

Establishing Thresholds for Clinical Importance for EORTC Questionnaire Modules for Eight Specific Groups of Cancer Patients

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INTRODUCTION

Patient-reported outcome (PRO) measures allow to assess the patients' perspective on cancer and its treatment. The most widely used PRO measures in oncology were developed by the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group (QLG)¹.

To facilitate interpretation of scores obtained from these measures and make them usable for symptom screening, thresholds for clinical importance (TCIs) have been introduced².

Clinical importance was defined based on a mixed method study with a focus on the importance of health issues for the clinical encounter and operationalized into anchor items³. The TCIs established for the EORTC measures support the interpretation of absolute PRO scores obtained from an individual patient at a single point in time.

OBJECTIVE

This study aims to establish thresholds for clinical importance (TCIs) for eight questionnaire modules from the EORTC measurement system that assess health-related quality of life and symptoms in patients with lung cancer (QLQ-LC29), prostate cancer (QLQ-PR25), breast cancer (QLQ-BR45), colorectal cancer (QLQ-CR29), endometrial cancer (QLQ-EN24), ovarian cancer (QLQ-OV28), head&neck cancer (QLQ-H&N43) and in elderly cancer patients (QLQ-ELD14).

>>> Here we present preliminary results for the elderly cancer module QLQ-ELD14

METHODS

PATIENT SAMPLES N=225 cancer patients are recruited for each of the eight study groups that match the target population of the eight included EORTC questionnaire modules. Patients are recruited at centres in 11 countries in Europe and Africa → N=1800 cancer patients in total

ASSESSMENT EORTC questionnaire module relevant to the study group
Anchor item questionnaire for the assessment of clinical importance for each domain of the questionnaire module (i.e. of limitations of everyday life, worries, and the need for help/treatment related to the health issue assessed by a questionnaire scale)

Example for anchor items assessing the clinical importance of health issues measured by the QLQ-ELD14 Mobility scale

- LIMITATIONS > "Have problems with your legs (e.g. swelling, heaviness) limited your daily life?"
- NEED FOR HELP > "Have you needed any help or care because of problems with your legs (e.g. swelling, heaviness)?"
- WORRIES > "Have problems with your legs (e.g. swelling, heaviness) caused you or your family/partner to worry?"

STATISTICAL ANALYSIS

TCIs were determined for each questionnaire module scale based on ROC analysis with a threshold being selected that provides balanced sensitivity and specificity. For the ROC analysis, patients were categorized as „positive cases“ on a questionnaire domain if they reported either limitations, need for help, or worries related to assessed health issue.

PRELIMINARY RESULTS FOR THE EORTC QLQ-ELD14 QUESTIONNAIRE MODULE

PATIENT CHARACTERISTICS (N=154)

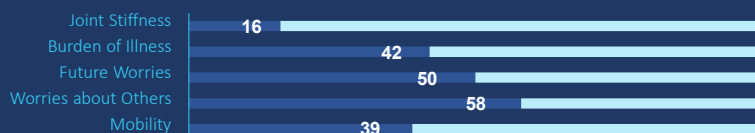
		Mean (Range)
AGE		76.6 (70-93)
		N (%)
SEX	Female	80 (55.2)
	Male	74 (44.8)
DIAGNOSIS	Breast cancer	43 (27.9)
(most frequent)	Head and neck cancer	20 (13.0)
	Gastrointestinal cancer	13 (8.4)

ROC ANALYSIS FOR PATIENT GROUPS DEFINED BY SEX, AGE, COMORBIDITY

Symptom Scale: MOBILITY	SEX	m	AUC	95% CI
		f	0.81	0.71-0.92
		f	0.84	0.84-0.97
	AGE GROUPS	≤75	0.86	0.77-0.95
		>75	0.86	0.77-0.94
	COMORBIDITY	No	0.86	0.80-0.93
		Yes	0.86	0.80-0.93

EORTC QLQ-ELD14 THRESHOLDS FOR CLINICAL IMPORTANCE *

Symptom Scales*	AUC	95% CI
Joint Stiffness	0.87	0.81-0.93
Burden of Illness	0.84	0.78-0.90
Future Worries	0.86	0.79-0.92
Worries about Others	0.82	0.75-0.89
Mobility	0.87	0.81-0.93



* The current recruitment status did not allow to calculate TCIs for the QLQ-ELD14 scales Family Support and Maintaining Purpose and for patients without comorbidities

CONCLUSION

The current study follows the same anchor-based approach as previous work establishing TCIs for other EORTC measures (the EORTC QLQ-C30, the EORTC QLQ-C15-PAL, and the EORTC CAT Core) to allow for a consistent interpretation of clinical importance across the EORTC measurement system. TCIs will facilitate the use of the EORTC questionnaire modules for symptom screening in daily clinical practice. Additionally, they can be used to calculate prevalence rates for symptoms and impairments and may be used for the definition of responders in trial endpoints.

REFERENCES

- Giesinger JM, Efficace F, Aaronson N, Calvert M, Kytte D, Cottone F, Cella D, Gamper EM. Past and Current Practice of Patient-Reported Outcome Measurement in Randomized Cancer Clinical Trials: A Systematic Review. Value Health. 2021 Apr;24(4):585-591.
- Giesinger JM, Loth FLC, Aaronson NK, Arraras JI, Caocci G, Efficace F, Groenvold M, van Leeuwen M, Petersen MA, Ramage J, Tomaszewski KA, Young T, Holzner B; EORTC Quality of Life Group. Thresholds for clinical importance were established to improve interpretation of the EORTC QLQ-C30 in clinical practice and research. J Clin Epidemiol. 2020 Feb;118:1-8.
- Giesinger JM, Aaronson NK, Arraras JI, Efficace F, Groenvold M, Kieffer JM, Loth FL, Petersen MA, Ramage J, Tomaszewski KA, Young T, Holzner B; EORTC Quality of Life Group. A cross-cultural convergent parallel mixed methods study of what makes a cancer-related symptom or functional health problem clinically important. Psychooncology. 2018 Feb;27(2):548-555.

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