Importance of Capturing the Patient Experience of Overall Symptoms and HRQoL Impact in Patients With ALK+ NSCLC

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INTRODUCTION

- Non-small cell lung cancer (NSCLC) makes up ~85% of lung cancer cases,[1] and 3–5% of patients with NSCLC have oncogenic rearrangements in the anaplastic lymphoma kinase (*ALK*) gene (ALK+)[2-4]
- Available treatments include several ALK tyrosine kinase inhibitors (TKIs), including crizotinib, alectinib, ceritinib, brigatinib, and lorlatinib, with some showing health-related quality of life (HRQoL) benefits[5,6]
  - Brigatinib improved HRQoL compared with crizotinib in patients with ALK inhibitor–naive advanced ALK+ NSCLC[5, 7]
- HRQoL, including disease- and treatment-related symptoms and impacts, is a significant factor when making treatment decisions and is very important for the patient's treatment preference[8]
- However, there is limited qualitative research on HRQoL among patients with ALK+ NSCLC to help inform those treatment decisions

OBJECTIVE

- The aim of this study was to better understand the overall symptom experience and HRQoL impact from the perspective of patients with ALK+ NSCLC

METHODS

Oncologist Interviews

- Expert oncologists were interviewed to provide clinical perspective and guide patient interviews

Patient Interviews

- Patients were referred by a lung cancer patient organization or a recruitment vendor and screened for eligibility
- Inclusion criteria included:
  - Confirmed diagnosis of NSCLC with *EGFR* or *ALK* mutation
  - Having experienced symptoms of NSCLC within the past 30 days
  - Willingness to participate, to provide written informed consent, and to be audio recorded
- Patients were blinded to the pharmaceutical company
- Semi-structured qualitative interviews were conducted
- During interviews, patients described symptoms and HRQoL impacts experienced before and after treatment
- Data from interviews were used to develop an analysis grid
- A mean bothersome score on a scale of 0 (least bothersome) to 10 (most bothersome) was assessed for each symptom reported by most participants
- The study was approved by an independent review board before any patients were enrolled

RESULTS

Oncologist Interviews

- Six oncologists were interviewed and provided their clinical perspective regarding identified symptoms in patients with NSCLC, particularly: shortness of breath (100%), fatigue (100%), cough (83%), pain (67%), and hemoptysis (67%)
- In addition, oncologists stated that the most common disease impacts on patients were anxiety (50%), depression (50%), and confusion/bewilderment surrounding the diagnosis (50%)
  - Patients with ALK+ NSCLC tend to be younger and never smokers, contributing to patient's confusion/bewilderment surrounding the diagnosis

RESULTS (CONT'D)

Patient Interviews

- A total of 36 patients with NSCLC were interviewed, including 8 patients with ALK+ NSCLC

Table 1. Demographic and Baseline Characteristics

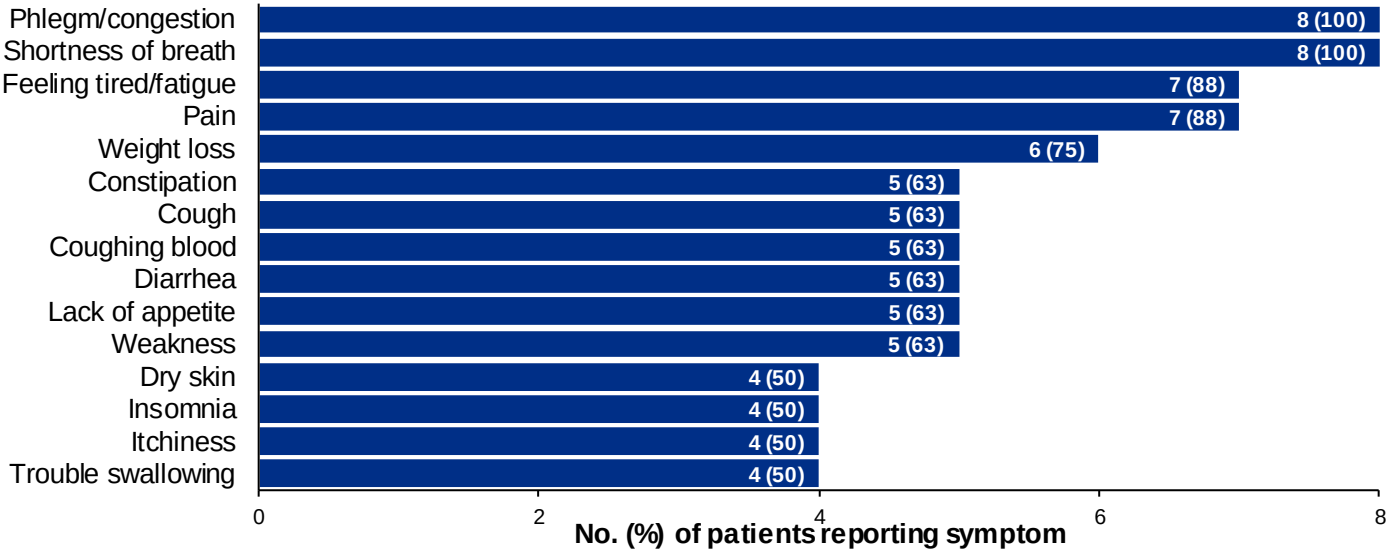
	Patients With ALK+ NSCLC (n=8)
Median age, y (range)	48.5 (28–53)
Female, n (%)	4 (50)
White, n (%)	8 (100)
Employment status, n (%)	
Full-/part-time employed	4 (50)
Disabled	3 (38)
Other	1 (13)
Disease duration in years, median (range)	2.8 (0–7)
Therapies received, n (%)	
Radiation	8 (100)
Chemotherapy	7 (88)
Targeted therapy[a]	5 (63)
Brain metastases, n (%)	5 (63)

[a] Targeted therapies included: lorlatinib and pembrolizumab (n=2 each); afatinib, alectinib, atezolizumab, brigatinib, carboplatin, ceritinib, cisplatin, and crizotinib (n=1 each)

RESULTS (CONT'D)

- The most common symptoms reported by patients with ALK+ NSCLC were phlegm/congestion, shortness of breath, feeling tired/fatigue, and pain

Figure 1. Symptoms Reported by ≥50% of Patients With ALK+ NSCLC (n=8)[a]



[a] Additional symptoms reported by 3 (38%) patients each were chest burning, rash, and tingling in hand or feet; symptoms reported by 1 (13%) patient each were abdominal pain, chest tightness, dizziness/lightheadedness/balance (not related to brain metastases), headaches (not related to brain metastases), petechiae, sore mouth or tongue, and wheezing

RESULTS (CONT'D)

- The symptoms that patients rated as the most bothersome (highest mean bothersomeness scores) were coughing up blood and shortness of breath

Table 2. Symptom Bothersomeness Reported by Patients With ALK+ NSCLC (n=8)

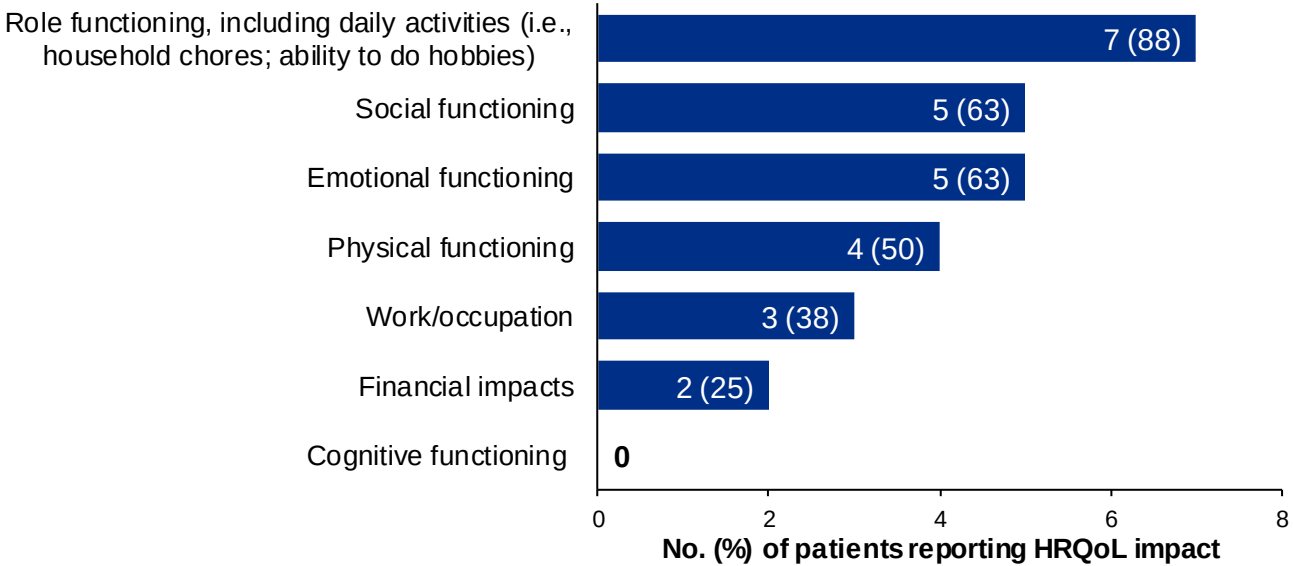
Symptom	No. of Patients Rating Symptom	Mean Bothersomeness Score[a]
Coughing up blood	2	10.0
Shortness of breath	8	8.3
Lack of appetite	3	7.7
Cough	5	7.5
Rash	2	7.0
Weight loss	4	6.5
Pain	6	6.4
Feeling tired/fatigue	7	6.1
Phlegm/congestion	8	4.7
Chest burning	2	3.0

[a] Symptoms reported by 1 patient each: tingling in hands or feet (bothersomeness score, 8.0); dry skin (5.0); diarrhea (4.0); and sores in mouth or tongue (2.0)

RESULTS (CONT'D)

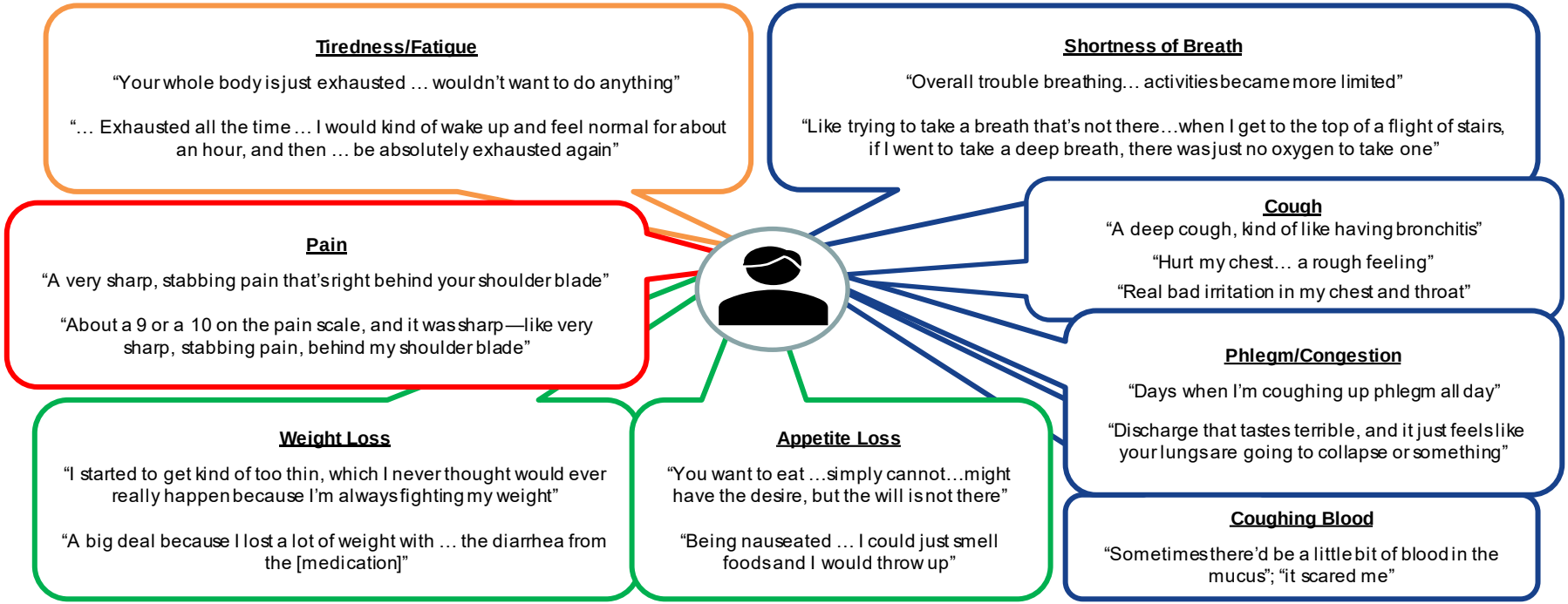
- Patients described experiencing negative HRQoL impacts on ability to function in daily activities, as well as social, emotional, and physical functioning

Figure 2. HRQoL Impacts Reported by Patients With ALK+ NSCLC (n=8)



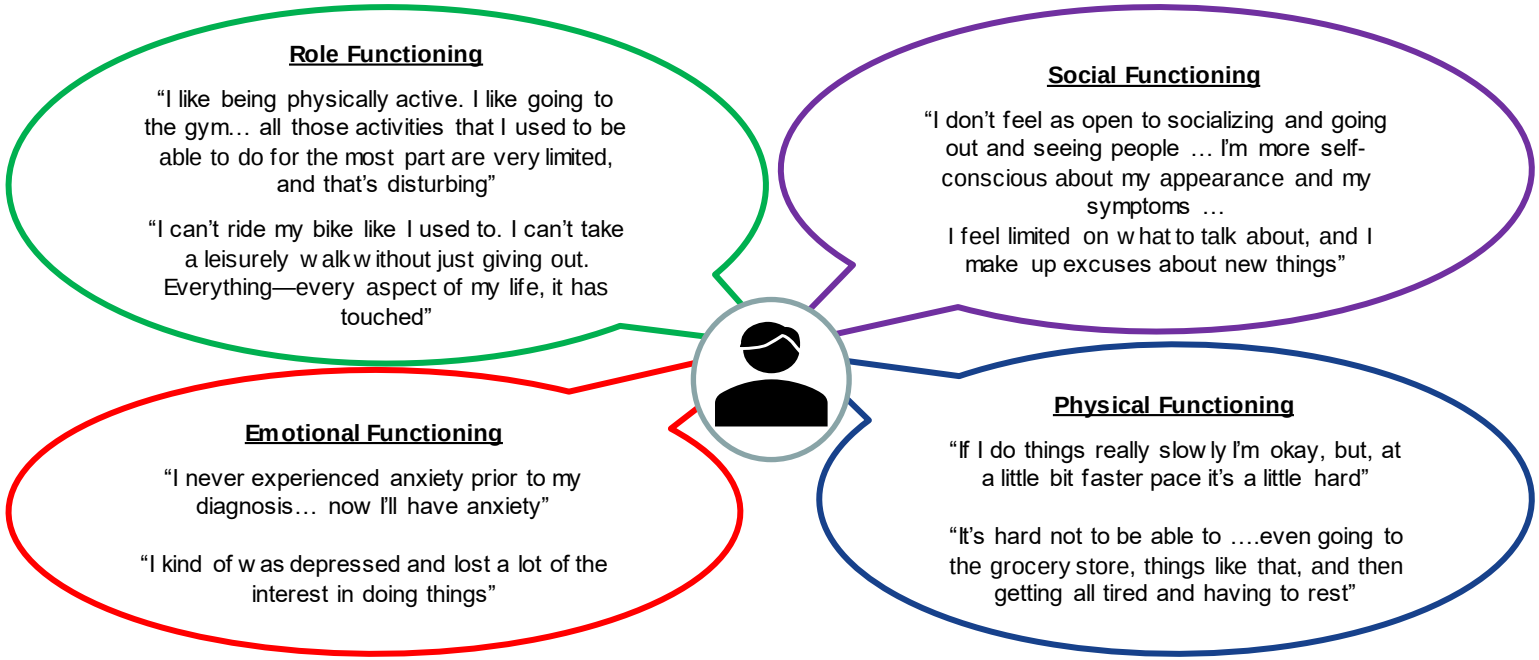
RESULTS (CONT'D)

Figure 3. Patient Quotes Regarding Symptoms



RESULTS (CONT'D)

Figure 4. Patient Quotes Regarding Impacts on Functioning



DISCUSSION

- The patient experience with the core symptoms of lung cancer (dyspnea, cough, and pain) among patients with NSCLC was similar across our sample, irrespective of mutation[9,10]
- This qualitative research also confirmed the selection of patient-reported outcome instruments to assess core concepts that best capture the patient experience of those with ALK+ NSCLC in a clinical trial setting, including a recent clinical trial of brigatinib versus crizotinib in first-line treatment of ALK+ NSCLC (ALTA-1L; NCT02737501)[5]
- In the ALTA-1L trial, patients taking brigatinib showed significant HRQoL benefits compared with those taking crizotinib in the most common symptoms or impacts reported in the current qualitative study, including[5]
  - Fatigue
  - Nausea and vomiting
  - Appetite loss
  - Constipation
  - Emotional and social functioning
  - Global health status/QoL

CONCLUSIONS

- Incorporation of the patient voice through direct patient engagement provided valuable in-depth insight about the patient experience in ALK+ NSCLC
- This qualitative research provides insights into unmet needs and patient goals for treatment, which may then be measured in clinical trials to demonstrate treatment benefit from the patient perspective
  - The most bothersome symptoms and functional burdens of ALK+ NSCLC identified by patients in this study were measured in clinical trials of brigatinib
- It is important to measure what matters most to patients to improve treatment decision-making

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ABBREVIATIONS

ALK, anaplastic lymphoma kinase; ALTA-1L, ALK in Lung Cancer Trial of BrigAtinib in 1st Line; *EGFR*, epidermal growth factor receptor gene; HRQoL, health-related quality of life; NSCLC, non-small cell lung cancer; TKI, tyrosine kinase inhibitor.

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DISCLOSURES

Author	Commercial Interest	Relationship
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