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LIPI and outcomes of durvalumab as consolidation therapy after ChRT in patients with locally-advanced NSCLC

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Introduction: The lung immune prognostic index (LIPI), which combines pretreatment derived neutrophils/[leukocytes minus neutrophils] ratio (dNLR) >3 and lactate dehydrogenase (LDH) > upper limit of normal (ULN), is associated with outcomes in advanced non-small cell lung cancer (NSCLC) patients treated with immune checkpoint inhibitors (ICI). We aimed to assess whether pretreatment LIPI correlates with durvalumab efficacy after concurrent chemoradiotherapy in the locally advanced setting. **Methods:** Multicenter retrospective study of locally advanced NSCLC patients treated with durvalumab consolidation in 21 European/US centers from 12/2015 to 5/2020. Clinical and biological data were collected before durvalumab treatment. PD-L1 expression by immunohistochemistry was also collected at diagnosis. LIPI was calculated according to previous reports and three groups were characterized: good (dNLR≤3+LDH≤ULN), intermediate (dNLR>3 or LDH>ULN) and poor (dNLR>3+LDH>ULN). The primary endpoint was progression-free survival (PFS). Response was assessed according to the clinical routine of each center. **Results:** A total of 267 patients were enrolled. One hundred eighty-five (69%) patients were male, 252 (94%) smokers, with median age of 67 [range 59-73] and 223 (98%) with Eastern Cooperative Oncology Group (ECOG) performance status (PS) ≤1. 260/266 (98%) were stage III, of which 96 were IIIA, 127 stage IIIB and 37 stage IIIC. 163 (63%) had non-squamous histology and 12/131 (27%) harbored driver alterations: 5 *EGFR*, 4 *BRAF*, 3 *MET*, 2 *ALK*; missing in 136 cases. PD-L1 was ≥1% in 191/233 (82%) patients both from Europe and US, missing in 34 cases. LIPI was evaluable in 143 patients: 90 were considered good (63%), 50 intermediate (35%) and 3 (2%) as poor LIPI group. dNLR >3 was found in 47/218 (22%) and LDH > ULN in 23/143 (16%) cases. Radiotherapy was delivered concurrent in 219 (82%) of cases. No differences in clinical characteristics were found between 3 LIPI groups, including the response to previous chemoradiotherapy. With a median follow-up of 13.4 months [95% confidence interval (CI), 12-15], the median PFS was 20 months [95% CI, 12.7-not reached (NR)]. Median PFS was 7.5 months [95% CI, 3.1-NR] for poor group vs. 10.7 months [95% CI, 5.1-NR] for intermediate group vs. 19.1 months [95% CI, 11.6-NR] for good LIPI group (P=0.020). Median overall survival (OS) was NR [95% CI 47-NR] in the entire cohort and therefore considered not mature. The first objective response rate under durvalumab was 44% (111/251), being 36% (18/50) for the intermediate-poor group and 38% (33/87) for the good group with no significant differences (P=0.099). No differences in PFS and OS between groups were found regarding PD-L1 status (P=0.5 and P=0.4, respectively). **Conclusion:** Pretreatment LIPI is associated with clinical outcomes in locally advanced patients treated with durvalumab as consolidation after chemoradiotherapy. This cohort is still ongoing to confirm our preliminary findings in a larger cohort. **Keywords:** lung immune prognostic index (LIPI), locally advanced NSCLC, Durvalumab

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High Concordance in Scoring PD-L1 in NSCLC Using the Roche Digital Pathology uPath system and PD-L1 Assessment Algorithm

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Introduction: Accurate and reproducible assessment of PD-L1 expression is crucial in guiding the use of anti PD-1/PD-L1 immunomodulatory therapy. Interpretation can be challenging and both intra- and inter-pathologist discordance has been shown to be potentially significant in affecting clinical outcomes. Digital pathology and algorithmic assessment tools provide an opportunity to increase accuracy and concordance when making this important assessment in non-small cell lung cancer (NSCLC). **Methods:** Sections of 198 NSCLCs, (84 EBUS aspirates or small tissue biopsies and 114 resections) immunolabelled for PD-L1 using the Roche-Ventana SP263 antibody were scanned with a Roche DP200 digital image scanner and analysed using uPath slide viewer and the Roche PD-L1 interpretative algorithm. Sections were assessed by three 'blinded' pathologists for expression of PD-L1 which was given as an absolute percentage, *the tumour proportion score (TPS)* in four ways; (1) *unassisted* (by pathologist using conventional microscopy), (2) *automated whole slide* (unsupervised uPath assessment of whole slide), (3) *automated annotated* (uPath assessment of slide annotated by pathologist) and (4) *assisted* (by pathologist using digital image assisted by uPath assessment of annotated slide). The last method of assessment was repeated after a six-week 'washout' period. Intraclass correlation co-efficient (ICC) and Cohen's Kappa (for clinical categories of <1%, 1-49% or ≥50% TPS)

Table 1. Comparison of TPS scoring methods

TPS assessment methods - Full Cohort	ICC	Kappa	p-value
Assisted vs unassisted	0.973	0.856	<0.0001
Assisted vs automated whole slide	0.911	0.475	<0.0001
Assisted vs automated annotated	0.953	0.598	<0.0001
TPS assessment methods - small biopsies/EBUS only			
Assisted vs automated annotated	0.952	0.836	<0.0001