EVALUATION OF PATIENT-REPORTED OUTCOME MEASURES TO ASSESS THE PHYSICAL SYMPTOMS IN LEPTOMENINGEAL DISEASE - A NARRATIVE REVIEW

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Introduction

- Leptomeningeal disease (LMD) arising from solid malignancy can cause a number of debilitating symptoms.
- To assess patients' functioning and wellbeing, patient-reported outcome measures (PROMs) are often used, covering symptoms and functions.

Objectives

1) Evaluate the physical symptoms in patients with LMD
2) Determine if these are captured by PROMs currently used in LMD trials.

Methods

The database of clinicaltrials.gov was searched using the term "leptomeningeal" under "condition or disease" since the inception of the database, to identify the PROM used in ongoing or completed clinical trials. A separate search was performed in MEDLINE and Google Scholar using the terms "leptomeningeal disease" and "symptoms" or "quality of life" to identify the most common physical symptoms in patients with LMD. The searching, screening and data extraction was done by AWC. Next, it was assessed to what extent these symptoms were covered by the PROMs used in clinical trials.

Results

Table 1

Common physical symptoms in patients with leptomeningeal disease

Cerebral hemisphere symptoms	Posterior fossa or cranial nerve symptoms
Headache	Double vision
Seizure	Facial weakness
Nausea or vomiting	Facial numbness
Mental changes	Visual loss
Dizziness	Hearing loss
Spinal symptoms	Swallowing difficulty
Radicular pain or neck / back pain	Hoarseness
Paresthesia over body	
Weakness of limbs	
Bladder and bowel dysfunction	

Abbreviations: EORTC QLQ-BN20= European Organization for the Research and Treatment of Cancer Brain Cancer Module; EORTC QLQ-C30 = European Organization for the Research and Treatment of Cancer Core Quality of Life Questionnaire; EORTC QLQ-C15-PAL = European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire Core 15 Palliative Care; MDASI-BT = MD Anderson Symptom Inventory - Brain Tumor; FACT-Br = The Functional Assessment of Cancer Therapy - Brain

Table 2

Patient-reported outcome measures used in clinical trials, the patient population in which the instruments were developed and validated, and the frequency of usage in clinical trials

Patient-reported outcome measures	Validated patient group	Number of items	Number of clinical trials which used this instrument
EORTC QLQ-BN20	Primary brain tumour	20	5
EORTC QLQ-C30	Cancer	30	4
EORTC QLQ-C15-PAL*	Cancer (palliative)	15	1
MDASI-BT	Primary brain tumour	28	2
FACT-Br	Primary brain tumour and brain metastasis	50	1

*The 15 Items in this PROM originate from the EORTC QLQ-C30

Results (cont')

The most common physical symptoms in patients with LMD are listed in Table 1. Ninety clinical trials were identified. The PROMs used in the clinical trials to assess the physical symptoms of LMD are listed in Table 2. None of the PROMs used have been validated in patients with LMD. Several physical symptoms arising from LMD were not captured by the PROMs used, especially symptoms related to cranial nerve and spinal involvement such as facial numbness, dysphagia, hearing loss, radicular pain and paresthesia.

Conclusion

Based on limited evidence, the currently used PROMs in clinical trials for patients with LMD do not cover all aspects that are relevant for this population. More research is needed to assess how these symptoms can be best captured, for example, by adapting an existing PROM or developing a new and specific one.

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