Validation of a patient-reported outcome instrument in head and neck oncology: Preliminary analysis

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Background & Objective

Background

The initial development of the Edmonton-33 (E-33) recognized that goals of treatment in head and neck oncology include not only survival but also function.[1,2] The latter can be represented by multiple dimensions, all having significant impact on health and quality of life for patients.[3,4] For head and neck oncology specifically, outcomes are highly patient-specific.[5] This emphasizes the importance of patient-reported outcomes (PRO), which are directly patient reported information about their how they experience function.[5] Acquiring patient-reported information during disease diagnoses and management is an integral part of ensuring care is patient-centered. Tools that elicit PRO can be self-administered, which makes them accessible for patients and clinicians. The tools when appropriately designed and validated make diverse patient experiences measurable and informative.

The E-33 is a PRO tool with 33 questions using a Likert scale. It has four functional domains prioritized and selected by patients, including swallowing, chewing, dry mouth, and speech (Fig. 1).[1] The aim of the E-33 is to serve as a single comprehensive measure for functional outcomes in multiple domains. There is a plethora of common tests that head and neck cancer patients may typically encounter. These include subjective inventories and objective clinical measures. As a single comprehensive measure, the E-33 could potentially be an alternative to one or more of the tests. This can hopefully create both convenience and variety to useful PRO tools in head and neck oncology.

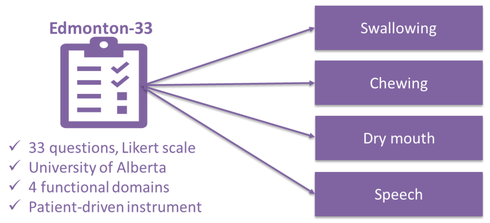

Figure 1. Schematic representation of four priority domains in the Edmonton-33 questionnaire.

Why validate PRO tools?

- ❑ Priorities selected by patients
- ❑ Relevant for functional status, quality of life, overall wellbeing and disease progression
- ❑ Ensures accuracy and minimize redundancy
- ❑ Contributes to patient-centered care

Objective

To explore construct validity of the Edmonton-33 (E-33; a patient-reported outcomes (PRO) instrument, developed with continuous patient engagement for assessing head and neck functions in patient-prioritized domains of swallowing, chewing, dry mouth, and speech) for adult patients with oral cavity squamous cell carcinoma (SCC) at the London Health Sciences Centre (LHSC) and the University of Alberta (UofA).

Method

The E-33 and other PRO instruments were distributed to eligible adult head and neck cancer patients with SCC of the oral cavity before and after surgical and radiation treatment at months 3, 6, 9, and one year (Fig. 2). Data were collected via REDCap and analyzed for correlation between domains of the E-33 and their domain-specific, previously validated counterparts before treatment (baseline) and after treatment (month 3 and month 6). The previously validated instruments included for the correlation analysis are: MD Anderson Dysphagia Inventory (MDADI)[6], European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck Module (EORTC QLQ-HN43)[7], University of Washington Quality of Life Questionnaire (UW-QoL)[8,9], Xerostomia Inventory (XI)[10], and Speech Handicap Index (SHI)[11].

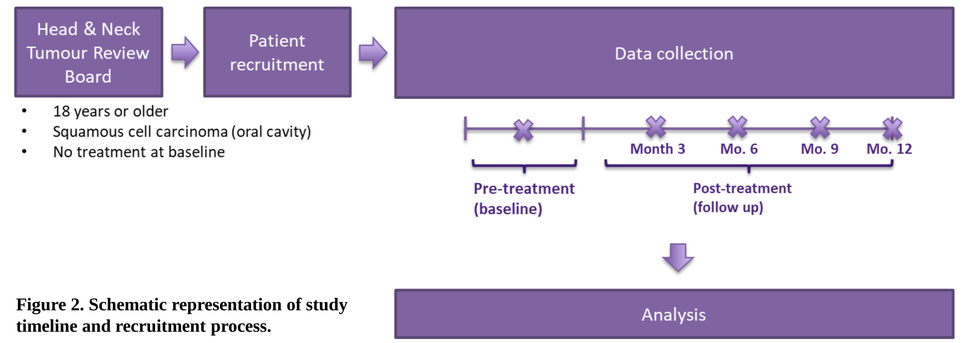

Figure 2. Schematic representation of study timeline and recruitment process.

Results

The analysis included 41 patients (8 female, average age 68.9 years; 33 male, average age 62.0 years) from the LHSC branch of the study from the present data set. There were statistically significant correlations ($p<0.05$) between all E-33 domains and their domain-specific counterparts at baseline (Table 1). At month 3, correlations between the swallowing domain and the MDADI ($p=0.0152$) as well as the UW-QoL #5 ($p=0.0009$), the dry mouth domain and the XI ($p=0.170$) and the EORTC QLQ-HN43 #12-13 ($p=0.0356$) were statistically significant (Table 2). At month 6, correlations were statistically significant between all E-33 domains and their respective counterparts except for swallowing and EORTC QLQ-HN43 #5-8 (Table 3).

Domain	Instruments	Correlation (Pearson)	Confidence Interval (alpha=0.05, Pearson), LOWER	Confidence Interval (alpha=0.05, Pearson), UPPER	P-Value
Swallowing	MDADI	0.81915	0.654906	0.909502	<.0001
	EORTC5-8	0.77469	0.579394	0.885858	<.0001
	UW5	0.80459	0.629808	0.901822	<.0001
Chewing	EORTC	0.78251	0.604237	0.886178	<.0001
	UW6	0.67456	0.435811	0.824620	<.0001
Dry mouth	XI	0.80552	0.635263	0.901112	<.0001
	EORTC12-13	0.71420	0.486715	0.850970	<.0001
	UW10	0.55348	0.253765	0.756228	0.0007
Speech	SHI	-0.78736	-0.888858	-0.612192	<.0001
	EORTC25-28	0.72116	0.506524	0.851637	<.0001
	UW7	0.79069	0.617687	0.890699	<.0001

Table 1. Pearson correlation coefficients, confidence intervals, and p-values for E-33 domains and previously validated, domain-specific counterparts from questionnaires completed at baseline (pre-treatment).

Domain	Instruments	Correlation (Pearson)	Confidence Interval (alpha=0.05, Pearson), LOWER	Confidence Interval (alpha=0.05, Pearson), UPPER	P-Value
Swallowing	MDADI	0.67695	0.129780	0.908072	0.0152
	EORTC5-8	0.53946	-0.089325	0.860778	0.0741
	UW5	0.81080	0.410658	0.949068	0.0009
Chewing	EORTC	0.07111	-0.552324	0.643535	0.8321
	UW6	0.26232	-0.400588	0.744969	0.4245
Dry mouth	XI	0.66927	0.115952	0.905577	0.0170
	EORTC12-13	0.61148	0.018333	0.886264	0.0356
	UW10	0.56987	-0.045587	0.871741	0.0556
Speech	SHI	-0.44467	-0.824590	0.211661	0.1563
	EORTC25-28	0.41566	-0.245404	0.812855	0.1893
	UW7	0.42200	-0.238163	0.815448	0.1818

Table 2. Pearson correlation coefficients, confidence intervals, and p-values for E-33 domains and previously validated, domain-specific counterparts from questionnaires completed at 3 months post-treatment.

Domain	Instruments	Correlation (Pearson)	Confidence Interval (alpha=0.05, Pearson), LOWER	Confidence Interval (alpha=0.05, Pearson), UPPER	P-Value
Swallowing	MDADI	0.90501	0.706134	0.971539	<.0001
	EORTC5-8	0.52788	-0.032583	0.835776	0.0538
	UW5	0.70314	0.248376	0.903925	0.0043
Chewing	EORTC	0.62511	0.113065	0.874793	0.0162
	UW6	0.56815	0.024993	0.852324	0.0343
Dry mouth	XI	0.95671	0.858020	0.987273	<.0001
	EORTC12-13	0.80556	0.457735	0.939531	0.0003
	UW10	0.82170	0.494670	0.944890	0.0002
Speech	SHI	-0.79451	-0.935825	-0.433135	0.0004
	EORTC25-28	0.77796	0.397255	0.930214	0.0007
	UW7	0.79824	0.441383	0.937080	0.0004

Table 3. Pearson correlation coefficients, confidence intervals, and p-values for E-33 domains and previously validated, domain-specific counterparts from questionnaires completed at 6 months post-treatment.

Conclusion

At the present time, the E-33 may demonstrate validity pre-treatment and post-treatment at month 6 for capturing swallowing, chewing, dry mouth, and speech data similarly captured by multiple other previously validated instruments. However, this validity seems to be limited to the swallowing and dry mouth domains at 3 months post-treatment. Additional data are needed to further explore functional or systematic factors to elucidate the strengths and limitations of the E-33 for capturing functional outcomes among head and neck cancer patients with oral cavity SCC.

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