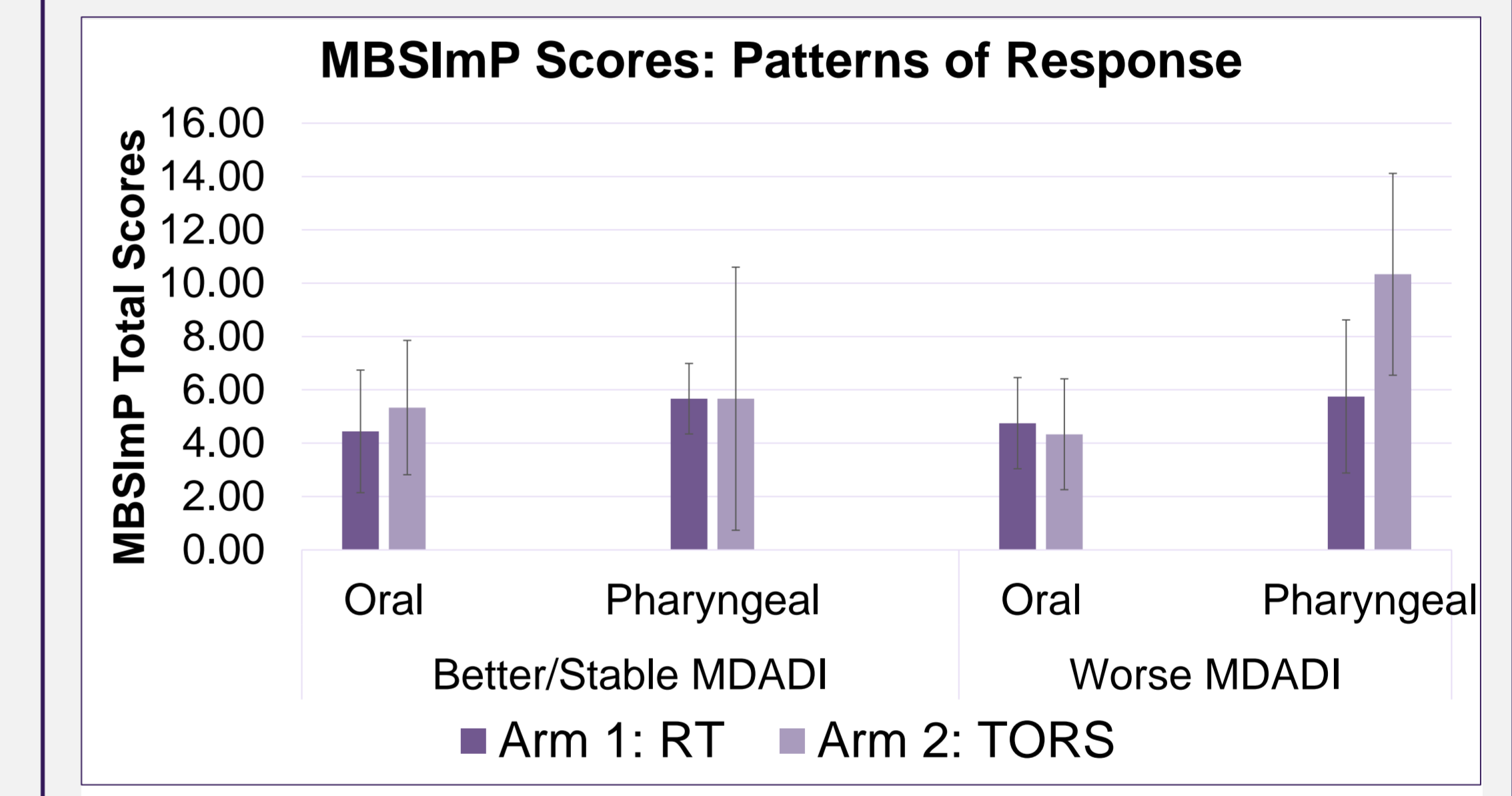


Figure 3. Mean MBSImP scores at 12M in patients with better/stable and worse (i.e., clinically meaningful decline) MDADI Composite scores

DESIGN & METHODS

This prospective cohort study was approved by the Health Sciences Research Ethics Board at Western University (REB #104328).

Recruitment: Patients with early stage OPSCC (amenable to TORS resection) enrolled in ORATOR between July 2014 and February 2017 were eligible to participate in the optional swallowing sub-study. Inclusion and exclusion criteria listed in Table 1.

Sub-study Participants (Table 2)

- 15 (2 female) patients from ORATOR Arm 1 (RT ± chemotherapy)
- 6 (0 female) patients in ORATOR Arm 2 (TORS ± ND)

Table 1. ORATOR Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• ≥18 years old	• Serious medical comorbidities
• ECOG 0-2	• Previous HNC history (5 yrs)
• OPSCC: T1-T2, N0-2, M0	• Distant metastases
• Good candidate for TORS, chemotherapy	• Previous invasive cancer

Table 2. Patient and Treatment Characteristics

	All patients (n=21)	Arm 1: RT group (n=15)	Arm 2: TORS group (n=6)
Age, mean yrs (SD)	56.3 (8.4)	56.2 (9.2)	54.8 (6.4)
Sex, n (%)			
• Male	19 (90%)	13 (87%)	6 (100%)
• Female	2 (10%)	2 (13%)	0 (0%)
Primary site			
• Tonsil	15 (71%)	12 (80%)	3 (50%)
• BOT	6 (29%)	3 (20%)	3 (50%)
Clinical T-stage			
• T1	10 (48%)	8 (53%)	2 (33%)
• T2	11 (52%)	7 (47%)	4 (67%)
Clinical N-stage			
• N0	7 (33%)	5 (33%)	2 (33%)
• N1	1 (5%)	1 (7%)	0 (0%)
• N2	13 (62%)	9 (60%)	4 (67%)
p16 positive	20 (95%)	14 (93%)	6 (100%)
Radiotherapy	19 (90%)	15 (100%)	4 (67%)
Chemotherapy	12 (57%)	11 (73%)	1 (17%)*

CONCLUSIONS

This first examination of swallowing function after RT vs. TORS for early-stage OPSCC using videofluoroscopy revealed subtle non-significant differences particularly related to pharyngeal swallow physiology. Future examination of outcomes following RT vs. TORS should include rigorous evaluation of swallowing physiology to elucidate the source of any swallowing-related QOL differences between treatment modalities.

References:
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