The efficacy of durvalumab in locally advanced lung carcinoma

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SUMMARY

Background: *The integration of durvalumab, an immune checkpoint inhibitor, as consolidation therapy following platinum-based chemoradiotherapy has redefined the standard of care for patients with stage III, unresectable non-small cell lung cancer (NSCLC) who have not experienced disease progression. Although clinical trials, particularly the PACIFIC study, demonstrated significant improvements in survival outcomes, real-world data are still needed to validate these findings in routine clinical settings. This retrospective study aimed to evaluate the real-world efficacy of durvalumab in patients treated at the Institute for Pulmonary Diseases of Vojvodina, focusing on key clinical endpoints, progression-free survival (PFS), duration of clinical benefit (DoCB), and overall response rate (ORR), while exploring the influence of demographic and tumor-related factors.*

Methods: *The study included 25 patients with stage III NSCLC, ECOG 0–1, and PDL-1 expression ≥1%, who received durvalumab after chemoradiotherapy. The treatment responses were evaluated using iRECIST criteria. The Kaplan-Meier analysis was used for survival metrics, and univariate Cox regression assessed the impact of histology, smoking status, PDL-1 expression, gender, and ECOG status.*

Results: *A partial response was achieved in 36% of the patients, stable disease in 40%, and progression in 24%, with an ORR of 36%. The mean PFS was 19.8 months, and DoCB 25 months. Although the adenocarcinoma subtype, female gender, lower pack-year index, and higher PDL-1 expression suggested more favorable outcomes, no statistically significant differences were found.*

Conclusion: *These findings confirm the clinical benefit of durvalumab consolidation in real-world practice, with outcomes comparable to pivotal trials. Despite the small sample size, the observed trends highlight potentially relevant prognostic markers. Expanding the patient cohort and extending the follow-up will further clarify these associations and support the evidence-based personalization of the NSCLC treatment.*

Keywords: *NSCLC; durvalumab; immunotherapy; real-world data; consolidation therapy; stage III lung cancer*

INTRODUCTION

Lung cancer is the second most common malignancy and the leading cause of cancer-related death globally and in Serbia (1–3). Around 2 million new cases are diagnosed annually, with non-small cell lung cancer (NSCLC) accounting for over 85% of all cases (4–8). Approximately 25–30% of NSCLC patients are diagnosed at stage III (9–11). For years, the standard treatment for unresectable, locally advanced NSCLC was platinum-based chemotherapy followed by radiotherapy (1,3,12,13). Still, this approach achieved limited long-term success, with 5-year survival rates of only 15–30% and frequent disease progression (7,14–16). Modifying this approach through continued chemotherapy, alternative systemic treatments, or higher radiation doses did not significantly improve the outcomes (15).

A major advancement came with the introduction of immunotherapy, particularly durvalumab (1). This immune checkpoint inhibitor is a monoclonal IgG1 antibody that binds to PD-L1 on tumor cells, blocking its interaction with PD-1 on T lymphocytes and enabling the immune system to recognize and eliminate cancer cells (7,17–20). The PACIFIC phase III trial demonstrated significantly improved overall survival and progression-free survival (PFS) with durvalumab compared to the placebo, establishing it as the standard of care for unresectable stage III NSCLC after chemoradiotherapy in non-progressing patients (9,11,15,21).

Based on these findings, we conducted a retrospective study to assess the real-world effectiveness of durvalumab at our institution. We aimed to evaluate its efficacy through clinical parameters such as PFS, the duration of clinical benefit (DoCB), and overall response rate (ORR), while also analyzing patient demographics, tumor characteristics, and prior therapies to explore their potential influence on treatment outcomes.

MATERIALS AND METHODS

Study Design and Participants

The study was carried out at the Department for Pulmonary Oncology of the Institute for Pulmonary Diseases of Vojvodina (IPDV) between December 2024 and February 2025. It was a retrospective, cross-sectional study using data from the hospital's electronic records, with January 18, 2025, as the cut-off date. Since durvalumab was approved in Serbia in 2022, all 28 patients who had received it at our center were included in the study. Full data were available for 25 of them, those who started durvalumab as consolidation therapy between May 19, 2022, and August 20, 2024. The inclusion criteria for the study were: patients over 18 years of age with ECOG (Eastern Cooperative Oncology Group) status 0 or 1, a histologically or cytologically confirmed diagnosis of non-resectable NSCLC (according to the eighth edition of the AJCC TNM classification), and completion of chemotherapy based on platinum agents and radiotherapy at a dose of at least 54 Gy in the first-line treatment. The additional inclu-

sion criteria included no progression of the primary disease after the first-line therapy, confirmed by control CT scans based on RECIST 1.1 criteria, and a PDL-1 tumor expression of 1% or higher. The exclusion criteria included histologically or cytologically confirmed small cell lung cancer, mixed small cell and non-small cell lung cancer, or metastasis from extrathoracic primary tumors, incomplete first-line chemotherapy, or a total radiation dose lower than 54Gy, ECOG status of 2 or higher, active or previous autoimmune disease, documented primary immunodeficiency, and PDL-1 expression less than 1%.

Durvalumab Therapy

Durvalumab was administered as an intravenous infusion of 1500 mg in 250 mL of saline over 60 minutes, once every 28 days. While 12 cycles were recommended, the treatment was stopped early if the disease progressed or side effects became too severe.

We evaluated the treatment response using iRECIST criteria, which involve selecting the largest tumors (up to two per organ, five in total) as target lesions. CT scans taken after chemoradiotherapy and before starting durvalumab served as the baseline. Follow-up scans were done after every four cycles to assess the response, which was categorized as a complete response (iCR), partial response (iPR), stable disease (iSD), or disease progression (iPD), based on the last version of iRECIST criteria (22,23). For this study, we recorded only the best response observed during the treatment.

Collected Data and Therapy Efficacy Parameters

Data were gathered from the Institute's health records, including basic patient information such as age, gender, place of residence, smoking history (as pack-years index), and ECOG performance status. Tumor characteristics, including the date of diagnosis, cancer stage, histology, and PDL-1 expression, were also examined. The details about the previous treatments were included as well, specifically the type and number of chemotherapy cycles, total radiation dose, end date of radiation, time to initiation of durvalumab, and best response to immunotherapy.

Based on this information, the effectiveness of durvalumab was evaluated using three main measures: progression-free survival (PFS), the overall response rate (ORR), and duration of clinical benefit (DoCB). PFS was defined as the time from durvalumab initiation until cancer progression or death. ORR represented the proportion of the patients who achieved either a complete or partial response to treatment. DoCB was measured as the time during which patients continued to benefit from therapy, either through stable disease or an initial response, before progression or death.

Ethical Considerations

The study was conducted with the approval of the Professional Council and the Ethics Committee.

Statistical Analysis

Statistical analysis was performed using JAMOVI version 2.6.19. Initial descriptive statistics included patient data, tumor characteristics, first-line chemoradiotherapy, and durvalumab immunotherapy. All values are expressed as mean±SD, median, or percentage.

PFS was evaluated using the Kaplan-Meier method, and the results were presented graphically and numerically as the proportion of progression-free patients over time. For PFS evaluation, all patients were considered, and patients without disease progression or death by the data extraction date were censored. Similarly, DoCB was evaluated using the same method, and patients who experienced disease progression during immunotherapy were excluded. Patients who did not experience disease progression after SD, PR, or CR were censored.

ORR was simply calculated as the percentage of the patients who responded completely or partially to durvalumab therapy.

During the statistical analysis, several variables (histological tumor type, sex, smoking status, PDL-1 expression level, and ECOG status) were selected for grouping patients. Using the log-rank test and univariate Cox regression, the impact of these variables on PFS and DoCB was determined, and any statistically significant differences in PFS and DoCB between the groups were assessed. For each factor, HR (hazard ratio), CI (confidence interval), and p values were determined, with $p<0.05$ considered statistically significant.

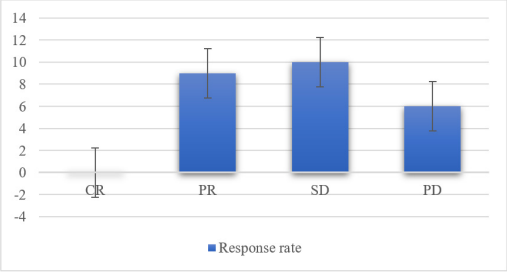
RESULTS

A total of 25 patients were included in the study, with an average age of 67.4±6.49 years (the youngest patient was 51, and the oldest was 79 years old, median=66 years). Of these, 60% of the patients (n=15) were male, and 40% (n=10) were female. The majority of the patients (76%, n=19) had an ECOG status of 0, while only 24% (n=6) had an ECOG status of 1. All patients included in the study were smokers, with an average pack-year index of 31.7±14.9.

Regarding the disease characteristics, we found that 36% (n=9) of the patients were diagnosed in stage IIIA, 48% (n=12) in stage IIIB, and 16% (n=4) in stage IIIC. Most (68%, n=17) had a confirmed diagnosis of squamous cell carcinoma, 24% of the patients (n=6) were diagnosed with adenocarcinoma, while the histological type of the tumor could not be determined in 8% of the patients (n=2). Before starting durvalumab therapy, the percentage of PDL-1 protein expressed in each patient's tumor was determined, with an average PDL-1 expression value of 37.6±35.1% (the minimum expression was 1%, and the maximum was 100%). The average sum of the diameters of target lesions after completing the first-line chemoradiotherapy, referred to as the baseline, was 51.8±21.6 mm, while the average sum of the diameters of target lesions after immunotherapy was 54.5±28.6 mm.

A total of 72% of the patients (n=18) received a combination of cisplatin and gemcitabine as first-line chemotherapy, 8% of the patients (n=2) received a

combination of cisplatin and paclitaxel, cisplatin and etoposide, and carboplatin and gemcitabine, while only one patient (4%) received a combination of carboplatin and paclitaxel. The average dose of applied radiotherapy was 54±2 Gy (the minimum dose was 54 Gy, and the maximum was 60 Gy). The average period between the completion of radiotherapy and the start of durvalumab therapy was 82.8±49.6 days, and only 1 patient received durvalumab within 42 days of the last dose of radiotherapy, as recommended in the available guidelines. Patients, on average, received 8.52±3.22 cycles of durvalumab, with the minimum number being two cycles in a patient who experienced a fatal outcome during therapy, while all other patients received 4 or more cycles, as the response to durvalumab therapy is evaluated based on CT scans only after four cycles of treatment. The best recorded response during immunotherapy was determined based on the iRECIST criteria. None of the patients included in the study achieved a complete response. A partial response to durvalumab therapy was achieved by 36% of the patients (n=9), 40% (n= 0) had stable disease, while 24% (n=6) experienced disease progression during immunotherapy, with one patient passing away (Figure 1).



CR, complete response; PR, partial response; SD, stable disease; PD, progressive disease.

Figure 1. The best observed response rate (RR) during durvalumab therapy.

The patients were divided into two groups based on histological tumor type, gender, pack-year index, PDL-1 expression level, and ECOG status. The percentage distribution of the patients in each of these groups is shown in Table 1.

A total of 25 patients were included in the PFS analysis, of which 9 experienced disease progression or death. In the DoCB analysis, 19 patients who had previously achieved stable disease or a partial response were considered, and only 3 patients experienced disease progression afterwards. The average duration of PFS was 19.8 months, while the average duration of DoCB was 25 months. The median values for PFS (95% CI: 11–NR (not reached)) and DoCB (95% CI: NR–NR) were not reached. The probability of PFS after two years was 57.7% (95% CI: 39.3 to 84.6%), while the probability of DoCB after the same period was 79.2% (95% CI: 60.2 to 100%). The probability of PFS and DoCB at various time points is also shown graphically (Figure 2). Since none of the patients achieved a complete response to durvalumab therapy, and only 9 patients experienced a partial response, the ORR is 36% (95% CI=30.04%-41.96%).

Table 1. Distribution of patients in groups based on the specified variables.

Patients and disease characteristics	n (%)
Histological tumor type	
squamous carcinoma	17 (74)
adenocarcinoma	6 (26)
Gender	
male	15 (60)
female	10 (40)
Pack/years index	
≤20	10 (40)
>20	15 (60)
PDL-1 expression	
≤50%	14 (56)
>50%	11 (44)
ECOG status	
0	6 (24)
1	19 (76)

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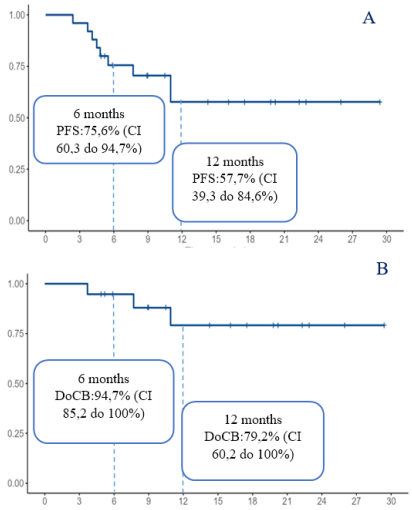

Figure 2. PFS (A) and DoCB (B) following durvalumab administration. The x-axis represents time in months, while the y-axis shows the probability of PFS (A) and DoCB (B). Vertical ticks on each curve indicate censored patients, while the dashed lines extending from the x-axis to the curve represent the probability of PFS and DoCB at 6 months and at one year.
CI–confidence interval.

The patients with adenocarcinoma had longer PFS compared to those with squamous cell carcinoma (median 22.3 vs. 10.5 months), though the difference wasn't statistically significant (HR=0.49, CI: 0.16–1.51, p=0.212). The female patients also showed more favorable PFS (HR=0.28, CI: 0.06–1.39, p=0.089), as did those with a pack-year index ≤20 (HR=0.81, CI: 0.29–2.27, p=0.673), but again without statistical significance. The patients with PDL-1 expression >50% had better PFS (HR=1.19, CI: 0.32–4.46, p=0.795), and ECOG status 0 was associated with improved outcomes compared to ECOG 1 (HR=0.4, CI: 0.05–3.22, p=0.38) (Figure 3).

For DoCB, adenocarcinoma was again linked to better outcomes (HR=0.68, CI: 0.06–7.7, p=0.758). Women (HR=0.45, CI: 0.04–5.02, p=0.515) and patients with a pack-year index ≤20 (HR=0.49, CI: 0.04–5.55, p=0.565) also had better DoCB, but the differences weren't significant. Lower PDL-1 expression (≤50%) was associated with worse outcomes (HR=1.81, CI: 0.16–20.3, p=0.63). No difference in DoCB was observed between ECOG 0 and 1 groups (HR=0.00, p=0.999) (Figure 4).

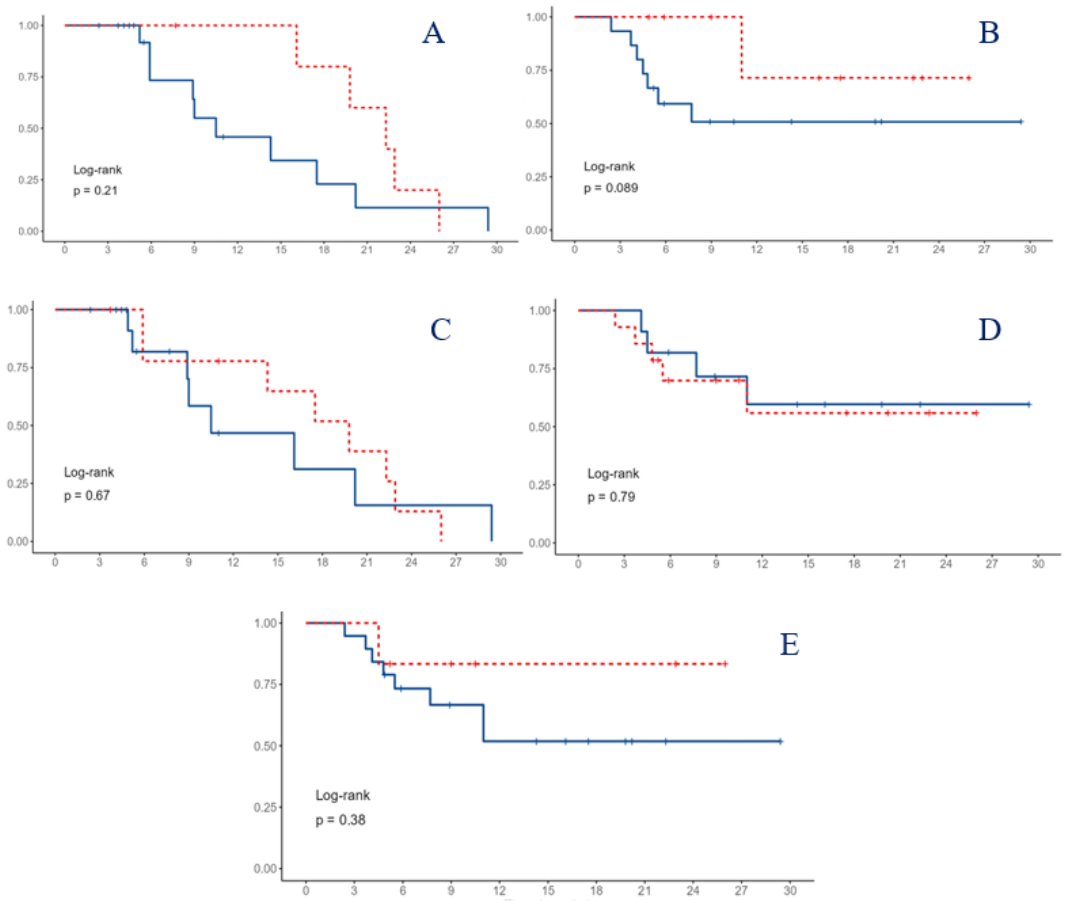

Figure 3. Figure 3. Comparison of PFS among patient groups.
A – PFS according to tumor histology (adenocarcinoma shown with the red curve, squamous cell carcinoma with the blue curve). B–PFS according to gender (female shown in red, male in blue). C–PFS according to pack-years index (≤20 in red, >20 in blue). D – PFS according to PD-L1 expression level (≤50% in red, >50% in blue). E–PFS according to ECOG performance status (ECOG 0 in red, ECOG 1 in blue).

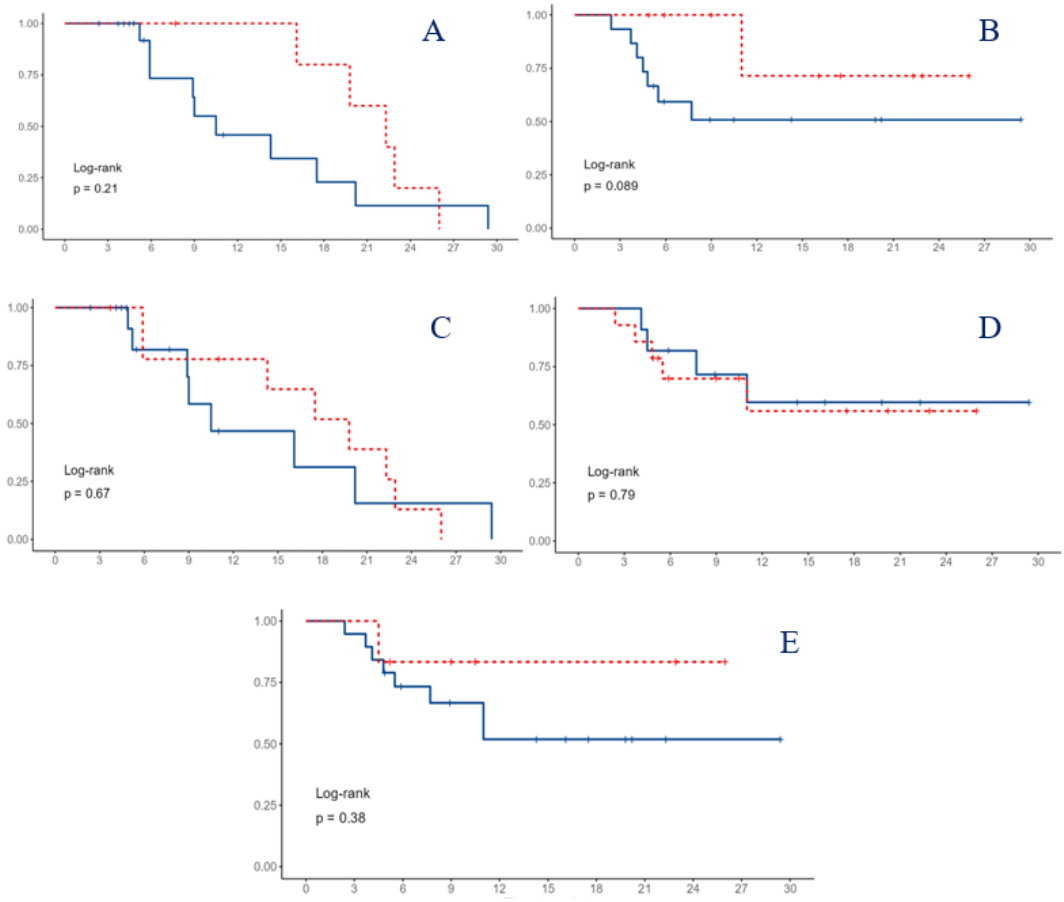

Figure 4. Comparison of DoCB among patient groups.
A–DoCB according to tumor histology (adenocarcinoma shown with the red curve, squamous cell carcinoma with the blue curve). B–DoCB according to gender (female shown in red, male in blue). C–DoCB according to pack-years index (≤20 in red, >20 in blue). D–DoCB according to PD-L1 expression level (≤50% in red, >50% in blue). E–DoCB according to ECOG performance status (ECOG 0 in red, ECOG 1 in blue). The x-axis represents time in months, while the y-axis shows the probability of DoCB.

DISCUSSION

In this study, the data from a retrospective analysis were presented, assessing the efficacy of durvalumab consolidation therapy after the first line of chemoradiotherapy in patients with stage III NSCLC treated at the Institute for Pulmonary Diseases of Vojvodina. Considering that durvalumab has been used in IPDV for just over two years, the limitations of our study include a small number of patients who, by the cutoff date, had the opportunity to receive this therapy, as well as the relatively short follow-up period. Another limitation is the retrospective nature of the study, which may result in the variability of documentation and missing data. These limitations contributed to the lack of certain results, such as median values for PFS and DoCB.

In our study, the 12-month PFS rate after starting durvalumab was 57.7%. Faivre-Finn et al. reported a similar result, with a PFS rate of 55.3% one year after initiating immunotherapy (15). Similar results were found by Socinski et al. (7), whose study showed a one-year PFS rate of 51.1% in patients aged 70 and older and 57.1% in those younger than 70, while Scott et al. (17) measured a PFS rate of 55.9%. Other authors report higher PFS rates, with values of 75% and 70.2%, respectively (10,11).

Six months after starting durvalumab, the DoCB rate was 94.7%, dropping slightly to 79.2% after one year. This means most patients still had some clinical benefit, stable disease, partial, or complete response at those time points. Unlike DOR (duration of response), which only measures the duration of the actual tumor response, DoCB includes disease stabilization, which we considered a meaningful outcome in lung cancer treatment. Since DOR is typically reported in clinical trials and data on DoCB with durvalumab in NSCLC are lacking, we chose to focus on DoCB in our study.

Disease progression occurred in 24% of the patients, with one patient dying, which is a higher percentage compared to the data presented by Scott et al., whose study showed disease progression in only 16.5% of the patients (17). A potential reason for the worse outcome in comparison to the aforementioned study could be that in our study, only one patient received durvalumab within the recommended 42-day period. The ORR (36%) was superior to the studies with which we compared our results (7,17-19). Naidoo et al. reported an ORR of 26.1%, almost 10% lower than our data (18). This could be due to the inclusion of patients with ECOG status 2 in their study, as well as the significantly

higher median age of their patients (78 years compared to the median of 66 in our study).

It was found that gender, histological tumor type, smoking history, and the degree of PDL-1 expression may affect the therapy's efficacy in terms of PFS and DoCB, but no statistically significant differences were found between groups of patients categorized based on these variables. On the other hand, the ECOG status showed an impact on PFS, but not on DoCB, though this effect was again not statistically significant. These results could be due to the small sample size mentioned earlier. Some studies have shown that the degree of PDL-1 expression is an important factor influencing therapy efficacy (16,20). Jazieh et al. found that 60% of the patients with tumors expressing less than 50% PDL-1 protein had disease progression, compared to only 16.7% in the group with tumors expressing PDL-1 ≥ 50% (20). A statistically significant difference in PFS between the two groups based on PDL-1 expression (with 50% as the cutoff) was also shown in another study by the same author (16). However, other studies have reported opposite results, claiming that the level of PDL-1 expression does not affect the efficacy of immunotherapy (24,25). These contradictory results could be due to the differences in the first-line therapy and its success, considering the literature data suggesting that increased PDL-1 expression follows the use of chemotherapy and radiotherapy (17,21). Additionally, tumor heterogeneity at the microscopic level cannot be macroscopically detected, which could result in taking tissue samples from tumor areas with very few cells expressing PDL-1 or, conversely, from tumor areas where the level of PDL-1 expression is significantly higher.

Similarly to the results of our study, the data presented in the research by Verschueren et al. suggest that ECOG status 0 and non-squamous tumor histology have a positive effect on PFS (11). However, no statistically significant difference was found in their study either. Filippi et al., on the other hand, found a statistically significant improvement in PFS over time in patients whose tumors did not have squamous histology (9).

As durvalumab remains a relatively recent addition to the treatment of stage III NSCLC, the understanding of predictive factors for therapeutic response is still evolving, highlighting the need for further large-scale, prospective studies.

CONCLUSION

Durvalumab has shown efficacy as a consolidation therapy following the first line of chemoradiotherapy in patients with stage III NSCLC, although the results of the study are limited by the small number of patients and the short follow-up period. The study demonstrated a 12-month PFS rate of 57.7%, while the DoCB rate was 79.2% after one year, indicating a clinical benefit in a significant number of patients. Compared to other studies, our data show a higher ORR (36%). Although factors such as gender, histological tumor type, smoking history, and PDL-1 expression showed a potential impact on therapy efficacy, no statistically significant differences were found. ECOG status had an impact on PFS but not on DoCB, although, again, the difference was not statistically significant, which may be attributed to the small sample size.

To truly assess the efficacy of durvalumab, including achieving median values for DoCB and PFS, as well as statistical significance regarding factors influencing therapy efficacy, a longer follow-up period and a larger number of patients treated with this therapeutic regimen are needed. In the future, we plan to conduct a new cross-sectional study to include a larger patient cohort and thus report on the true efficacy of durvalumab consolidation therapy to improve therapeutic approaches and predict the treatment response in patients with locally advanced non-small cell lung cancer.

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