PATIENT REPORTED TOXICITIES: DEVELOPMENT AND VALIDATION OF PATIENT REPORTED SYMPTOM MEASURE FOR LUNG CANCER PATIENTS RECEIVING IMMUNOTHERAPY

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BACKGROUND

- There is increasing interest in patient-reported outcomes (PROs) which provide complementary information to provider-rated adverse events.
- While several studies have been published of PROs in lung cancer patients receiving immune checkpoint inhibitors, to our knowledge all have focused on PROs collected as part of a clinical trial.
- Clinical trial participants tend to be younger and healthier than patients who receive standard of care.
- The goal of this interim analysis is to describe patient-reported toxicities and quality of life **outside the context of a clinical trial** in lung cancer patients treated with immune checkpoint inhibitors.
- The study will validate a PRO questionnaire for patients treated with immunotherapy. At the conclusion of the study, our measure will be validated and ready to use in future clinical trials and other research on immunotherapy.

METHODS

- The Addario Lung Cancer Foundation (ALCF) international patient registry was used to collect patient-reported clinical information.
- Eligibility:
  - English-speaking
  - Reported current or past treatment with an FDA-approved immune checkpoint inhibitor
- Patient-Reported Measures:
  - Sociodemographic and clinical characteristics: age, gender, race, country of origin, type of immunotherapy, time on treatment, treatment delay, ER visit, hospitalization, Charlson Comorbidity Index

METHODS (CONT'D)

- Patient-Reported Measures (cont'd):
  - Side effects: An item bank was previously generated from interviews with 9 oncology providers, 14 patients receiving an immune checkpoint inhibitor, and 7 informal family caregivers. Patients rated 40 side effects on a five-point scale (0=none, 4=very much).
  - Quality of life: The Functional Assessment of Cancer Therapy General (FACT-G) total score was used; higher scores indicate better quality of life.

RESULTS

- Participants (n=197)
  - Mean age: 59 years (range: 28-91)
  - 135 (69%) female
  - 168 (85%) Caucasian
  - 173 (88%) from North America
  - 95 (48%) on an immune checkpoint inhibitor $\leq$ 6 months
  - 101 (51%) treated with nivolumab, 72 (37%) with pembrolizumab, 3 (2%) with both

Table 1. Frequency of Patient-Reported Side Effects: n (%)

Side Effect	Any Severity	Moderate to Severe
Fatigue	130 (66%)	84 (43%)
Aching joints	78 (40%)	46 (23%)
Insomnia	68 (35%)	30 (15%)
Aching muscles	63 (32%)	34 (17%)
Back pain	50 (25%)	21 (11%)
Shortness of Breath	50 (25%)	26 (13%)
Skin dryness	50 (25%)	29 (15%)
Change in the way food tastes	49 (25%)	32 (16%)
Itching	48 (24%)	27 (14%)
Bone pain	44 (22%)	22 (11%)
Cough (new or worsening)	44 (22%)	24 (12%)
Diarrhea	44 (22%)	27 (14%)
Loss of appetite	44 (22%)	26 (13%)
Numbness or tingling in hands or feet	43 (22%)	20 (10%)
Feeling bloated	42 (21%)	27 (14%)
Constipation	41 (21%)	23 (12%)
Headache	40 (20%)	15 (8%)
Increased skin sensitivity	38 (19%)	17 (9%)
Problems with concentration	37 (19%)	16 (8%)
Frequent urination	35 (18%)	20 (10%)

RESULTS (CONT'D)

Table 1. Frequency of Patient-Reported Side Effects: n (%) (cont'd)

Side Effect	Any Severity	Moderate to Severe
Problems with memory	35 (18%)	17 (9%)
Reflux or heartburn	34 (17%)	20 (10%)
Rash	33 (17%)	25 (13%)
Nausea	32 (16%)	22 (11%)
Hives	31 (16%)	17 (9%)
Abdominal pain	30 (15%)	13 (7%)
Problems with balance or coordination	28 (14%)	13 (7%)
Weakness in arms or legs	28 (14%)	14 (7%)
Wheezing	26 (13%)	18 (9%)
Blurred Vision	24 (12%)	7 (4%)
Dizziness	24 (12%)	8 (4%)
Easy bruising or bleeding	24 (12%)	5 (3%)
Chest pain	22 (11%)	8 (4%)
Arm or leg swelling	20 (10%)	11 (6%)
Shivering or shaking chills	18 (9%)	10 (5%)
Mouth sores	15 (8%)	8 (4%)
Swelling in the face	12 (6%)	3 (2%)
Vomiting	9 (5%)	8 (4%)
Blood in stool	4 (2%)	3 (2%)
Vitiligo	3 (2%)	2 (1%)

- Due to immune-related toxicity:
  - 101 (55%) of patients took medication to treat side effects
  - 41 (22%) of patients experienced a treatment delay
  - 24 (13%) of patients went to the ER
  - 17 (9%) of patients had been hospitalized
- Mean FACT-G total score was 71.07 (SD=17.81), lower than previously-published normative data for cancer patients[1]

CONCLUSIONS

- This study is among the first to evaluate patient-reported toxicities of immune checkpoint inhibitors outside the context of a clinical trial.
- Results indicate that patient-reported toxicities of immune checkpoint inhibitors are common in lung cancer patients.
- This research will result in a final set of items reflective of common patient-reported toxicities in patients receiving immunotherapy and assess the reliability and validity of the measure for use in future research.
- Additional research is needed to understand the longitudinal course of symptomatic toxicities.

[1]Pearman et al. Cancer. 2014; 120: 2902-2909