P1.16-02
Support and Information Needs for Patients with NSCLC Receiving Concurrent Chemo-Radiotherapy: Findings from the INSIGHT Study

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Background: The curative intent pathway for patients with non-small cell lung cancer (NSCLC) is complex and burdensome. Concurrent chemotherapy and radiotherapy (chemo-radiotherapy) is used as first line treatment for inoperable stage 3 cancer,and requires the patient to attend multiple investigational procedures, separate appointments for chemotherapy and radiotherapy, intensive monitoring during treatment and multiple follow-up visits post treatment for up to 5 years to monitor late-toxicities and disease recurrence. The aims of this study are to identify the information needs of patients and their carers at key points along the treatment pathway and the preferred methods for information provision. A grant was awarded by the NLCFN to fund this patient experience, qualitative research study. **Method:** Semi-structured interviews were conducted with 15 patients, and their carer dyads where appropriate, recruited from a cancer centre in Manchester, U.K. **Result:** Data collection is now complete with 15 patients recruited, of whom 6 were interviewed with a carer dyad. Thematic analysis is on-going and has been employed inductively to identify some of the emerging themes and key issues from the data collected. These include; preferred means of receiving information and level of information given, burden of treatment and earlier access to supportive care, information about life after treatment and the after effects of treatment, and preferred methods to access appropriate support. **Conclusion:** Further research is needed into the on-going needs of this patient cohort and data collection so far highlights areas for consideration when providing information to this patient cohort. Emerging themes highlight that a specific booklet on concurrent chemo/radiotherapy would be preferred, covering all aspects of treatment, including a personalised treatment plan to include, where relevant mask wearing, the impact of side effects of treatment and how assess support. Early indications are that patients prefer a combination of verbal, written and visual information giving. Collaboration work to link these patients on the concurrent treatment pathway in with early supportive care is optimal. Implementation of this service as part of the Concurrent treatment pathway will commence as a pilot study in July 2018, to assess the impact of earlier intervention to manage disease burden and treatment side effects, with an aim to reduce hospital admissions. The evidence suggests further work is needed to improve information giving and support to these patients both pre and post treatment. Additional advice is required to support proactive management, to enhance recovery, whilst addressing the fear and anxiety patients and carers experience due to uncertain outcomes. **Keywords:** patient, Experience, treatment

P1.16-03
Prognostic Significance of PD-L1 in Stage II/III Non-Small Cell Lung Cancer

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Background: Prognostic significance of PD-1/PD-L1 axis expression in non-small cell lung cancer (NSCLC) remains uncertain despite being a predictive biomarker for novel immunotherapeutics. In this study, we have investigated PD-1/PD-L1 expression and its effect on disease prognosis and overall survival in stage II-III NSCLC patients. **Method:** Clinic and pathologic features of stage II and stage III NSCLC patients were retrospectively analyzed from patients' records in this study. PD-1 and PD-L1 immunohistochemistry staining were carried out to archived tumor specimens of the eligible patients. Percentages of PD-1 positive lymphocytes, PD-L1 positive tumor cells and PD-L1 positive tumor infiltrating immune cells were evaluated and considered as positive if $\geq$1% of the cells displayed staining. **Result:** Sixty-six male (89,2%) and 8 female (10,8%) of total 74 patients were eligible for the study. Thirty-three (44,6%) patients were diagnosed as stage II disease while 41 patients (55,6%) were diagnosed as stage III. PD-1 expression, PD-L1 expression in tumor cells and PD-L1 expression in tumor infiltrating immune cells were positive in 83,8% (n = 62), 45,9% (n = 34), 67,6% (n = 50) of total 74 patients, respectively. Three-year overall survival (OS) rate was calculated as 57,7%. Univariate analyses did not reveal any significant difference in 3-years OS between those with PD-1 and PD-L1 expression in tumor infiltrating immune cells and those without expression. (p = 0,413 and p = 0,099; respectively) However, 3-years OS was more favorable in those with PD-L1 expression in tumor cells than in those without PD-L1 expression (76,6% vs %41%, p = 0.031). In multivariate analyses, a positive trend was revealed in 3-years OS between those with PD-L1 expression in tumor cells and those without expression. (HR: 0,405; 95% CI: 0,153, 1,074; p = 0,069) **Conclusion:** In this study, better prognosis was obtained with positivity of PD-L1 in tumor cells. Therefore, it should be taking into consideration while designing adjuvant immunotherapy trials which are generally formed with stage I-III NSCLC patients, that expression of PD-1/PD-L1 pathway may have a positive prognostic effect.

P1.16-04
Outcomes of Patients <70 or ≥70 Years of Age in PACIFIC

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Background: In the Phase 3 PACIFIC study of durvalumab versus placebo in patients with stage III, unresectable NSCLC without progression after concurrent chemoradiotherapy (cCRT), the co-primary endpoint PFS was significantly longer with durvalumab (stratified HR 0.52, 95% CI, 0.42−0.65; P<0.0001). In a prespecified analysis, PFS benefit with durvalumab was observed regardless of a 65-year age cutoff. However, median age at NSCLC diagnosis is 70 (CA Cancer J Clin, 2014). We therefore performed subgroup analyses to explore outcomes using a 70-year age cutoff. **Method:** PACIFIC (NCT02125461) was a Phase 3, randomized, double-blind, all-comers study of patients with WHO PS 0/1 who did not progress following ≥2 cycles of platinum-based cCRT. Patients were stratified by age, sex, and smoking history and randomized (2:1) 1−42 days after cCRT to receive durvalumab 10 mg/kg IV Q2W or placebo up to 12 months. Co-primary endpoints were PFS (BICR, RECIST v1.1) and OS (not available). Secondary endpoints included ORR, time to death/distant metastasis (TTDM), and safety.

Between-treatment endpoint comparisons were performed for patients <70 and ≥70 years. **Result:** As of Feb 13, 2017, 713 patients were randomized; 78% and 22% were <70 and ≥70 years, respectively. Baseline patient and tumor characteristics were generally well balanced across subgroups. However, patients ≥70 were more likely to be male, have PS 1, and, within the placebo arm, to be Asian. Older patients more commonly received carboplatin-based CT than younger patients. Durvalumab demonstrated PFS benefit compared with placebo, regardless if patients were <70 years (median 16.9 vs 5.6 months, HR=0.53, 95% CI: 0.42−0.67) or ≥70 years (median 12.3 vs 6.1 months, HR=0.62, 95% CI: 0.41−0.95). Durvalumab improved TTDM (<70 years: HR=0.53, 95% CI: 0.39−0.71; ≥70 years: HR=0.66, 95% CI: 0.39−1.13) and ORR (<70 years: 27.6% vs 15.4%; ≥70 years: 31.9% vs 17.6%) regardless of age. Younger patients on durvalumab received treatment longer (median total duration 45.5 vs 36.0 weeks). Regardless of treatment, older patients discontinued more due to AEs (durvalumab: 22.0% vs 13.7%; placebo: 16.1% vs 7.8%) and had more grade 5 AEs (durvalumab: 10.9% vs 2.7%; placebo: 9.1% vs. 4.5%). Among patients receiving durvalumab, older patients experienced more all-cause SAEs (42.6% vs 24.9%) and grade 3/4 AEs (41.6% vs 29.4%) but fewer AESIs (56.4% vs 67.9%) than younger patients. **Conclusion:** Patients achieved clinical benefit with durvalumab regardless of age. Increased AEs/SAEs observed in older patients across treatments may reflect age/cCRT related morbidity. **Keywords:** elderly, PACIFIC, durvalumab

P1.16-05
Effect of Induction Chemotherapy in the PACIFIC Study

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Background: The Phase 3 PACIFIC study of patients with stage III, unresectable NSCLC without progression after concurrent chemoradiotherapy (cCRT) demonstrated significantly longer PFS with durvalumab versus placebo (stratified HR 0.52; 95% CI 0.42−0.65; P<0.0001). Overall, 26% and 29% in the durvalumab and placebo groups, respectively, received induction chemotherapy (ICT) before cCRT. Here, we report exploratory analyses of baseline characteristics, disposition, and outcomes from this study based on the presence or absence of prior ICT. **Method:** PACIFIC (NCT02125461) was a Phase 3, randomized, double-blind study of patients with WHO PS 0/1 and any tumor PD-L1 status without progression after ≥2 cycles of platinum-based cCRT. Patients were stratified by age, sex and smoking history and randomized (2:1) to durvalumab 10 mg/kg IV Q2W or placebo up to 12 months. Co-primary endpoints were PFS (blinded independent central review, RECIST v1.1) and overall survival (not available). We investigated associations between the presence/absence of ICT and disposition, baseline characteristics, and efficacy and safety endpoints. **Result:** As of February 13, 2017, 713 patients were randomized; 27% had prior ICT. Baseline characteristics were similar between treatment arms; however, patients with ICT were generally younger, less frequently Asian, had lower incidence of squamous histology, and more often had stage IIIB disease. There were no differences between groups in terms of prior RT dose. PFS benefit with durvalumab was demonstrated irrespective of ICT use (ICT: HR=0.61, 95% CI, 0.41−0.88; no ICT: HR=0.54, 95% CI, 0.42−0.69). Similarly, ORR with durvalumab was numerically higher than with placebo irrespective of ICT use (ICT: 16.1% vs 13.1%; no ICT: 32.9% vs 17.1%). ICT did not affect treatment duration for durvalumab or placebo. Between-treatment safety differences were minimal across subgroups; however, patients with ICT experienced fewer SAEs, treatment-related SAEs and pneumonitis/radiation pneumonitis regardless of treatment arm. **Conclusion:** Durvalumab demonstrated clinical benefit irrespective of ICT. The safety profile of durvalumab was consistent in patients with or without ICT. A lower rate of toxicity was observed in patients with ICT regardless of treatment arm. **Keywords:** induction chemotherapy, PACIFIC, durvalumab

P1.16-06
Expanded Efficacy and Safety Analysis of PACIFIC Based on a PD-L1 Cutpoint of 25%

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Background: In the Phase 3 PACIFIC study of patients with stage III, unresectable NSCLC without progression after concurrent chemoradiotherapy (cCRT), PFS was significantly longer with durvalumab versus placebo (stratified HR 0.52; 95% CI 0.42−0.65; P<0.0001). We report exploratory analyses of PACIFIC outcomes by PD-L1 expression assessed in tumor samples collected prior to cCRT. **Method:** PACIFIC (NCT02125461) was a Phase 3, randomized, double-blind study of patients with WHO PS 0/1 without progression after ≥2 cycles of platinum-based cCRT. Eligibility was irrespective of PD-L1 expression; archived samples were optional for testing (VENTANA PD-L1 [SP263] assay). No samples were obtained after cCRT, prior to infusion with durvalumab or placebo. Patients were randomized (2:1) to durvalumab 10 mg/kg IV Q2W or placebo up to 12 months, stratified by age, sex and smoking history. Co-primary endpoints were PFS (blinded independent central review, RECIST v1.1) and OS (not available). Secondary endpoints included ORR and safety. We investigated associations between subgroups of patients with PD-L1 expression on tumor cells (TC) of <25% or ≥25% and efficacy. **Result:** As of February 13, 2017, 713 patients were randomized; 451 (63.3%) had known PD-L1 status (TC<25%, 64.7%; TC≥25%, 35.3%; **Table**). Baseline characteristics and prior therapy (including best response to prior therapy) were generally well balanced between arms across both PD-L1 subgroups. PFS benefit with durvalumab was demonstrated irrespective of PD-L1 status (HR 0.59; 95% CI, 0.43−0.82 for TC<25% and HR 0.41; 95% CI, 0.26−0.65 for TC≥25%) (**Table**). ORR was greater with durvalumab compared to placebo regardless of PD-L1 status (**Table**). The overall safety profile of durvalumab in each PD-L1 subgroup was consistent with the ITT population treated with durvalumab.