

# PATIENT-REPORTED DISTRESS WITH IMMUNOTHERAPY-BASED FIRST-LINE TREATMENT FOR MNSCLC: A REAL-WORLD EVIDENCE STUDY

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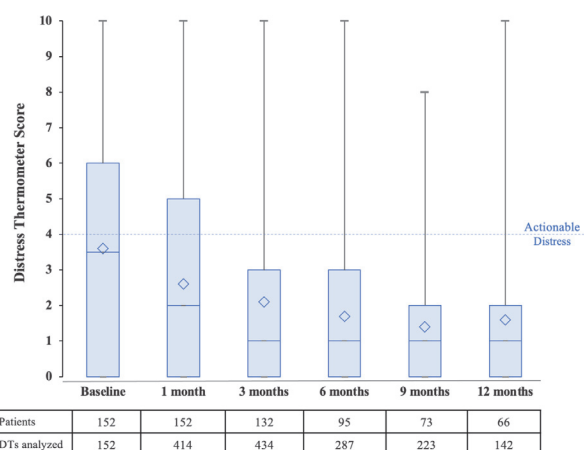
**Background** There are limited published real-world data about patient-reported outcomes with immunotherapies (IO) in metastatic non-small cell lung cancer (mNSCLC). We describe the patient experience with first-line IO-based treatments vs. chemotherapy in this setting.

**Methods** We conducted a retrospective chart review of adult patients with mNSCLC treated at Duke University from March 2015-June 2020. At each visit, patients self-reported their distress level and sources of distress using the NCCN Distress Thermometer (DT) tool, consisting of an 11-point ordinal scale reporting overall distress and a 39-item Problem List (PL). We abstracted demographic, clinical, distress, response data (by investigator assessment), then analyzed these data using descriptive statistics and generalized estimating equations accounting for clustering of clinic visits within participants and generalized linear models accounting for study exposure time.

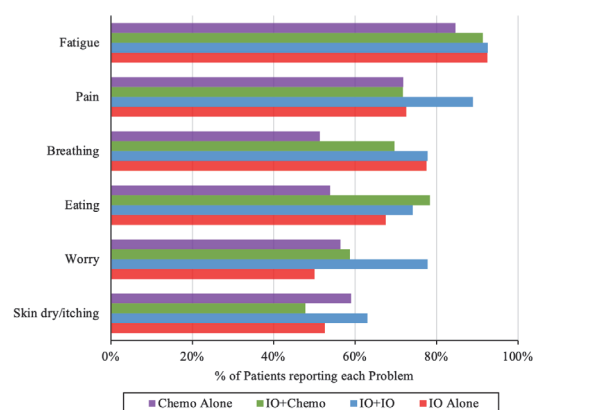
**Results** 152 patients were analyzed in four groups: single agent immunotherapy (IO alone, n=40), dual immunotherapy (IO+IO, n=27), chemo-immunotherapy (IO+Chemo, n=46), and chemotherapy alone (n=39). Patients were followed for up to 1 year or earliest of: death, last contact, or 2nd line therapy start. Participants' mean age was 65.7 years. In all patients, overall distress was worst before treatment start (figure 1), and the odds of actionable distress (DT score >4) decreased over time by 10% per month (OR=0.901, 95% CI:0.813, 0.998, p=0.045). There were no significant differences in actionable distress across treatment groups. Symptom distress remained high over time, while other sources of distress (practical, family, and emotional) decreased. The most frequent sources of symptom distress were fatigue (90% of patients ever reported, 40% of all DTs), pain (75% of patients, 30% of DTs), and breathing (68% of patients, 22% of DTs) (figure 2). Treatment with chemotherapy alone yielded the fewest tumor responses (50%) and lowest clinical benefit rate (74.4%) compared to any IO therapy. Unplanned healthcare utilization was significantly different across treatment groups; IO+IO resulted in the lowest utilization rate (0.57, 95% CI:0.36, 0.90), while chemotherapy yielded the highest (1.46, 95% CI:1.00,2.12). Palliative care was utilized in 40% of patients; among those with actionable distress at any time (n=113; 74%), 53% (n=60) had a palliative care visit.

**Conclusions** This single-center, real-world evidence study demonstrates that patients with mNSCLC experience significant distress prior to starting first-line treatment, with persistent symptom distress over time. Furthermore, IO treatment is associated with reduced healthcare utilization compared to chemotherapy. Increased utilization of integrated palliative care services may improve the patient experience of mNSCLC treatment, especially for management of symptom distress.

**Ethics Approval** This clinical study involves retrospective analyses of data extracted from medical charts and was approved by Duke University School of Medicine Institutional Review Board (IRB#106013).



Abstract 636 Figure 1 Overall distress thermometer scores over time



Abstract 636 Figure 2 Most frequently reported problems by treatment type

**Consent** As there was no prospective enrollment of subjects, consent was obtained through a Waiver or Alteration of Consent and Authorization and Decedent Research Notification of the Health Insurance Portability and Accountability Act (HIPAA) 1996.

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